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## RISK FACTORS

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*You should carefully consider all of the information set out in this document, including the risks and uncertainties described below, before making an investment in our Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] of our Shares could decline due to any of these risks, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.*

### **RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR DRUG CANDIDATES**

**Our business and financial prospects depend substantially on the success of our clinical stage and preclinical stage drug candidates. However, if we are unable to successfully complete their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.**

Our ability to generate revenue and become profitable is substantially dependent on our ability to successfully complete the development of our drug candidates, obtain necessary regulatory approvals, and manufacture and commercialize our drug candidates. We have invested and will continue to invest substantial efforts and resources in our drug candidates. The success of our drug candidates will depend on several factors, including but not limited to:

- favorable safety, immunogenicity and efficacy data from our clinical trials and other studies;
- successful enrollment of patients in, and completion of, clinical trials, as well as completion of preclinical studies;
- sufficient resources to acquire or discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- competition with other drug candidates and marketed drugs;
- obtaining sufficient supplies of any drug products or marketed drugs that are used in combination with our drug candidates, competitor drugs, or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- the performance by CROs or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;

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- receipt of regulatory approvals from the NMPA, the FDA or other comparable regulatory authorities for our drug candidates;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- establishing sufficient commercial manufacturing capabilities;
- successfully launching commercial sales of our drug candidates, including our Core Product EMB-01, if and when approved;
- obtaining market acceptance by hospitals, doctors, key opinion leaders (“KOLs”) and others in the medical community for our Core Product, EMB-01, and other drug candidates as viable treatment options, if and when approved;
- setting appropriate and favorable prices for EMB-01 and other drug candidates and obtaining and maintaining favorable governmental and/or private reimbursement from third-party payers, if and when approved;
- building up our in-house commercialization team and collaborating with third parties to launch and commercialize EMB-01 and other drug candidates;
- continued acceptable safety profile of our drug candidates following regulatory approval, if and when received; and
- stable and supportive domestic policies, favorable international environment and good relationships among nations.

If we do not achieve one or more of the aforementioned factors in a timely manner or at all, we could experience significant delays or difficulties in obtaining approvals for and/or successfully commercializing our drug candidates.

Some of our drug candidates represent an approach to therapeutic needs compared with more commonly used medical methods, which carries inherent development risks and could result in delays in clinical development, regulatory approval or commercialization. Any modification to the protocols related to the demonstration of safety or efficacy of our drug candidates may delay the clinical program, regulatory approval and/or commercialization, and we may be required to supplement, modify, or withdraw and refile our applications for the regulatory approval. This may have a material impact on our ability to generate revenue from our drug candidates, which in turn may materially and adversely affect our business, financial condition and results of operations. For instance, our EM1032 targets CD3 and ALPP(G), a novel target for which no drug has been approved globally. We may not be able to generate meaningful economic value taking into consideration the potentially significant efforts to promote our TCE candidates, which in turn may materially and adversely affect our competitive position, business, financial condition and results of operations.

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As of the Latest Practicable Date, all of our drug candidates were in various phases of clinical trials and preclinical studies and we did not have any drug candidates that are at NDA/BLA stage with the relevant competent regulatory authorities. We therefore do not yet have experience in filing for regulatory approval for our drug candidates, and we have not yet demonstrated the ability to receive regulatory approval for our drug candidates. As a result, our ability to successfully obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals.

**We face intense competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do, which may adversely affect our ability to successfully commercialize our drug candidates.**

The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological changes. Major pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions have commercialized or are commercializing or pursuing the development of drugs competing with our drug candidates. For example, there are a number of bispecific antibody companies that have successfully brought FDA-approved bispecific antibody drugs to market. Specifically, as of the Latest Practicable Date, amivantamab has already received global approval for the NSCLC indication and is currently leading in Phase III clinical progress for CRC indications compared to our EMB-01. These companies have, among others, demonstrated their leadership in biopharmaceutical innovation by developing therapies that target complex diseases with high efficacy.

Some of our competitors have greater financial, technical and human resources, more established commercialization infrastructure, more drug candidates in late-stage clinical development, more seasoned research and development staff and more established marketing and manufacturing teams than we do. For example, some multi-national pharmaceutical companies are also developing antibodies against the same targets of our drug candidates for oncology and/or immunology indications. Even if our drug candidates have been successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, we will still face competition in terms of safety, efficacy, tolerability, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price, patent position and other factors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or gain better acceptance for the same target markets as ours, which will undermine our competitive position.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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Competition may further intensify as a result of advances in the commercial applicability of technologies and availability of capital for investment in the industry. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective with a lower cost than our drug candidates, or achieve earlier patent protection, regulatory approvals, product commercialization and market penetration than we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability or safety in order to overcome price competition and to be commercially successful. Furthermore, disruptive technologies and medical breakthroughs may further intensify the competition and render our drug candidates obsolete or noncompetitive. Technologies developed by our competitors may render our potential drug candidates uneconomical or obsolete, and we may not be successful in marketing our drug candidates against competitors.

**We have limited experience in the commercialization of drugs. If we are unable to effectively build up our in-house commercialization team as we expected, manage our in-house sales network, or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, or if we otherwise fail to effectively commercialize our drugs including EMB-01 after obtaining the regulatory approval, our business, financial condition, results of operations and prospects may be materially and adversely affected.**

We have not yet demonstrated an ability to launch and commercialize any of our drug candidates, including EMB-01, our Core Product. 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 in launching and marketing drug candidates. We will be competing with many companies that currently have commercialization teams and extensive sales and marketing operations. With limited experience in sales and marketing, we may be unable to compete successfully against these more established companies.

As of the Latest Practicable Date, we have not established an in-house sales and marketing team. In the long term, we may determine to develop and expand our in-house marketing organization and sales force, which will require significant expenditures, management resources and time. We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities, we will likely pursue collaborative arrangements regarding the sales and marketing of our drugs. 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. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates.

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There can be no assurance that we will be able to successfully develop and maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaboration partners to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

**We may not be able to identify, discover or develop new drug candidates, or to identify additional therapeutic opportunities for our drug candidates, to expand or maintain our product pipeline.**

The success of our business depends upon our ability to identify, discover, develop and commercialize drug candidates. We cannot guarantee that we will be successful in identifying potential new drug candidates. Furthermore, drug candidates that we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Some drug candidates such as tri-specific antibodies for oncology and/or immunology that we intend to identify could also be technically challenging to develop and manufacture. Research programs to identify new drug candidates and drug targets or to pursue the development of our drug candidates for additional indications require substantial technical, financial and human resources. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including but not limited to the following factors:

- the research methodology used may not be successful in identifying potential indications and/or new drug candidates;
- there may be a lack of transferability of experimental results obtained in the laboratory testing in cells or from animals into clinical treatment and safety outcomes in human subjects, including unexpected toxicities in humans;
- potential drug candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired safety and efficacy;
- it may take greater resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates, thereby limiting our ability to diversify and expand our drug portfolio; or
- we may not be able to manufacture the right dosage form to match the appropriate route of administration during the development of our drug candidates.

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Accordingly, there can be no assurance that we will be able to identify new drug candidates or additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially and adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

**We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which may not be successful attempts.**

The oncology and immunology markets are constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. Our research and development expenses amounted to RMB184.6 million, RMB122.6 million, RMB92.8 million and RMB96.9 million in 2023, 2024 and the nine months ended September 30, 2024 and 2025, respectively. We need to continue to invest in human resources and technologies that will allow us to enhance the scope and quality of our research and development. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital- and time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or innovative drugs to market, obtain sufficient or any patent or other intellectual property protection for such new or innovative drugs, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such drugs are introduced to the market, that those drugs will achieve market acceptance. Any failure to do so may make our technologies obsolete, which could harm our business and prospects.

**Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials and commercializing our drug candidates on a timely basis.**

To obtain regulatory approval for the sale of our drug candidates, we are required to conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical trials are expensive, difficult to design and implement, and the clinical outcomes are subject to high uncertainty. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay us in or prevent us from receiving regulatory approvals for the development and commercialization of our drug candidates, including but not limited to situations whereby:

- we or our investigators may be required to commence a clinical trial or conduct a clinical trial at an unexpected trial site;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;

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- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- our CROs and CDMOs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;
- our drug candidates may lack meaningful clinical responses, which may expose the participants to unacceptable health and safety risks;
- our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials;
- regulators may require that we or our investigators suspend or terminate clinical research for reasons such as non-compliance; and
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or be required, to conduct additional clinical trials or abandon drug development programs.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, or if we are unable to successfully complete clinical trials of our drug candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may be delayed in obtaining regulatory approval for our drug candidates or not obtain regulatory approval at all, or obtain approval for proposed indications that are not as broad as intended. We may have the drug removed from the market even after obtaining regulatory approval. We may also be subject to additional post-marketing testing requirements and restrictions on how the drug is distributed or used.

Delays in clinical trials and other testing or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule. Significant clinical trial delays could also shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drug candidates and may have an adverse effect on our business and results of operations.

