

RISK FACTORS

[REDACTED] in our Shares involves significant risks. You should carefully consider all of the information set out in this document, including the risks and uncertainties described below, before making an [REDACTED] in our Shares. In particular, we are a biopharmaceutical company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the biopharmaceutical industry involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your [REDACTED] in our Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The trading price of our Shares could decline due to any of these risks, and you may lose all or part of your [REDACTED]. 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.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, which will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward Looking Statements” in this document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to development, clinical trials and regulatory approval of our drug candidates; (ii) risks relating to manufacturing and commercialization of our drug candidates; (iii) risks relating to our financial prospects; (iv) risks relating to our intellectual property rights; (v) risks relating to our business and industry; (vi) risks relating to doing business in the PRC; and (vii) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also have a material adverse effect on our business, financial condition and operating results. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

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

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may be unable to commercialize our drug candidates on a timely basis.

Before obtaining regulatory approval for the sale of our drug candidates, we must 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, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing or studies and early clinical trials may not be predictive of the success of later clinical trials, and successful interim or preliminary results of a clinical trial do not necessarily predict successful final results.

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We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or a finding that participants are being exposed to unacceptable health risks;
- regulators may require that we or our investigators suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our drug candidates may be greater than we anticipate; or
- 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.

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 in humans. If the results of the 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;

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- we may be required to create a medication guide outlining the risks of the adverse effects for distribution to patients;
- we may be required to implement a risk evaluation and mitigation strategy program, including medication guides, doctor communication plans and other risk management tools with restricted distribution methods and patient registries;
- 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; or
- 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 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, our business, financial condition, results of operations and prospects would be materially and adversely affected.

If we lose the Fast Track Designation or the Orphan Drug Designation by the FDA for our drug candidates, the time and cost we incur to obtain regulatory approvals may increase.

HTD1801 is the first primary sclerosing cholangitis (“PSC”) drug that has obtained Fast Track Designation from the FDA, followed by an Orphan Drug Designation in the United States, according to CIC. However, there is no assurance that an Orphan Drug Designation or Fast Track Designation will not be lost. Any future policies, or changes to current policies might require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our drug candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our drug candidates, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our drug candidates or any other drug candidates that we may in-license, acquire or develop in the future.

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The regulatory approval processes of the NMPA, FDA, EMA and other comparable regulatory authorities are time-consuming and may evolve over time, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain the approval of the NMPA, FDA, EMA, TGA and other comparable regulatory authorities is inherently uncertain and depends on numerous factors, including the substantial discretion of the regulatory authorities. Generally, such approvals take years to be obtained 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.

We cannot guarantee that we will be able to obtain regulatory approvals for our other existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future. Our drug candidates could fail to receive the regulatory approval of the NMPA, FDA, EMA, TGA or a comparable regulatory authority for many reasons, including but not limited to:

- 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;
- 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 or other submissions or to obtain regulatory approval;
- failure of our drug candidates to pass current GMP, inspections during the regulatory review process or across the production cycle of our drug candidates;
- failure of our clinical sites to pass audits carried out by the NMPA, FDA, EMA, TGA or other comparable regulatory authorities, resulting in a potential invalidation of our research data;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for obtaining approvals; or
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

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The NMPA, FDA, EMA, TGA 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. Legislative and regulatory proposals may also, from time to time, be made to expand existing requirements. For example, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, and potentially introduce more stringent product labeling and post-marketing conditions. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

We may not be able to identify or discover new drug candidates.

We may fail to identify drug candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful adverse effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. We have devoted significant resources to compound discovery efforts through our biotechnology platform, and we cannot guarantee that we will be successful in identifying potential drug candidates.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets 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 research methodology used may not be successful in identifying potential indications and/or drug candidates;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially 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.

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If we encounter delays or difficulties enrolling subjects in our clinical trials, clinical development of our drug candidates could be delayed or otherwise adversely affected.

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

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

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

Even if we are able to enroll a sufficient number of patients or participants 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 prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

We work with various third parties to develop our drug candidates. If these third parties fail to duly perform their contractual obligations or meet expected timelines, we may be unable to obtain regulatory approvals for, or commercialize, our drug candidates, and our business, financial condition and results of operations could be materially and adversely affected.