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**If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. This challenge may be especially significant for clinical trials of late line treatment targeting late-stage cancers, where patient recruitment may be more difficult.**

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to timely enroll a sufficient number of patients who opt to participate and remain in the trial until its conclusion. We may fail to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in our clinical trials, or if there are delays in the enrollment of eligible patients as a result of the competitive clinical enrollment environment. The inability to enroll a sufficient number of patients who meet the applicable criteria for our clinical trials would result in significant delays or even failure of our trials, or incur substantial costs to find proper patients. A limited patient pool can also affect the quality and reliability of the clinical trial data. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including but not limited to:

- the design of the trial;
- the patient eligibility criteria defined in the protocol;
- the severity of the disease under investigation;
- the size and demographics of the patient population;
- the size of the study population required for analysis of the trial's primary endpoints;
- our ability to obtain and maintain patient consents;
- the experience and competencies of our third-party contractors;
- our ability to select clinical trial sites and to recruit clinical trial investigators with the appropriate competencies and experience;
- the proximity of patients to trial sites;
- clinicians' and patients' perceptions of the potential advantages and side effects of the drug candidate being studied compared to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- the risk that patients enrolled in clinical trials will not complete a clinical trial;

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- the outbreak of epidemics or pandemics; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

The challenge of patient recruitment may be specifically significant for clinical trials of late line treatment targeting late-stage cancers. The field of cancer treatment has advanced rapidly in recent decades, progressing from surgery and radiotherapy, to chemotherapy and, more recently, to targeted drugs and immunotherapies. Immunotherapies can be characterized as first-line, second-line or third-line based on the timing of the treatment. First-line treatment or therapy simply refers to the initial, or first treatment recommended for the cancer, which, for most people, is expected to provide the best results with the fewest number of side effects. In contrast, second-line treatments are used when the first-line treatment failed to improve a cancer, or if the first-line treatment worked initially before and then the cancer progressed. Third-line treatment may be adopted if previous treatments failed. For example, our Core Product EMB-01 and key products EMB-06 and EMB-07 are mainly developed to initially target second-line or later-stage treatment for cancer patients, who have failed prior treatments, limiting its target patients group in nature. Regulatory authorities also may establish narrower definitions around when a patient is ineligible for other treatments than we have used in our clinical trials, and that would reduce the size of the patient population eligible for our drug candidates and therefore enhance our difficulties in recruiting patients for our clinical trials.

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients may opt to enroll in a trial conducted by one of our competitors instead of ours. As the number of qualified clinical investigators and clinical trial sites is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

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

**Adverse events caused by our drug candidates could interrupt, 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 drug candidates, or caused by our drug candidates when used in combination with other drugs, could cause significant negative consequences, including but not limited to the following:

- clinical trials of our drug candidates could be interrupted, delayed, or halted;

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- we may be required to cease further development of, or delay or even be denied approval of, our drug candidates for any or all targeted indications if results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events;
- we may be required to withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug, issue safety alerts or other communications containing warnings or other safety information of such approved drug, or impose other limitations on such approved drug;
- we may suspend, delay or alter development or marketing of our drug candidates;
- we may be required to develop a risk evaluation mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the existing strategy, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to change the way the drug candidate is administered or conduct post-market studies;
- the patient enrollment may be insufficient or slower than we anticipate, or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;
- we could be required to recall our drug candidates and subject to litigation proceedings and regulatory investigations and held liable for harm caused to patients exposed to or taking our drug candidates; and
- our reputation may suffer.

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

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### **Results of early clinical trials may not be predictive of future trial results.**

The results of preclinical studies and early clinical trials may not be predictive of the success of later phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily predict successful final results. Our drug candidates in later stages of clinical trials may fail to show the desired safety, immunogenicity and efficacy traits.

In some instances, there can be significant variability in safety, immunogenicity and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and demographics of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. As 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. Differences in the number of clinical trial sites and countries involved may also lead to variability between earlier and later-phase clinical trials. Constantly updated standard therapies may change patient resistance, which may affect the efficacy of our medicines. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives. In addition, our future clinical trial results may differ from earlier trials and may not be favorable. Even if our future clinical trial results show favorable efficacy, not all patients may benefit. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and other than as predicted, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. If so, we would have expended a significant amount of capital to progress the relevant drug candidates to that stage, and would not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially and adversely affect our business, financial condition, results of operations and prospects.

**If 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.**

Before obtaining regulatory approvals for the commercialization of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates for their proposed indications in humans. We may conduct clinical trials with larger subject sample sizes as our clinical trial plan advances, and our drug candidates may not show the promising safety, immunogenicity and efficacy results that were observed in earlier clinical trials with fewer subjects. Undesirable adverse events caused by our drug candidates could cause the interruption, delay, suspension or termination of our clinical trials and result in a more restrictive label or the delay or denial of regulatory approval. Results of our clinical trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our clinical trials could be suspended or terminated and we may be required to cease further development of, or deny approval of, our drug candidates for any or all targeted

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indications. Adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial, and result in potential product liability claims. In addition, our clinical trials may not generate meaningful clinical response or have other unexpected characteristics, such as the short-term duration of response and insufficient enhancement of overall survival benefits.

If the results of clinical trials of our drug candidates are not positive or only modestly positive for proposed indications, or if they raise safety concerns, any or some of the following would occur:

- regulatory approvals for our drug candidates would be delayed or denied;
- we may be required to conduct additional clinical trials or other testing of our drug candidates beyond our current development plan;
- we may be required to add labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of the side effects for distribution to patients;
- we may be required to implement a risk evaluation and mitigation strategy program, including but not limited to medication guides, doctor communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk management tools;
- we may not be able to obtain regulatory approvals for all the proposed indications as intended;
- we may be subject to restrictions on how the drug is distributed or used;
- we may be sued or held liable for injury caused to individuals exposed to or taking our drug candidates;
- we may be unable to obtain reimbursement for use of the drug; and
- conditional regulatory approval of our drug candidates 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 drug candidates, if such drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would not

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be able to realize any revenue on such drug candidates if they then or ultimately fail to receive regulatory approvals due to unsatisfactory clinical trial results, thereby materially and adversely affecting our business, financial condition, results of operations and prospects.

In addition, if one or more of our drug candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, it could result in a number of potentially significant negative consequences, including but not limited to, the following situations whereby:

- we may be forced to suspend marketing of the drug;
- approvals for the commercial sales of the drug may be withdrawn;
- additional warnings on the label may be required to be added;
- we may be required to develop risk evaluation and mitigation measures for the drug or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;
- we may be required to conduct post-market studies;
- we could be required to recall our products and be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

**We may allocate our limited resources to pursue particular drug candidates or indications and fail to capitalize on other 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 our pipeline on research platforms and drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development platforms and drug candidates for specific indications may not yield any commercially viable products. Accordingly, our resource allocation decisions may cause us to fail to capitalize on other viable commercial products or profitable market opportunities. If we cannot accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

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

We collect, aggregate, process, and analyze data and information from our preclinical studies and clinical trials. We also engage in substantial information gathering following the identification of a promising drug candidate. Because data in the healthcare industry is fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we often discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer.

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

In addition, we rely on certain third parties to monitor and manage data for some of our ongoing preclinical studies and clinical trials and control only certain aspects of their activities. If any of our CROs, CDMOs or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For details, see “— Risks Relating to Our Reliance on Third Parties — We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. 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.” In addition, for instance, data from clinical trials conducted or to be conducted by Candid, our collaboration partner, for EMB-06 outside China (including Hong Kong, Macau and Taiwan) may affect our clinical development of EMB-06 in China.

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

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

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

Moreover, others may not accept or agree with our assumptions, estimates, calculations, conclusions analyses, or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of our particular product candidates.

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

We face an inherent risk of product liability as a result of the clinical trials and any future commercialization of our drug candidates inside and outside China. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against 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.

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Liability claims may result in decreased demand for our drug candidates, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals, or labeling, marketing or promotional restrictions, loss of revenue, exhaustion of any available insurance and our capital resources, the inability to commercialize any approved drug candidate, and a decline in the [REDACTED] of our Shares.

To cover such liability claims arising from clinical trials, we purchased clinical trial insurance to cover adverse events in our clinical trials during the Track Record Period. 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.

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

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

As of the Latest Practicable Date, we had not commercialized any drug candidates. As of the Latest Practicable Date, we did not have in-house manufacturing facility that was operational. In line with industry practice, we mainly engaged qualified CDMOs for the clinical supply of our selected drug candidates during the Track Record Period.

As a result, we have limited experience in manufacturing biopharmaceutical products on a commercial scale, which is a complex process, in part due to strict regulatory requirements. 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.

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## RISK FACTORS

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In addition, we also face certain risks in relation to the CDMOs we engage for manufacturing activities. We cannot assure you that issues relating to the manufacturing of our drug candidates will not occur in the future. See “— Risks Relating to Our Reliance on Third Parties — We may rely on third parties to manufacture our drug products for clinical development and commercial sales and to provide a stable and adequate supply of quality materials and products for our drug development and commercialization needs. 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.”

Manufacturing methods and formulation are sometimes altered through the development of drug candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such alterations carry the risk that they will not achieve these intended objectives. Any of these alterations could cause the drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay the commercialization of drug candidates and require bridging studies or the repetition of one or more clinical trials, which may result in increases in clinical trial costs, delays in drug approvals and jeopardize our ability to commence product sales and generate revenue.

We may also encounter problems with achieving adequate or clinical-grade products that meet the NMPA, FDA, or other comparable regulatory authorities standards or specifications, maintaining consistent and acceptable production costs, and experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to manufacturing facilities or the equipment in them. In these cases, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable to us, or at all. Such an event could delay our clinical trials and/or the availability of our future drug products for commercial sale, incurring spend significant time and costs for us to remedy these deficiencies.