We have worked with and may continue to work with third parties on our ongoing preclinical and clinical programs. For example, we rely on CROs, clinical trial sites, consultants and other third parties to monitor, support and/or conduct preclinical studies and clinical trials of our drug candidates. We work with these parties to execute our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for

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ensuring that each of our studies is conducted in accordance with the applicable protocols, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the NMPA, FDA, EMA, TGA and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with the applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, FDA, EMA, TGA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with products produced under GMP regulations. Any failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. If CROs fail to duly perform their contractual obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approvals for, or successfully commercialize, our drug candidates. Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. Any of the foregoing events may cause cost increases, restrict our ability to generate revenue and have a material adverse effect on our business and prospects.

Our ability to generate future revenue is dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approvals. Our arrangements with collaborators will be critical to the successful commercialization of our drug candidates and future products. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process, and to assist with our commercialization efforts. We do not control our collaborators, and therefore there can be no assurance that these third parties will adequately and timely perform all of their obligations under their agreements with us. If they fail to complete the remaining studies successfully, or at all, it could delay or adversely affect the obtaining of regulatory approvals. There can be no assurance of the satisfactory performance of any of our collaborators, and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the product which could materially and adversely affect our business, financial condition, cash flows and results of operations. In addition, we may rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately carried out and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on us until deficiencies are remedied.

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

Our relationships with principal investigators (“**PIs**”), key opinion leaders (“**KOLs**”), physicians and experts play an important role in our research and development and marketing activities. We have established extensive interaction channels with PIs, 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 new market-responsive drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with our PIs and KOLs, physicians and experts, or that our efforts to maintain or strengthen such relationships will yield 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. Moreover, we cannot assure you that our academic promotion and marketing strategy will continue to serve as an effective marketing strategy. 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 to our efforts spent. If we are unable to develop new drugs or generate returns from our relationships with industry participants as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

Results of earlier clinical trials may not be predictive of results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later phase clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial and early phase clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Future clinical trial results may not be favorable for these and other reasons.

In some cases, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. As drug candidates are developed through preclinical to early- to late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, which could delay completion of clinical trials, delay approval of our drug candidates and/or jeopardize our ability to commence commercialization of our drug candidates.

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All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with relevant laws and regulations may adversely affect the business and results of operations of our Group.

All jurisdictions in which we intend to conduct our biopharmaceutical industry activities regulate these activities in great depth and detail. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ extensive regulations governing the development, approval, manufacturing, marketing, sales and distribution of pharmaceutical products. Differences in regulatory regimes across jurisdictions may lead to a higher compliance burden.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. 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 but are not limited to: refusal to approve pending applications; withdrawal of an approval; license revocation; clinical hold; mandatory product recalls; product seizures; total or partial suspension of production or distribution; injunctions, refusals of government contracts; injunctions, fines and other civil or criminal penalties. Failure to comply with these regulations could therefore have a material adverse effect on our business.

We may not be able to comply with ongoing regulatory obligations and continued regulatory review even if we receive regulatory approval for our drug candidates.

Once our drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, post-marketing studies, and submission of safety, efficacy, and other post-market information in different jurisdictions, such as the United States, China and Europe. For example, in order to produce drugs for sales, we may become subject to extensive laws and regulations enforced by the NMPA, FDA, EMA, TGA and other applicable regulatory authorities, including those ensuring that quality control and manufacturing procedures conform to current GMP regulations. Moreover, any new legislation addressing drug safety issues could result in increased costs to ensure compliance with ongoing regulatory requirements.

The NMPA, FDA, EMA, TGA or other applicable regulatory authorities may withdraw its approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the drugs reach the market. Later discovery of previously unknown problems with our drug candidates, including but not limited to adverse events of unanticipated severity or frequency, or with our manufacturing processes, or failure to comply with regulatory requirements, may result in voluntary or mandatory product recalls; revocation of or refusal to grant permits and approvals; revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation program.

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The NMPA, FDA, EMA, TGA and other applicable regulatory authorities also strictly regulate the marketing, labeling, advertising and promotion of products 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 NMPA, FDA, EMA, TGA and other applicable 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.

Moreover, the biopharmaceutical market is heavily regulated in China. 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 will lower the entry barrier for potential competitors, or an increase in regulatory requirements which may cause difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects.

RISKS RELATING TO MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

We work with third parties to manufacture a portion of our drug candidates for clinical development and commercial sales. Our business could be harmed if those third parties fail to deliver sufficient quantities of products or fail to do so at acceptable quality levels or prices.

We currently do not have in-house manufacturing facilities. Currently and in the long term future, we plan to work with qualified CDMOs (including CMOs) to manufacture product candidates for preclinical and clinical supply. We also procure technical services, including CRO and CDMO services and consulting services that support our clinical trials and preclinical studies.

Reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited and the NMPA, FDA, EMA, TGA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates;
- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection and other government regulations by the NMPA, FDA, EMA, TGA or other comparable regulatory authorities to ensure strict compliance with GMP. We do not have control over third party manufacturers’ compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;

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- manufacturers 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;
- manufacturers may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact commercialization of our future approved drug candidates.

We have limited experience in commercializing our drug candidates. If we are unable to establish sales network, we may not be able to generate sales revenue.

We have yet to demonstrate our capabilities in commercializing any of our drug candidates. This process is challenging and uncertain, and requires significant investment of time and resources. In particular, we have not initiated production at a commercial scale, or arranged for a third party to do so on our behalf, or engaged in extensive sales, marketing and distribution activities necessary for the successful launch of our drug candidates.

We may engage third parties as our business partners to pursue collaborative arrangements for 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 such arrangements will lead to satisfactory outcome. Sales we achieve will partially depend on the capabilities and efforts of such third parties. We may have little or no control over such third parties, and the profitability of selling drugs through collaboration may be even lower than selling the drug candidates ourselves.

We will also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug candidates.

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

Even if we are able to receive the requisite regulatory approvals of our existing and future drug candidates, such drug candidates may fail to gain sufficient market acceptance by physicians, patients, third-party payers and other relevant parties in the medical community. If drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from our product portfolio and we may not become profitable. The degree of market acceptance of our drug candidates will depend on a number of factors, including but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians’ and patients’ perception of our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the NMPA, FDA, EMA, TGA or other applicable regulatory authorities;
- limitations or warnings contained in the labeling approved by the NMPA, FDA, EMA, TGA or other applicable regulatory authorities;
- the timing of market introduction of our drug candidates as well as competing drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage and reimbursement by government authorities under the National Reimbursement Drug List (“NRDL”) (《國家醫保藥品目錄》) and other government-sponsored medical insurance programs, or by third-party payers;
- 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; or
- the effectiveness of our sales and marketing efforts.

If our drug candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue. Even if our drugs achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, are more cost effective or render our drugs obsolete.

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

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide, as well as academic institutions research organizations.

We are developing our drug candidates in competition with a number of biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs for the same indications. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Our competitors may develop generic or biosimilar drugs if the patent protection of our drug candidates will be expired. For more details, see “Industry Overview”. Many of our competitors have significantly greater financial, development, manufacturing, marketing, sales and supply resources or experience than we do. Our commercial opportunity and success will be reduced or eliminated, if any competing products become available that are more effective or cost-efficient than ours.

Our drugs may not be covered by reimbursement programs or may become subject to unfavorable reimbursement practices, either of which could harm our business.

Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities and/or third-party payers, such as private health insurers and health maintenance organizations. The regulations that govern reimbursement for new therapeutic drugs vary substantially from country to country.

In China, the NRDL and Provincial Reimbursement Drug Lists (“**PRDL**”) (《省級醫保藥品目錄》) 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 drug candidates will be included in the NRDL or the PRDL after initial approval for commercial sale. Pharmaceutical products included in the NRDL or the PRDL are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL or the PRDL due to cost constraints. 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 PRDL, our revenue from commercial sales will be highly dependent on patient self-payment, which can make our products less competitive.

In addition, a key trend in the global healthcare industry is cost containment. Government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. As a result, even if our drug candidates are successfully approved by the NRDL or PRDL or any other reimbursement programs sponsored by government health administration authorities and third-party payers, our potential revenue from

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the sales of these products could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in such reimbursement programs due to price control policies. 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 assure you that reimbursement will be available for our drug candidates that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any approved drug candidate that we commercialize. Obtaining or maintaining reimbursement for approved drug candidates 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 candidate that we successfully develop.

There may also be significant delays in obtaining reimbursement for approved drug candidates, and reimbursement coverage may be more limited than the approved indications of the drug candidates by the NMPA, FDA, EMA, TGA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the uses of the drugs and the clinical setting in which the drugs are 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 by mandatory discounts or rebates required by government healthcare programs or private payers and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices. Our inability to promptly obtain reimbursement coverage at intended payment rates from both government funded and private payers for our drug candidates and any new drug candidates that we develop could have a material adverse effect on our business, operating results, and overall financial conditions.

The manufacture of pharmaceutical products is a highly exacting and complex process, and if we encounter problems in manufacturing our products, our business could be materially and adversely affected.