### **We may not be able to main 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 operate a comprehensive quality control system, which is established and refined in accordance with the rigorous regulations and guidelines. See “Business — Research and Development, Chemistry, Manufacture and Control — Quality Control and Assurance.” However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol 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.

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## RISK FACTORS

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**The actual market size of our product candidates might be smaller than expected considering the low incidence of the indications targeted by our products. Our drug candidates, once approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for our drug candidates' commercial success.**

Our drug candidates, once approved, may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. Potential patients and their physicians may be inclined to use conventional standard-of-care treatments rather than trying out a novel approach. Further, given the novelty of our drug candidates, patients and medical personnel may need substantial education and training. In addition, physicians, patients and third-party payers may prefer other products to ours. If our drug candidates do not achieve an adequate level of acceptance, the commercialization of such drug candidates may become less successful or profitable than we had expected.

The degree of market acceptance of our drug candidates, if approved for commercial sales, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved and the market demand for approved products that treat those indications;
- efficacy and safety of our drug candidates;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- acceptance by physicians, operators of hospitals and clinics and patients of our products as a safe and effective treatment;
- product labeling or package insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our drug candidates;
- the availability of adequate coverage, reimbursement and pricing by third-party payers and government authorities;
- price control or downward adjustment by the government authorities or other pricing pressure;

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## RISK FACTORS

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- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- adverse publicity about our products or favorable publicity about competitive products; and
- the effectiveness of our sales and marketing efforts.

If any approved drug candidates that we commercialize fail to achieve market acceptance among physicians, patients, third-party payers 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 newly introduced products or technologies 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 and adversely affect our business, financial condition, results of operations and prospects.

**The national, provincial and other third-party drug reimbursement practices and drug pricing policies or regulations are evolving from time to time, which could impact our business. If our drug candidates including EMB-01 are not included in or are removed from national, provincial or other government sponsored medical insurance programs when approved, our business, financial condition, results of operations and prospects could be materially and adversely affected.**

The regulations that govern regulatory approvals, pricing and reimbursement for medical products vary widely from country to country. Our ability to commercialize any drug candidates 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. Government authorities and third-party payers may control costs by limiting coverage and the amount of reimbursement for particular medications.

The national or local medical insurance catalogs, as well as drug reimbursement lists are reviewed and updated regularly, which affects the amounts reimbursable to program participants for their purchases of drugs. In China, the National Reimbursement Drug List (“**NRDL**”) and Provincial Reimbursement Drug Lists (“**PRDL**”) include drugs under the national medical insurance catalogue, which affect the amounts reimbursable to program participants for those drugs. There can be no assurance that any of our future approved drugs, including our Core Product, EMB-01, will be included in the national, provincial or local medical insurance catalogs. Drugs or medical products included in the national, provincial or local medical insurance catalogs are generally generic and essential drugs. Innovative drugs similar to our drug candidates have historically been subject to higher requirements to be included in such medical insurance catalogs. Even if our drug candidates have already obtained regulatory approval, any adverse pricing limitations may hinder our ability to recoup our

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## RISK FACTORS

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investment in one or more drug candidates. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL or the PRDL, our revenue from commercial sales will be highly dependent on patient self-payment, which can make our products less competitive.

In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, 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-effective 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. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drugs. Patients are unlikely to use any of our future approved drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs. Because some of our drug candidates have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

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

There may be delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced for rebates required by government healthcare programs or private payers. 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.

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## RISK FACTORS

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**The illegal and/or counterfeit pharmaceutical products may reduce demand for our drug candidates, which could have a negative impact on our reputation and business.**

The illegal import 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 jurisdictions where we plan to commercialize our drug candidates. Illegal imports of prescription drugs may continue to occur or even increase as the ability of patients and other customers to obtain these lower-priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our drugs and exert commercial pressure on pricing within one or more markets. Any future legislation or regulations that increase consumer access to lower-priced imported medicines where we operate could have a material adverse effect on our business.

Certain pharmaceutical products distributed or sold in our target markets may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their usage or manufacturers. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future approved drug candidates.

Counterfeit pharmaceutical products are unlikely to meet our or our collaboration partners’ 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 pharmaceutical products sold under our or our collaboration partners’ brand name(s). In addition, theft of inventory at warehouses, plants or while in-transit, which is not properly stored and which is sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

**If safety, efficacy, or other issues arise with any medical product that is used in combination with our drug candidates, we may be unable to market such drug candidates or may experience supply shortages or be subjected to regulatory measures, and our business could be materially harmed.**

We plan to develop certain of our drug candidates for use as combination therapies. For example, we are actively exploring the combination potential of our Core Product and chemotherapy. For details, see “Business — Our Bispecific and TCE Pipeline.” Combination therapy development carries a higher risk of failure compared to single agent development due to greater risk of combined drug toxicity as well as lower efficacy due to drug-drug interactions as well as toxicity limitations on efficacy. The development risks of failure are even higher if both agents are investigational. There are additional regulatory requirements for combination development to ensure patient safety during development, including the requirement for separate combination IND review and the trial designs which are also more complex and require close monitoring. If any regulatory agency revokes its approval of any pharmaceutical products or therapy we intend to use in combination with our drug candidates, we will be

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forced to terminate or re-design the clinical trials, or will not be able to market our drug candidates in combination with such revoked pharmaceutical products or therapies. If safety or efficacy issues arise with these or other therapies that we seek to combine with our drug candidates in the future, we may be subjected to regulatory measures, and we may be required to redesign or terminate the relevant clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline, or at all.

### **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 candidates, either directly or indirectly relative to our competitive drug candidates, could result in current or potential decreased use of, sales of, and revenues from one or more of our drug candidates. Furthermore, our success depends in part on our ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third parties’ guidelines, recommendations or studies.

### **RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES**

#### **We have entered into license and collaboration agreements with third parties and may seek additional collaboration opportunities and strategic alliances or enter into licensing arrangements in the future. We may fail to identify suitable business partners or may not realize the benefits of such partnerships as expected.**

We have in the past formed, and may continue to seek, strategic partnerships or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our drug development, manufacturing and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. To date, we have entered into several out-licensing and collaboration deals with reputable industry players worldwide, including Almirall and Candid. See “Business — Material Collaboration and Licensing Arrangements” for details.

Our results of operations have been, and may continue to be, affected by our collaboration and licensing arrangements. During the Track Record Period, all of our revenue was generated from such arrangements. Collaboration and licensing agreements involving our drug candidates are subject to various risks, which may include the followings:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

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- the collaboration and licensing agreements could be terminated upon a short notice, and our collaborators may elect to cease collaboration due to a change in their strategic focus, potential acquisition of competitive drugs, availability of funding, or other external factors;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, discontinue a clinical trial, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- the milestone payments and royalties under the agreements are conditioned upon the achievements of certain regulatory, development and commercialization targets. We cannot guarantee that we will be able to receive the aggregate amount as set out in the relevant collaboration and licensing agreements;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause a delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators could independently develop, or develop with third parties, drugs that compete with our drug candidates or future drugs;
- collaborators may own or co-own intellectual property covering our drug candidates or future drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right over such intellectual property; and
- the collaboration and licensing relationships may be affected by cross-border data transmission restrictions and geopolitical tensions, including trade policies and export controls.

For these and other reasons, we may not achieve the outcomes and synergies expected from our collaboration and licensing arrangements. These collaboration and licensing arrangements are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. We may face operational and financial risks including increase in near- and long-term expenditures, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention. Even if we achieve the expected benefits, we may not be able to do so within the anticipated time frame. In addition, any material and

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adverse changes to our relationships with our collaborating partners may have an impact on the technological and financial resources available to us under these collaboration and licensing arrangements, which may in turn affect our R&D activities and business operations.

We face significant competition in seeking appropriate strategic partners and the negotiation process can be time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we may be required to relinquish some or all of the control over the future success of that drug candidate to the third party. The collaborators may also consider alternative drug candidates or technologies that may be available.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expenses. If we elect to fund and undertake development, manufacturing or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. Even with existing collaboration agreements in place, we may not receive sufficient or timely reimbursement from our collaborators for development costs, or our collaborators may delay or withhold payments due to disputes over compliance with agreement terms or other factors. Additionally, development costs may exceed our initial estimates or agreed reimbursement caps, requiring us to fund the excess amounts while any reimbursement disputes are being resolved, which could be prolonged and may not result in full recovery of our costs. These situations could strain our financial resources and potentially impair our ability to advance our development programs as planned. If we fail to enter into collaboration and licensing arrangements face difficulties in securing adequate reimbursement from existing collaborators, or do not have sufficient funds or expertise to undertake the necessary development, manufacturing and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

As a result, we cannot be certain that, following a collaboration and licensing arrangement, we will achieve the revenue or net income that justifies such transaction or such other benefits that caused us to enter into the arrangement. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects.

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**We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. 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. We rely on these parties for the execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with 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. Regulatory authorities may enforce these GCP, GLP or other regulatory requirements through periodic inspections of trial sponsors, investigators and trial sites. 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. Notwithstanding the remedies available to us under our agreements with our CROs, 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. There can be no assurance the regulatory authorities will determine that our clinical trials comply with all the applicable requirements. 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.

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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, the use of third-party service providers requires us to disclose our proprietary information or confidential information concerning the subjects enrolled in our clinical trials to these third parties, which could increase the risk that such information will be misappropriated. Though we carefully manage our relationships with our CROs and other third-party service providers, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material and adverse impact on our business, financial condition, results of operations and prospects.