The manufacturing of our drug candidates is highly complex and we have limited experience in commercial manufacturing. Problems may arise during manufacturing for a variety of reasons, including but not limited to equipment malfunction, failure to follow specific protocols and procedures, changes in product specification, low quality or insufficient supply of raw materials, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and other environmental factors. Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

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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 changes carry the risk that they will not achieve these intended objectives. Any of these changes 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.

If the market opportunities for our drug candidates are smaller than we believe they are or any approval we obtain is based on a narrower definition of the patient population, our business may suffer.

Our estimates regarding our eligible patient population, pricing and available coverage and reimbursement determine our estimated market size, which may differ significantly from the actual market addressable by our drug candidates. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and analysis. These estimates have been derived from a variety of sources, including patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our drug candidates may be limited or may not be receptive to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. If the market opportunities for our drug candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

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 relative to our competitive drug candidates, could result in current or potential decreased use and/or sales of, and revenue 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.

RISK FACTORS

RISKS RELATING TO OUR FINANCIAL PROSPECTS

We have incurred significant net losses since inception and we may continue to incur net losses and may fail to achieve or maintain profitability in the future. As a result, you may lose substantially all of your [REDACTED] in us if our business fails.

Investment in pharmaceutical or biotechnology companies is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We have incurred significant expenses related to the research and development of our drug candidates. For the years ended December 31, 2021 and 2022, our research and development costs amounted to RMB84.0 million and RMB182.7 million, respectively. In addition, we also incurred other expenses related to our operations including administrative expenses. As a result, we recorded net losses of RMB221.1 million and RMB190.2 million for the years ended December 31, 2021 and 2022, respectively.

We expect to continue to incur significant expenses and operating losses for the foreseeable future 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;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- commercialize any of our drug candidates for which we may obtain marketing approval;
- seek to identify additional drug candidates;
- address any competing technological and marketing developments, including new drugs developed by competitors;
- maintain, protect and expand our intellectual property portfolio; and
- create additional infrastructure to support our operations as a public company and our drug development and future commercialization efforts.

We cannot guarantee that we will be able to obtain regulatory approvals for any of our drug candidates in a timely manner, or at all. In addition, none of our drug candidates has been approved for marketing in China or any other jurisdictions yet. Substantial investments may be incurred before we generate any revenue from product sales. Considering the numerous risks and uncertainties associated with regulatory approval, we are unable to accurately predict the timing or amount of additional expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the NMPA, FDA, EMA, TGA or other applicable authorities to perform studies in addition to those that we currently anticipate. Even if our drug candidates are approved for commercial sale, we expect to continue incurring significant costs associated with the manufacturing and the commercial launch of the drug candidates.

RISK FACTORS

We had net operating cash outflows and net liabilities during the Track Record Period. We will need to obtain additional financing to fund our operations, and if we are unable to obtain additional financing to fund our operations, we may be unable to complete the development and commercialization of our product candidates.

Since our inception, our operations have consumed substantial amounts of cash. We had operating cash outflows of RMB90.5 million and RMB172.4 million in 2021 and 2022, respectively. We had net liabilities of RMB272.3 million and RMB470.5 million as of December 31, 2021 and 2022, respectively. Our net liabilities position was in part due to the accounting treatment for convertible redeemable preferred shares in relation to our Preferred Shares, which are classified as financial liabilities measured at FVTPL. Our Preferred Shares will be converted into Shares upon the [REDACTED], but we may still retain accumulated losses due to the loss on the fair value change of our Preferred Shares after the [REDACTED].

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, initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates.

Additionally, we are exposed to credit risk on the cash and cash equivalents deposited in financial institutions. In the event that any of them becomes insolvent and is taken into receivership by the relevant government agencies, there will be uncertainty as to the timing and extent to which we will be able to recover our cash on deposit at such financial institution.

While we believe we have sufficient working capital to fund our current operations for the next 12 months, we expect that we may experience net cash outflows from our operating activities for the foreseeable future. We may need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on reasonable terms, we could have to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

We have never generated any revenue from sales of drug products, and our ability to generate revenue from sales of drug products and become profitable depends significantly on our success in a number of factors.