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. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

**We may rely on third parties to manufacture our drug products for clinical development and commercial sales and to provide a stable and adequate supply of quality materials and products for our drug development and commercialization needs. 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.**

To date, we have relied primarily on third-party service providers, including CDMOs, to manufacture our drug candidates. See “Business — Research and Development — Chemistry, Manufacture & Controls — Collaborations with CDMOs” for details. Going forward, we intend to continue to engage third-party CDMOs to manufacture our drug candidates for our research and development activities and commercial sales. Our reliance on third-party CDMOs exposes us to certain risks, including, but not limited to, the following:

- we may be unable to identify CDMOs that may meet some or all acceptable terms because the number of potential manufacturers is limited and the NMPA, the FDA or other comparable regulatory authorities must approve any manufacturers as part of their regulatory oversight of our drug candidates;
- our CDMOs may have limited capacity or limited manufacturing slots, which may affect the timeline for the production of our drugs;
- our CDMOs are subject to periodic inspections and other government regulations by the NMPA, the FDA or other comparable regulatory authorities, including to ensure strict compliance with the cGMP. We do not have full control over our CDMOs’ compliance with these regulations and requirements;

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- our CDMOs might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and future commercial needs, if any;
- our CDMOs may not be able to execute our manufacturing procedures and other logistical support requirements appropriately, or may otherwise fail to perform as agreed;
- our CDMOs may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- our CDMOs may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- our CDMOs could terminate their agreements with us;
- raw materials and products supplied by certain CDMOs may not be readily obtainable elsewhere; and
- our CDMOs and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters, which may lead to interruption of supply.

See also “— Risks Relating to the Manufacturing and Commercialization of our Drug Candidates — The manufacturing of biopharmaceutical products is a complex process, and we have limited experience in manufacturing biopharmaceutical products on a large commercial scale.”

In addition, during the Track Record Period, we and our CDMOs relied on third parties to supply certain raw materials and products used in our research and development and clinical trials. We expect to continue to rely on third parties to supply raw materials for the research, development and commercialization of our drug candidates. Any disruption in production or the inability of our suppliers or suppliers of our CDMOs to provide adequate quantities to meet our or our CDMOs’ needs could impair our operations and the research and development of our drug candidates. Moreover, we expect our demand for such raw materials and products to increase as we expand our business scale and commercialize our drug candidates, but there is no assurance that current suppliers have the capacity to meet our demand.

The quality of the raw materials procured and products manufactured by CDMOs will depend significantly on the effectiveness of our quality control and quality assurance and that of our CDMOs. We cannot assure you that these quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our operating procedures will be complete or updated at all times. Any

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significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, jeopardize our drug approvals or licenses and/or harm our market reputation and relationship with business partners. Any such developments may have a material and adverse effect on our business, financial condition and results of operations.

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

Our business partners, such as CROs, CDMOs and suppliers, on whom we may rely 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 inspections, examinations, inquiries or audits 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.

**We may fail to effectively manage our network of distributors after our drug candidates are successfully launched. Actions taken by our distributors could materially and adversely affect our business, prospects and reputation.**

We may rely in part on third-party distributors to distribute our drug candidates upon their commercialization. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely and effective delivery of our products to the relevant markets. We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors would not breach the distribution agreements and the policies and measures we have in place to manage their distribution. If our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected:

- breaching the distribution agreements or our policies and measures;
- failing to maintain the requisite licenses, permits or approvals, or failure to comply with applicable regulatory requirements when selling our products; or
- violating anti-corruption, anti-bribery, competition or other laws and regulations of China or other jurisdictions.

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Any violation or alleged violation by our distributors of the distribution agreements, our policies or any applicable laws and regulations could expose us to liabilities and monetary damages, a decrease in the market value of our brand and an unfavorable public perception about the quality of our products, resulting in a material and adverse effect on our business, financial condition, results of operations and prospects.

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

Our relationships with principal investigators, key opinion leaders (“KOLs”), physicians and other industry experts play an important role in our research and development and marketing activities. We have established extensive interaction channels with principal investigators, KOLs, physicians and experts to gain first-hand knowledge of unmet clinical needs and clinical practice trends, which is critical to our ability to develop market-responsive drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, 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. Even if their insights and perceptions are correct, we may fail to develop commercially viable products. Industry participants may no longer want to collaborate with us or attend our conferences, and our marketing strategy may no longer be able to yield results that are commensurate with our efforts spent. If we are unable to develop and maintain our relationships with industry participants as anticipated, our business, financial condition and results of operations may be materially and adversely affected.

### **RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS**

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

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and

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technology that we consider commercially important by filing patent applications, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. In particular, we have sought patents for our core and major products. For further information on our patent portfolio, see “Business — Intellectual Property” in this document. If we or our collaborators are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive drugs in all such fields and jurisdictions. Moreover, some of our patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

There is no uniform requirement or standard on patentability. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our collaborators are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired and our business, financial condition, results of operations, and prospects may be adversely affected.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies or defects in the patent applications or lack of novelty or an inventive step of the underlying invention or technology. We cannot assure you that all of our patent applications will be granted. For further information on our patent portfolio, see “Business — Intellectual Property” in this document. It is also possible that we will fail to identify patentable subject matter of our research and development output in time to obtain patent protection. In addition, parties that have access to confidential or patentable subject matter of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties may breach their non-disclosure or confidentiality agreements with us and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific

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literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we or our collaborators were the first to file for patent protection of such inventions. Furthermore, China and the United States have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. If a third party can establish that we were not the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable, and third parties may be granted a patent relating to a technology which we invented.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged. We may be subject to a third-party pre-issuance submission of prior art, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or drug candidates and compete directly with us. Moreover, we may have to participate in interference proceedings declared by the intellectual property offices to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or drug candidates will be protectable or remain protected by valid and enforceable patents globally. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights with respect to our drug candidates in all other jurisdictions throughout the world would be prohibitively expensive for us. Our intellectual property rights in certain jurisdictions may have a lessor or different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of our target markets. Consequently, in some cases, we may not be able to obtain issued patents or other intellectual property rights covering our drug candidates in jurisdictions outside our target markets and, as a result, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions in and into our target markets or

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other jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent and other intellectual property protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patents or other intellectual property protection. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Legal systems in certain jurisdictions may not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights in these jurisdictions. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and other intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a commercial advantage from the intellectual property that we develop or license. Any of the foregoing could have adverse impact our competitive position, business, financial conditions, results of operations and prospects.

**Even if we obtain patent protection for our drug candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially and adversely affected.**

The term of a patent, and the protection it affords, is limited. Even if we successfully obtain patent protection for a drug candidate, such drug candidate may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office; thus, we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant drug candidate exclusively, which would have a material adverse effect on any potential sales of that drug candidate. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates. For the expiration dates of our issued patents for our drug candidates, see “Business — Intellectual Property” in this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

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Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In case of the occurrence of the foregoing events, our competitive position, business, financial conditions, results of operations and prospects may be materially and adversely affected.

**We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful.**

Competitors or other third parties may challenge the ownership, validity and enforceability of our patents, infringe, misappropriate or otherwise violate our other intellectual property rights. To counter infringement, misappropriation or any other 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. Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can. Accordingly, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue 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, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

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Moreover, we may not be able to uncover infringement against our patents. Even if we uncover infringement by a third party of any of our patents, we may choose not to pursue litigation against or settlement with such third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first uncovered and when the suit was brought. Such legal defenses may make it impossible for us to enforce our patents against such third party.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our collaboration partner, our or their patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates, leave our technology or drug candidates without patent protection, allow third parties to commercialize our technology or drug candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our drug candidates without infringing third-party patent rights. Even if a defendant does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

Moreover, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our drug candidates. We may also be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed (if any in the future) patents, patent applications, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have ownership or inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our drug candidates or technology or who may otherwise believe that they have a claim of ownership for our drug candidates or technology. Litigation may be necessary to defend against these and other claims challenging ownership or inventorship of our owned or in-licensed patents, patent applications, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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**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 commercial success depends in part on our ability to avoid infringing, misappropriating, or otherwise violating intellectual property rights of third parties. However, 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. 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.

In the event that third parties assert infringement claims against us, there is no assurance that the outcome would be in our favor, as whether a drug candidate or technology infringes on third parties' intellectual property rights involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and the burden of proof required to successfully challenge or invalidate a third-party intellectual property right may be high. 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 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.

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

Our trademark registrations and trademark applications may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. We cannot assure you that any currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections that we are unable to overcome. In addition, in proceedings of many jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially and adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially and adversely affected.

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Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

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

In addition to our issued patents and pending patent applications, we rely on our trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaboration partners, outside scientific collaboration partners, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them.

However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

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Furthermore, our employees, consultants and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisors, including each member of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management. As of the Latest Practicable Date, we were not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management.