We have no drug products approved for commercial sale, have not generated any revenue from drug product sales, and do not anticipate generating any revenue from drug product sales until sometime after we have received regulatory approval for the commercial sale of our drug candidates. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including but not limited to:

- completing research regarding, and nonclinical and clinical development of, our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical studies;

RISK FACTORS

- developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates, intellectual property and technologies;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trademarks, trade secrets, and know-how; or
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the NMPA, FDA, EMA, TGA or other regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the market for the relevant product in China or the relevant jurisdictions, the accepted price for the product to be paid with out-of-pocket expenses and the ability to get reimbursement for any amount. If the number of patients with our addressable disease is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We benefit from certain preferential tax treatments and government grants, the expiration of or changes to which could adversely affect our profitability.

We currently benefit from certain preferential tax treatments. Shenzhen HighTide has been approved as a high technology enterprise under the relevant tax rules and regulations, and accordingly, is entitled to a preferential corporate income tax rate of 15% from 2022 to 2024. We cannot assure you that these preferential tax treatments will continue to be available to us in the future or that these preferential tax treatments will not be changed as a result of changes in government policy, administrative decisions or otherwise, in which case our financial condition and results of operations may be adversely affected.

RISK FACTORS

During the Track Record Period, we recognized RMB9.8 million and RMB8.0 million of government grants in other income and gains for the years ended December 31, 2021 and 2022, respectively. The timing, amount and criteria of government financial incentives are determined at the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project by project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions. If we fail to satisfy any such condition, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives may have an adverse effect on our results of operations. In addition, we may not be able to receive government grants in the future, which may have an adverse effect on our financial condition and results of operations.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our commercial success will depend, in large part, on our ability to obtain and maintain patent and other intellectual property protection with respect to our drugs and drug candidates. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our drug candidates, or otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. Patent applications we had applied may not be granted in the end. As such, we do not know the degree of future protection that we will have on our drugs and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our drug candidates could have a material adverse impact on our business.

The scope of patent protection in various jurisdictions is uncertain. Changes in either the patent laws or their interpretation in the United States, the PRC, or other countries or regions may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any future granted patents will provide sufficient protection from competitors.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or

RISK FACTORS

otherwise provide us with any competitive advantage. In addition, the patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been a common subject of litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration (“CNIPA”), the United States Patent and Trademark Office (“USPTO”) and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The CNIPA, the USPTO and other governmental patent agencies also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. We work with our counsel and professionals to help us comply with these requirements with respect to our intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include the failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property rights throughout the world or prevent unfair competition by third parties.

We focus on protecting our intellectual property rights in our target markets, primarily the United States, China and Europe. Filing, prosecuting, maintaining and defending patents on drug candidates in all other countries throughout the world could be prohibitively expensive for us. Our intellectual property rights in other jurisdictions, if obtained, can have a 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. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in markets such as the United States. Consequently, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions into our target markets or other jurisdictions. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

RISK FACTORS

We may from time to time be involved in lawsuits to protect or enforce our patents and other intellectual property, which could be expensive, time-consuming and unsuccessful and may delay us from developing or commercializing our drug candidates. Our patent rights relating to our drug candidates could be found invalid or unenforceable if being challenged.

Litigation relating to patents and other intellectual property rights is common in the pharmaceutical industries, and is inherently uncertain. Even if successful, litigation may result in substantial costs and reputational harm, and distraction of our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be inevitably compromised by disclosure during discovery.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In any infringement proceeding, the defendant may be able to counterclaim that our patent is invalid and/or unenforceable, and a court may uphold such claims, or otherwise refuse to stop the opposing party from using the technology at issue, on the potential grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent application at risk of not being issued.

On the other hand, if a third party were to assert claims of patent infringement, misappropriation of trade secrets, or violation of other intellectual property rights against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents and rights are valid, enforceable and infringed, and the holders of any such patents and rights may be able to block our ability to commercialize the applicable product unless we obtained a license from them, or until such patents or rights expire or are finally determined to be invalid or unenforceable. Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could also be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or [REDACTED] perceive these announcements as negative, the perceived value of our drug candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our Shares may decline. Such announcements could also harm our reputation or the commercialization of our drug candidates, which could have a material adverse effect on our business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials and continue our in-house research programs.

RISK FACTORS

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize our drug candidates.

If third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology, or barred from developing and commercializing our drug candidates. Prohibitions against using certain technologies, or prohibitions against commercializing our drug candidates, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed.

We may face intellectual property disputes with our business partners.

We may be subject to claims that former employees, collaborators, contractors or other third parties have an interest in our patents or other intellectual property, for example as an inventor or co-inventor. When enforcing our rights in our patents or other intellectual property, we may be subject to counterclaims that we do not own or possess clean title to one or more patents or patent applications that cover development, manufacture, and commercialization of one or more of our drug candidates. If we are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents, or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we are unsuccessful in any inventorship or ownership disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our patents.