While we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing intellectual property assignment agreements with each party, such as an employee, consultant or contractor, who develops intellectual property that we regard as our own. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

**Intellectual property laws and regulations are subject to change, which could impact the value of our intellectual property and impair the intellectual property protection of our drug candidates.**

As is the case with other pharmaceutical companies, our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in China, the United States or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

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In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, the fourth Amendments to the PRC Patent Law was put into effect on June 1, 2021, and provides a patent term extension and patent term adjustment. Patent term extension of up to five years is available to invention patents claiming new drugs, to compensate for the time occupied by review and approval for marketing the new drugs. Patent term adjustment is available to all invention patents. The third Amendments to Implementing Rules of the Patent Law of the People's Republic of China put into effect on January 20, 2024, and stipulated detailed implementation rules for patent term extension and adjustment, including, for example, the eligible type of patents, requirements for the application for patent term extension and adjustment, how to calculate the extension, and limitations during the extended patent term. As a result, patents owned by third parties eligible for submitting applications for a patent term extension or adjustment may be extended, which may in turn affect our ability to commercialize our drug candidates without facing infringement risks. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our drug candidates non-competitive. We cannot guarantee that any other future changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Under the America Invents Act enacted in 2011, the United States moved to First Inventor to File system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Publications of discoveries in the scientific literatures often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the applicable authorities, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights. Any of the foregoing could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

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**Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated due to non-compliance with those requirements.**

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the applicable patent agencies in several stages over the lifetime of a patent. These governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. Failure to comply with these requirements can, in some cases, result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application 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 any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

The intellectual property legal systems vary across different countries and regions, introducing uncertainty to the protection of corporate intellectual property. The intellectual property protection in various countries has its limitations, which may be insufficient to fully safeguard our business or enable us to maintain a competitive edge. The limitations of the intellectual property protection system include:

- others may be able to make products that are similar to any of our drug candidates or utilize similar or alternative technology that is not covered by the claims of the patents that we own or license now or in the future;
- we or our current or future collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;
- we or our current or future collaboration partners might not have been the first to file patent applications covering certain of our or their inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;

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- patents that may be issued from our pending patent applications may not provide us with any competitive advantages, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sales of the related product, the commercial value of our patents may be limited;
- the proprietary technologies on which we rely may not be patentable;
- the patents of others may materially and adversely affect our business; and
- we may choose not to file a patent for certain trade secrets or know-how, yet a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

**During the Track Record Period, we had net loss in 2023 and the nine months ended September 30, 2025, and generated all of our revenue in 2024 and the nine months ended September 30, 2025 from the license fee income under the relevant out-licensing and collaboration agreements. Such historical performance may not be indicative of our future performance.**

During the Track Record Period, we entered into a number of out-licensing and collaboration agreements for our TCE asset and platform technologies, and generated revenue in relation to these agreements of RMB458.9 million in 2024 and RMB91.7 million in the nine months ended September 30, 2025, as compared to that of nil in 2023; we recorded net profit of RMB47.7 million in 2024, as compared to net loss of RMB594.8 million in 2023 and RMB64.9 million in the nine months ended September 30, 2025. Our net loss recorded in 2023 and the nine months ended September 30, 2025 was primarily resulted from expenses in relation to our R&D activities and administrative activities, as well as fair value changes of financial liabilities at fair value through profit or loss in relation to our Preferred Shares. Our results in 2024 may not be indicative of our future growth or performance. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing our drug candidates into later stages of clinical development, obtaining regulatory approvals for each drug candidate, and achieving successful commercialization of our drug candidates, which we may not be able to do in a timely manner or at all.

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

- continue to advance the clinical trials and preclinical studies of our drug candidates;
- initiate preclinical, clinical or other studies for new drug candidates;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- commercialize our drug candidates for which we have obtained marketing approvals;
- establish commercial manufacturing capabilities;
- attract and retain skilled personnel, and grant equity-settled awards to our employees under our share incentive schemes;
- develop and expand our commercialization team to commercialize any drug candidates in our pipeline for which we may obtain regulatory approval;
- maintain, protect, expand and enforce our intellectual property portfolio;
- enforce and defend any intellectual property-related claims; and
- acquire or in-license other drug candidates, intellectual property assets and technologies.

The size of our future net losses will depend, in part, on our future expenses resulted from costs and expenses incurred by our research and development programs and in relation to our operations, the cost of commercializing any approved drug candidates, our ability to generate revenues, and the timing and amount of milestone and other payments we make or receive with or through arrangements with third parties. If any of our drug candidates fails during clinical trials or does not obtain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our business, financial condition and results of operation.

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**We historically incurred net liabilities, net current liabilities and net operating cash outflows, which may continue into the foreseeable future and expose us to liquidity risk.**

As of December 31, 2023, 2024 and September 30, 2025, we had net liabilities of RMB2,333.8 million, RMB2,344.3 million and RMB2,396.3 million, respectively, and had net current liabilities of RMB2,385.2 million, RMB2,383.8 million and RMB2,432.7 million, respectively, primarily due to our convertible redeemable Preferred Shares issued to [REDACTED] investors, and because our convertible redeemable Preferred Shares issued to [REDACTED] investors are recorded as current liabilities. A net liabilities position and net current liabilities position can expose us to liquidity and financial risks. This in turn could require us to seek financing from external sources such as debt issuance and bank borrowings, which may not be available on terms favorable or commercially reasonable to us or at all. See also “— We may need to obtain additional financing to fund our operations even if we consummate the [REDACTED], and if we fail to obtain such financing, we may be unable to complete the development and commercialization of our primary drug candidates.”

In 2023 and the nine months ended September 30, 2025, we incurred net operating cash outflows of RMB159.0 million and RMB61.3 million, respectively, from our operations. Substantially all of our operating cash outflows resulted from our research and development expenses and administrative expenses. We may experience net cash outflows from our operating activities from time to time. See also “Financial Information — Liquidity and Capital Resources.” Our forecast of the period of time through which our capital resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect.

If we are unable to maintain adequate working capital or obtain sufficient financings to meet our capital needs, we may be unable to continue our operations according to our plan, default on our payment obligations and fail to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

**Uncertainty over the fair value changes in our Shares and related valuation may materially affect our financial performance and results of operations.**

As of December 31, 2023, 2024 and September 30, 2025, our convertible redeemable Preferred Shares amounted to RMB2,653.5 million, RMB2,747.1 million and RMB2,743.8 million, respectively. In addition, the fair value change of the Preferred Shares shall be charged to the fair value change on convertible redeemable Preferred Shares in profit or loss, therefore directly affecting our financial performance and results of operations. The estimated changes in fair value involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. As such, the financial liabilities valuation has been, and will continue to be, subject to uncertainties in accounting estimation, which may not reflect the actual fair value of these financial liabilities and result in significant fluctuations in profit or loss from year to year,

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which could materially and adversely affect our financial performance and results of operations. The financial liabilities of such Preferred Shares will be derecognized and credited to equity as a result of the automatic conversion into Ordinary Shares upon the [REDACTED], after which we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable Preferred Shares.

**We have historically received financial incentives, such as government subsidies, and we may not continue to receive such incentives in the future.**

We have historically received various government subsidies, including subsidies from different PRC governmental authorities to support the research and development for our drug candidates. We recognized government grants as other income of RMB4.7 million, RMB2.8 million and RMB6.3 million in 2023, 2024 and the nine months ended September 30, 2025, respectively. There is no assurance that we could continue to enjoy or maintain financial incentives or government subsidies at the historical levels, or at all, or apply for new financial incentives or government subsidies. Any change, suspension or termination of these government subsidies, or government financial incentives in other forms, may have a negative impact on our business, financial condition and results of operations.

**We may need to obtain additional financing to fund our operations even if we consummate the [REDACTED], and if we fail to obtain such financing, we may be unable to complete the development and commercialization of our primary drug candidates.**

During the Track Record Period, we funded our operations primarily through equity financing and revenue from our out-licensing and collaboration agreements. 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 offerings, debt financing, collaborations or licensing arrangements or other sources.

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

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

We have adopted share incentive plans for the purpose of granting share-based payment awards to employees, officers, or directors to incentivize their performance and align their interests with ours. In 2023, 2024 and the nine months ended September 30, 2024 and 2025, we incurred RMB6.5 million, RMB6.9 million, RMB4.9 million and RMB12.9 million of share-based payment expenses relating to share options granted under our share incentive plans, respectively. We believe the granting of share-based payment is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based payment awards to employees in the future. As a result, our expenses associated with share-based payment 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 payment charges in the reporting periods following the [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. In 2023 and 2024, we recorded net foreign exchange gains of RMB2.6 million and RMB2.1 million, respectively. In the nine months ended September 30, 2025, we recorded foreign exchange losses of RMB2.9 million. 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 a 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. 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.

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## RISK FACTORS

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### 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 adversely affect our business.**

Our commercial success depends significantly on the continued service of our senior management. For more details on our senior management, see “Directors and Senior Management” in this document. The loss of any of our senior management could have a material adverse effect on our business and operations. Our formal employment agreements with each of our executive officers do not prevent our executives from terminating their employment with us at any time.

We could experience difficulties attracting and retaining qualified employees in the future. Competition for qualified employees in the pharmaceutical 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 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. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biopharmaceutical companies for similar personnel. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. 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.

#### **Our business is dependent on Dr. Wu.**

Our Company’s success depends significantly on the expertise, leadership, and strategic oversight of Dr. Chengbin Wu, our founder and chief executive officer, who brings over 20 years of biopharma experience in biologics drug research and innovation, antibody engineering, and project leadership from concept to regulatory filing. His extensive expertise

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and proven track record in antibody development and biologics R&D significantly bolster our technological capabilities and strategic objectives. Should Dr. Wu reduce or cease his involvement with us, our business, financial condition and results of operations could be adversely affected.

**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 growing company working on an expanding pipeline of drug candidates. 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. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

As our development and commercialization plans and strategies evolve, we must hire a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant additional responsibilities on our management, including but not limited to:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- continuing to innovate and develop advanced technologies in the highly competitive pharmaceutical industry;
- managing our relationships with third parties, including suppliers and collaboration partners;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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 and adversely affect our business, financial condition, results of operations and prospects.

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**We may engage in acquisitions or strategic partnerships, which may increase our capital requirements, cause dilution for 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, joint ventures and strategic partnerships, including licensing or acquiring drug products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- the loss of key employees and personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals;
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- changes in accounting principles relating to recognition and measurement of our investments that may have a significant impact on our financial results.

We may not be able to identify suitable targets, and we have limited experience in acquisitions. In addition, we may not be able to successfully acquire the targets identified. Furthermore, integration of an acquired company, its intellectual property or technology into our own operations is a complex, time-consuming and expensive process. The successful integration of an acquisition may require, among other things, that we integrate and retain key management, sales and other personnel, integrate the acquired technologies or services from both an engineering and a sales and marketing perspective, integrate and support preexisting supplier, distribution and customer relationships, coordinate research and development efforts, and consolidate duplicate facilities and functions. The geographic distance between companies, the complexity of the technologies and operations being integrated, and the disparate corporate

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cultures being combined may increase the difficulties of integrating an acquired company or technology. In addition, it is common in our industry for competitors to attract customers and recruit key employees away from companies during the integration phase of an acquisition. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

**We face risks related to natural disasters, health epidemics, acts of war or terrorism and other factors beyond our control.**

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

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

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

**We may be exposed to risks of conducting our business and operations in international markets. Disruptions in the financial markets and economic conditions could affect our ability to raise capital.**

International markets are an important component of our growth strategy. We will continue to seek licensing and co-development opportunities with global partners and expand our global clinical programs. For more details, see “Business — Our Strategies.” However, such activities may subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including but not limited to:

- changes in a specific country’s or region’s political and cultural climate or economic condition;

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- unexpected changes in laws and regulatory requirements in local jurisdictions;
- differences between national and local practice with respect to laws and regulatory requirements in a specific jurisdiction;
- difficulty of effective enforcement of contractual provisions in certain jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert 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 economic weakness, including inflation or political instability;
- inadequate intellectual property protection in certain jurisdictions;
- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;
- the enforcement of anti-corruption and anti-bribery laws against us;
- trade protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, and greater difficulty in accounts receivable collection;
- non-compliance with tax, employment, immigration and labor laws;
- the effects of applicable local tax regimes and potentially adverse tax consequences;
- significant adverse changes in local currency exchange rates; and
- business interruptions resulting from geo-political actions and cultural climate or economic condition, including war and acts of terrorism, natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or the impact of public health pandemics or epidemics.

Furthermore, global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis, as well as a variety of other factors, including extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify

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these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

**We may become involved in lawsuits or other legal proceedings, 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, CDMOs 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.

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

We maintain industry-standard benefit plans in accordance with relevant laws and regulations, based on our assessment of our operational needs and industry practice. The insurance coverage we maintain for adverse events in clinical trials 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.

In line with general market practice, we have elected not to maintain certain types of insurances, such as business interruption insurance or key man insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

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

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees, including management, technical, research and development, business development, production, quality control and other personnel. 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. Increasing market competition may cause market demand and

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competition for qualified employees to intensify. 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 and adversely affect our results of operations. In addition, we could face labor disputes with our employees, which could lead to fines by governmental authorities and settlement costs to resolve the disputes. Labor disputes could also make it more difficult to recruit new employees due to the reputational damage caused. Any of the foregoing changes could have a material adverse effect on our business, results of operations and prospects.

**If we or our CROs, CDMOs and other business partners fail to comply with environmental, health and safety laws and regulations, we could be subject to fines or penalties and other negative consequences that could have a material adverse effect on the success of 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, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. 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. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological, hazardous or radioactive materials. 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.

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

**We may be unable to detect, deter and prevent all instances of fraud, bribery or other misconduct committed by our employees or third parties.**

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other 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, and we may be unable to prevent, detect or deter all such instances of misconduct. 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 and results of operations.

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**Any failure to comply with the PRC regulations regarding contribution of social insurance premium or housing provident funds may subject us to fines and other legal or administrative sanctions.**

According to the Social Insurance Law of PRC, the Regulations on Management of Housing Provident Fund and other applicable PRC regulations, any employer operating in China must contribute social insurance premium and housing provident funds for its employees. Any failure to open a social insurance or housing provident fund registration account may trigger an order of correction, and where correction is not made within a specified period of time, the competent authority may further impose fines. Any failure to make timely and adequate contribution of social insurance premium or housing provident funds for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium or housing provident funds within a specified period of time, and the competent authority may further impose fines, penalties or enforcement. During the Track Record Period, we were not in strict compliance with the requisite social insurance contribution requirements in relation to some foreign employees. For more details, see “Business — Employees.” In 2023, 2024 and the nine months ended September 30, 2025, the shortfall of social insurance contributions amounted to RMB0.4 million, RMB0.4 million and RMB0.3 million, respectively. Furthermore, in light of the Article 19 of Interpretation (II) of the Supreme People’s Court on Issues Concerning the Application of Law in the trial of Labor Dispute Cases (the “**New Judicial Interpretation**”), promulgated on July 31, 2025, and effective as of September 1, 2025, if an employer and an employee agree or the employee undertakes that social insurance contributions are not required to be paid, the People’ Court shall deem such agreement or undertaking invalid. Furthermore, where an employer fails to pay social insurance contributions in accordance with the law, and the employee seeks to terminate the labor contract and claims economic compensation from the employer pursuant to Item (3) of Article 38 of the PRC Labor Contract Law, the People’ Court shall support such claims, in which case, the employer remains liable for paying economic compensation to the employee. See “Regulatory Overview — Regulations on Employment and Social Welfare” for details.

We cannot assure you that the competent authority will not require us to rectify any non-compliance by making contribution of overdue social insurance premium or to pay any overdue fine or penalty related thereto. This in turn may adversely affect our financial condition and results of operations.

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

We have leased one property in China as our office and R&D facility. Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. We may not be able to constantly

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fulfill the foregoing requirements. If any of our leases is terminated or becomes unenforceable as a result of challenges from third parties, we would need to seek alternative properties and incur relocation costs. Any relocation could lead to disruptions to our operations and adversely affect our business, financial conditions and results of operations. As our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

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

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

**Our reputation is important to our business success, and damage to our reputation may adversely affect our business.**

We, our Shareholders, Directors, officers, employees, collaboration partners, suppliers, or other third parties we cooperate with or rely on may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees, collaboration partners, suppliers or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Any negative publicity regarding our industry could also affect our reputation and commercialization. As a result, we may be required to spend significant time and incur substantial costs to respond and protect our reputation, and we cannot assure you that we will be able to do so within a reasonable period of time, or at all, in which case our business, results of operations, financial condition and prospects may be materially and adversely affected.

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### RISKS RELATING TO GOVERNMENT REGULATIONS

**All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with existing or future regulations and industry standards or any adverse actions by drug approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.**

All jurisdictions in which we operate or intend to operate our business regulate the research, development, manufacturing and commercialization of biopharmaceutical products in great depth and detail. We intend to implement a global development strategy and intend to focus our activities in the major markets including China and the United States. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so, they employ a broad range of strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. Evolutions and differences in these regulatory regimes could lead to an increased and costly regulatory compliance burden.

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

In many countries or regions where a drug is intended to be ultimately sold, including China, the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop such drug. For example, we may need to obtain clearance from the NMPA or other regulatory authorities as part of an IND application to seek authorization to begin clinical trials, and file an NDA, a BLA or other similar applications to seek marketing approval. Any failure to comply with existing laws, regulations and industry standards could result in fines or other punitive actions against us, the termination of ongoing research and the disqualification of data for submission to regulatory authorities, or a ban on the future sales of our drugs, each of which could have a material adverse impact on our reputation, business,

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financial condition, results of operations and prospects. In addition, any action against us for violation of the relevant laws, regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management’s attention from the operation of our business, and adversely affect our reputation and financial results.

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

Changes in government regulations or in practices relating to the biopharmaceutical industry, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures, which would lower the entry barrier for potential competitors, or an increase in regulatory requirements, which may increase the difficulty for us to satisfy such requirements, and may impact our business, financial condition, results of operations, and prospects. In response to emergent situations for public interests, governments in the world may take actions to protect their citizens that could affect our ability to control the production and export of medical products or otherwise impose burdensome regulations on our business.

**The regulatory approval processes relating to the marketing of our drug candidates are lengthy, time-consuming and can be changed. If we are unable to obtain, without undue delay, any regulatory approval for our drug candidates in our targeted markets, our business may be substantially harmed.**

Generally, approval from the NMPA and FDA take many years to obtain, following the commencement of preclinical studies and clinical trials. 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. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes.

Our drug candidates could fail to receive the regulatory approval of the NMPA, the FDA or a comparable regulatory authority for many reasons, including, without limitation:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective and potent for its proposed indication;
- failure of our clinical trial results to meet the level of statistical significance required for approval;
- failure of our clinical trial process to pass relevant GCP inspections;
- failure to demonstrate that a drug candidate’s clinical and other benefits outweigh its safety risks;

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- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficient data collected from the clinical trials of our drug candidates to support the submission and filing of an NDA, a BLA or other submissions or to obtain regulatory approval;
- failure of our drug candidates to pass cGMP inspections during the regulatory review process or across the production cycle of our drug;
- failure of our clinical sites to pass audits carried out by the NMPA, the FDA or comparable regulatory authorities, resulting in a potential invalidation of our research data;
- findings by the NMPA, the FDA or comparable regulatory authorities of deficiencies related to the manufacturing of our products;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval; and
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

The NMPA, the FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. 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, or approve a drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

**We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security in data storage and data transfer, 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.**

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects' private or medical records without their consent, they will be held liable for damage caused thereby. We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure,

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transfer and other processing of personal data in the jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. Currently, we are primarily subject to numerous PRC laws and U.S. federal and state laws governing data protection and privacy.

The PRC authorities promulgated a series of laws and regulations governing the various aspects of information security, data collection and privacy protection, including, among others, the Cybersecurity Law of the PRC, the Provisions on Protection of Personal Information of Telecommunication and Internet Users, the Cybersecurity Review Measures, the Data Security Law of the PRC, and the Personal Information Protection Law of the PRC. Under the Personal Information Protection Law of the PRC, in case of any personal information processing, such individual’s prior consent shall be obtained, unless otherwise specified. Further, any data processing activities that are in relation to the sensitive personal information, such as biometrics, medical health and personal information of teenagers under fourteen years old, are not allowed, unless such activities have a specific purpose, are highly necessary and strict protective measures have been taken. In addition, the Measures for the Security Assessment of Outbound Data Transfer took effect on September 1, 2022, which apply to the security assessment of data processors’ provision of important data and personal information collected and generated in their operations within the territory of the PRC to overseas recipients, and require relevant data processors to submit a data security assessment to the regulatory authority for review prior to certain outbound data transfer activities in order to prevent illegal data transfer activities. In addition, certain industry-specific laws and regulations affect the collection and transfer of data in China. The Regulations on the Administration of Human Genetic Resources of the PRC was promulgated by the State Council in May 2019 and further amended in March 2024. It stipulates that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect or preserve China’s human genetic resources within the PRC, or provide China’s genetic resources abroad. Where a foreign organization or an institution established or actually controlled by a foreign organization or foreign individual needs to use China’s human genetic resources to conduct scientific research activities, it shall cooperate with China’s scientific research institutions, universities, medical institutions and enterprises. The provision or opening of access to human genetic resources to foreign organizations, individuals, or institutions established or actually controlled by them must be filed with the competent health authority under the State Council and submitted with information backup. Where such activities may affect public health, national security, or public interest in China, a security review organized by the competent health authority under the State Council is required. In October 2020, the SCNPC promulgated the Biosecurity Law of the PRC, which became effective in April 2021. The Biosecurity Law of the PRC reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China’s human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. The interpretation and implementation of the HGR Regulation and the related laws and regulations may vary from time to time. Given such circumstance, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC and other applicable laws in our utilizing of and dealing with China’s human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation and the Biosecurity Law of the PRC and the applicable laws and regulations.

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Numerous U.S. federal and state laws and regulations relate to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, known as "protected health information," and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations may require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act, and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, our clinical trials also frequently involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including principal investigators, hospitals, CROs, and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted

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purposes. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could have a material adverse effect on our business, financial condition and results of operations.

**Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.**

If the NMPA, the FDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, storage, distribution, adverse event reporting, advertising, promotion, sampling, record-keeping and post-marketing studies for the drug will be subject to extensive and ongoing or additional regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any chemistry, manufacturing and controls, variations, continued compliance with GMPs, cGMPs, GCPs, good storage practices and good vigilance practices and potential post-approval studies for the purposes of license renewal.

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 the conditions of approval, or contain requirements for potentially costly post-marketing studies for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved, it is 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 candidates, 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 drug recalls;
- fines, warning letters or holds on our clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- refusal to accept any of our other IND approvals, NDAs or BLAs;
- suspension or revocation of existing drug license approvals;

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- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

Regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of drugs that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. 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 have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and the United States. These laws may impact, among other things, our proposed sales and marketing programs. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with governments.

In addition, we are subject to similar healthcare laws in other jurisdictions, some of which may be broader in scope or stricter than others, and if we fail to comply with any such requirements, we could be subject to penalties.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from

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participation in governmental healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations.

Furthermore, we are subject to anti-bribery laws that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Moreover, although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. There is no assurance that our policies and procedures designed to ensure compliance with anti-bribery laws by us, our employees, and our agents will prevent our agents, employees and intermediaries from engaging in bribery activities. 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. 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, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

**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 global 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 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.

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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. Recently, members of the U.S. House of Representatives proposed pending legislation, namely the BIOSECURE Act (the “Act”). If the Act is enacted in its proposed form, it would prohibit U.S. federal executive agencies from: (1) procuring or obtaining any biotechnology equipment or service produced or provided by a “biotechnology company of concern”, (2) entering into or renewing a contract with an entity that uses such biotechnology equipment or enters into a contract requiring the use of such biotechnology equipment after the applicable effective date of the prohibition, or (3) providing loan or grant funds to perform either of these functions. For details, see “Regulatory Overview.”

Specifically, although the Act did not become law in the 118th Congress the House passed its version on September 9, 2024, and substantially similar provisions could be reintroduced in a subsequent Congress. If it is reintroduced and subsequently enacted in the proposed form, it could prohibit the U.S. government and recipients of federal funds from entering into contracts with us or with our customers if, in performing customer contracts, we supply equipment or services provided by a “biotechnology company of concern” under the Act. For example, such a law, if enacted in that form, could apply to some of the biotechnology equipment and services provided or produced we procure. As a result, continued use of these biotechnology equipment and services provided or produced could affect not only our ability to enter into contracts with the U.S. government, but also our customers’ ability to enter into contracts with, obtain loans or grants from, or participate in other assistance or joint research and development opportunities with the U.S. government.

Consequently, we may need to re-evaluate or adjust our established supply chains, should the Act or other similar legislation 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. Since the Act has not been enacted, its form, scope and context remain subject to changes, and such changes, if material, could also adversely affect our business, financial condition and results of operation.

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

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

**Changes in international trade policies may cause significant disruptions to our business and results of operations.**

We are susceptible to constantly changing international economic, regulatory, social and political conditions, and local conditions in countries and regions. Tensions and political concerns among countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. Political relationships among countries and regions may affect the prospects of our relationship with third parties, such as business partners, suppliers and future customers. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships among countries or regions. Any tensions and political concerns among 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 among countries and regions. For example, on February 21, 2025, U.S. President Donald J. Trump issued a memo titled 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, directed energy, and other areas implicated by the PRC’s national military-civil fusion strategy. 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 drug candidates, any rising trade and political tensions or unfavorable government policies on international trade, such as capital controls or tariffs, may affect the competitive position of our drug products. In addition, rising trade and political tensions, heightened government scrutiny or unfavorable government

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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 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.

**The interpretation and implementation of the PRC Foreign Investment Law may evolve from time to time, which may impose new burdens on us.**

The PRC Foreign Investment Law, or the FIL, was enacted by the National People’s Congress of the PRC on March 15, 2019, and became effective on January 1, 2020. The FIL replaces a trio of previous laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. The FIL embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Implementation Rules to the Foreign Investment Law were promulgated by the State Council on December 26, 2019 and became effective on January 1, 2020. However, the changes in interpretation and implementation of the FIL and its Implementation Rules may increase our compliance costs or set higher standards for our corporate governance practice. For example, the FIL imposes information reporting requirements on foreign investors or foreign-invested enterprises. Failure to take timely and appropriate measures to cope with any of these or other regulatory compliance requirements under the FIL may lead to rectification obligations, penalties or other regulatory sanctions on us.

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**Any failure by the Shareholders or beneficial owners of our Shares to make required applications and filings pursuant to regulations relating to offshore investment activities could restrict our ability to distribute profits and subject us to liabilities.**

The State Administration of Foreign Exchange has promulgated several regulations requiring PRC residents to register before engaging in direct or indirect offshore investment activities, including the Circular on Relevant Issues Concerning the Administration of Foreign Exchange on Domestic Residents’ Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, issued and effective on July 4, 2014. SAFE Circular 37 requires PRC residents (including PRC individuals and PRC bodies as well as foreign individuals that are deemed PRC residents for foreign exchange administration purpose) to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with onshore or offshore assets or equity interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle.” SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC resident does not complete the required registration or update the previously filed registration, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be subject to restrictions when making additional capital contributions to its PRC subsidiaries. Moreover, violations such as unauthorized outbound transfer of onshore foreign exchange or engaging in other foreign exchange evasion activities may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including (i) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas, and (ii) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

According to the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments, or SAFE Circular 30, Administrative Measures for the Outbound Investment of Enterprises and other regulations, if our Shareholders who are PRC entities do not complete their registration with the competent SAFE, NDRC or MOFCOM branches, our PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to us, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. In addition, our Shareholders may be required to suspend or stop the investment and complete the registration within a specified time, and may be warned or prosecuted for relevant liability. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restrictions.

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On February 13, 2015, SAFE promulgated the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment, or SAFE Circular 13, which came into effect on June 1, 2015, pursuant to which local banks shall review and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration under SAFE Circular 37 and SAFE Circular 30, while the application for remedial registrations shall still be submitted to, reviewed and handled by the relevant local branches of SAFE.

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

**We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could affect our ability to conduct our business.**

We are a holding company incorporated as an exempted company in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our Shareholders or to service any debt we may incur. If any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiaries are required to set aside at least 10% of their after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such statutory reserve funds cannot be distributed to us as dividends. In addition, the ability of our PRC subsidiaries to make payments to us is subject to any changes in the laws and regulations relating to the currency conversion, capital outflow management and cross-border transactions.

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### **Dividends paid by our PRC subsidiaries to us may be subject to PRC withholding taxes.**

The PRC Enterprise Income Tax Law (“**Enterprise Income Tax Law**”) and its implementation rules provide that China-sourced income of non-PRC resident enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. As a result, dividends paid to us by our PRC subsidiaries are expected to be subject to the PRC withholding tax at a rate of 10%.

Pursuant to the Arrangement between Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with respect to Taxes on Income, the withholding tax rate on dividends paid by our PRC subsidiary to our Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of our PRC-sourced income, and it directly holds 25% or more interests in our PRC subsidiaries. On February 3, 2018, the State Administration of Taxation issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement, also known as Circular 9, which provides guidance for determining whether a resident of a contracting state or region is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner. There is no assurance that the reduced withholding tax rate will be available to our Hong Kong subsidiary.

### **We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law and become subject to tax liabilities.**

Under the Enterprise Income Tax Law, an enterprise established outside the PRC with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it is treated in a manner similar to a Chinese enterprise for the PRC enterprise income tax (“EIT”) purposes. The implementing rules of the Enterprise Income Tax Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties” of the enterprise. In addition, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following conditions are met: (i) senior management personnel and departments that are responsible for daily production, operation and management are located or resident in China; (ii) financial and personnel decisions are made by, or are subject to approval by, institutions or personnel located in China; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders’ meetings are located or kept in China; and (iv) half or more of senior management or directors having voting rights are resident in China. State Administration of Taxation of the PRC has subsequently provided further guidance on the implementation of Circular 82.

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If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC EIT purposes, a number of tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to EIT at a rate of 25% on our worldwide taxable income, as well as to PRC EIT reporting obligations. Second, although under the EIT Law and its implementing rules, dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax. Finally, dividends paid by us to our non-PRC shareholders, and any gain realized from the transfer of our Shares by our non-PRC shareholders, may be treated as income derived from sources within China. As a result, dividends paid to our non-PRC resident enterprise shareholders may be subject to PRC withholding tax and gains realized by our non-PRC resident enterprise shareholders from the transfer of our Shares may be subject to PRC tax. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise.

**We and our Shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company.**

Pursuant to the Circular on Issues of Enterprise Income Tax Concerning Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Circular 7, an “indirect transfer” of “PRC taxable assets,” including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC EIT. As a result, gains derived from such indirect transfer may be subject to PRC EIT. When determining whether there is a “reasonable commercial purpose” for the transaction arrangement, factors to be taken into consideration mainly include: whether the main value of the equity interest of the relevant offshore enterprise directly or indirectly derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consists of direct or indirect investment in China or if its income mainly derives from China; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure of the relevant offshore enterprise; the foreign income tax liabilities arising from the indirect transfer of PRC taxable assets; the replicability of the transaction by direct and indirect transfer of PRC taxable assets; and tax treaties or similar arrangements applicable to such indirect transfer of PRC taxable assets in China. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC EIT pursuant to Circular 7 where such shares were acquired in a transaction through a public stock exchange. However, the sale of our Shares by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC EIT under Circular 7.

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Circular 7 may be determined by the tax authorities to be applicable to sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries may be requested to assist in the filing. Furthermore, we, our non-PRC resident enterprises and PRC subsidiaries may be required to spend resources to comply with Circular 7 or to establish that we and our non-PRC resident enterprises should not be taxed under Circular 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries.

The PRC tax authorities commence investigations and make adjustments to indirect transfer of PRC taxable assets under Circular 7. If the PRC tax authorities make adjustments to the taxable income of the transactions under Circular 7, we and our Shareholders may incur increased income tax costs associated with such potential acquisitions or disposals.

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

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

The convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency into and out of China are subject to PRC foreign exchange regulations. Under existing PRC foreign exchange regulations, payments of current account items, such as trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate governmental authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies.

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### **Failure to comply with PRC regulations regarding the foreign exchange 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 Listed Company. 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 the same stock incentive plan of an overseas publicly listed company are required to register with SAFE through a domestic qualified agent, which could be the PRC subsidiaries of such overseas-listed company, and complete certain other procedures. In addition, an overseas-entrusted institution must be retained to handle matters in connection with the exercise, purchase or sale of stock and interests. We and our executive officers and other employees who are PRC citizens or non-PRC citizens living in China for a continuous period of not less than one year and have been granted options will be subject to these regulations when our company becomes an overseas-[REDACTED] company upon the completion of the [REDACTED]. Failure to complete SAFE registrations may subject them or us to fines or supervision measures. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors, executive officers and employees.

In addition, the 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.

### **You may experience difficulties in effecting service of legal process, enforcing foreign judgments against us or our management named in the documents.**

We are a holding company incorporated as an exempted company in the Cayman Islands with substantially all of our assets located in China. In addition, certain of our Directors and senior management personnel reside within mainland China, and substantially all of their assets are located within the PRC. Therefore, it may be difficult for investors to directly effect service of legal process upon us or our Directors and senior management personnel in the PRC.

On July 14, 2006, the Supreme People's Court of the PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned, or the Arrangement, which was taken into effect on August 1, 2008.

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Pursuant to the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a mainland court is expressly selected as the court having sole jurisdiction for the dispute.

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, or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong SAR and the mainland China. On January 29, 2024, the New Arrangement became effective and replaced the Arrangement. However, the New Arrangement does not apply to certain judgments of civil and commercial matters. Furthermore, in the absence of relevant treaties or arrangements, there remain uncertainties as to the outcome of any applications to recognize and enforce such judgments and arbitral awards in the PRC.

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

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

Prior to the completion of the [REDACTED], there has been no public market for our Shares. There can be no guarantee that an active [REDACTED] market for our Shares will develop or be sustained after completion of the [REDACTED]. The [REDACTED] is the result of negotiations between our Company and the [REDACTED] (for themselves and on behalf of the [REDACTED]), which may not be indicative of the [REDACTED] at which our Shares will be [REDACTED] following completion of the [REDACTED]. The [REDACTED] of our Shares may drop below the [REDACTED] at any time after completion of the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will not decline following the [REDACTED].

The [REDACTED] price and [REDACTED] volume of our Shares may be volatile and could fluctuate widely in response to factors beyond our control, including general market conditions of the securities markets in Hong Kong, China, the United States and elsewhere in the world. In particular, the performance and fluctuation of the [REDACTED] of other companies with business operations located mainly in China that have [REDACTED] their

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securities in Hong Kong may affect the volatility in the price of and [REDACTED] volumes for our Shares. A number of China-based companies have [REDACTED] their securities, and some are in the process of preparing to [REDACTED] their securities, in Hong Kong. Some of these companies have experienced significant volatility. The [REDACTED] performances of the securities of these companies at the time of or after their [REDACTED] may affect the overall investor sentiment towards China-based companies [REDACTED] in Hong Kong and consequently may impact the [REDACTED] performance of our Shares. These broad market and industry factors may significantly affect the [REDACTED] and volatility of our Shares, regardless of our actual operating performance, and may result in losses on your investment in our Shares.

In addition to market and industry factors, the [REDACTED] and [REDACTED] volume for our Shares may be highly volatile for specific business reasons. In particular, factors such as variations in our revenue, earnings, and cash flow could cause the [REDACTED] of our Shares to change substantially. Any of these factors may result in large and sudden change in the volume and [REDACTED] of our Shares.

**Raising additional capital may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.**

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per [REDACTED] immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in pro forma consolidated net tangible asset value. There can be no assurance that if we were to immediately liquidate after the [REDACTED], any assets will be distributed to Shareholders after the creditors' claims. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, limitations on our ability to acquire or license intellectual property rights or declaring dividends, or other operating restrictions.

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

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

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

There can be no assurance that we will declare and pay dividends because the declaration, payment and amount of dividends are subject to the discretion of our Directors, depending on, among other considerations, our operations, earnings, cash flows and financial position, operating and capital expenditure requirements, our strategic plans and prospects for business development, our constitutional documents and applicable law. For more details on our dividend policy, see “Financial Information — Dividend” in this document.

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

Our corporate affairs are governed by our Memorandum and Articles of Association as well as the Cayman Companies Act and the common law of the Cayman Islands. The rights of shareholders to take action against the Directors, the rights of minority shareholders to institute actions and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those in Hong Kong and other jurisdictions. These differences may mean that the remedies available to the Company’s minority shareholders may be different from those they would have under the laws of Hong Kong or other jurisdictions. See “Appendix IV — Summary of the Constitution of Our Company and the Cayman Islands Company Law” in this document for further information.

**Facts, statistics and forecasts obtained from various government sources in this document relating to the pharmaceutical industry may not be fully reliable.**

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources, comprising information provided or published by government agencies, and we can guarantee neither the quality nor reliability of such source materials. We believe that the information originated from appropriate sources and was extracted and reproduced after taking reasonable care. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, neither we, the Joint Sponsors, [REDACTED], [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

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pharmaceutical 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.

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

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

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