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

We own registered trademarks. We may not always be able to obtain and ensure trademark protection in territories that we consider of significant importance to us. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to protect our rights to these trademarks and trade names, which we will need in order to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

RISK FACTORS

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

As it is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents and trademarks of our trade names. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The illustrative examples include but are not limited to:

- others may be able to make products that are similar to our drug candidates but that are not covered by the claims of the patents that we own;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our 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 our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we receive NDA approval for drugs containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- 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 drugs for commercialization in our major markets;
- we may fail to develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our drug candidates for one or more indications; or
- our competitors might develop biosimilar drugs if the patent protection of our drug candidates will be expired.

RISK FACTORS

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

The life of patent protection is limited, and third parties could be able to circumvent our patents by developing similar or alternative products and technologies in a non-infringing manner, or 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 adversely affected.

The life of a patent and the protection it affords is limited. For example, in China, if all maintenance fees are timely paid, the invention patents, design patents and utility model patents are valid for 20 years, 15 years and 10 years from its filing date, respectively, with potential patent term extension or adjustment for invention patents under the current Patent Law of the PRC. Even if we successfully obtain patent protection for an approved product candidate, it may face competition from generic or biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would materially adversely affect any potential sales of that product.

Patent terms may not be adequate to protect our competitive position on our product candidates in the absence of patent linkage, patent term extensions and other exclusivities. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product 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. The pending patent applications, if issued, for our product candidates are expected to expire on various dates as described in “Business — Intellectual Property”. Upon the expiration of our patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors, which would materially adversely affect our business, financial condition, results of operations and prospects.

According to Article 42 of the Patent Law of the PRC issued on October 17, 2020 and implemented on June 1, 2021, for the purpose of compensating for the time taken to evaluate and approve a new drug to be put on market, CNIPA shall grant compensation for duration of patent right for invention of a new drug approved to be put on market in China upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent right for a new drug approved to be put on market shall not exceed 14 years.

RISK FACTORS

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

In addition to our patents, we rely on trade secrets and confidential information, including but not limited to unpatented know-how, technology and other proprietary information to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets and confidential information, in part, by entering into confidentiality agreements with parties that have access to them, such as our employees, outside collaborators, CROs, consultants and other third parties. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Substantiating and winning 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 may have no means to prevent them from using that technology or information to compete with us, and our competitive position would be harmed.

Furthermore, many of our employees including our senior management, were previously employed at other pharmaceutical or biotechnology companies, which may include our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants and advisors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any of the former employers of such employees, consultants and advisors. We are not aware of any such claims threatened or pending as of the Latest Practicable Date, but there is no assurance that we will not be subject to such claims or involved in litigations to defend against such claims in the future. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and reputational harm, and be a distraction to our management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with every party who is actually involved in developing intellectual property that we regard as our own. Further, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel and could have a material adverse effect on our business, financial condition, results of operations and prospects.

RISK FACTORS

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

Depending on decisions by the National People’s Congress and the CNIPA, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, the Patent Law of the PRC, as amended by the Standing Committee on October 17, 2020, came into effect on June 1, 2021. The potential influence on our existing patent rights and future patent applications remains uncertain. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. The United States has enacted and is currently implementing wide-ranging patent reform legislation. The United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations recently. 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.

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our drug candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, sales and marketing capabilities or contract with third parties to provide these capabilities for us. In addition, we may need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant additional responsibilities on our management. Our future financial performance and our ability to commercialize our drug candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We cannot assure you that we will be able to successfully develop and commercialize our drug candidates and build suitable manufacturing, sales, marketing and managerial teams to meet our growth targets. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

We may be subject to product liability lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability caused by our drugs. Any such product liability claims may include allegations of defects in manufacturing, defects in design, improper, insufficient or improper labelling of products, insufficient or misleading disclosures of side effects or dangers inherent in the product, negligence, strict liability and a breach of warranties. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates or any resulting products;
- injury to our reputation;

RISK FACTORS

- withdrawal of clinical trial participants;
- 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;
- the inability to commercialize our drug candidates; and
- a decline in our Share price.

If we are unable to defend ourselves against such claims in the PRC, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products are found to be defective. In addition, we may be required to recall the relevant products, suspend sales or cease sales. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management.

We may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.

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

We are subject to the risks of doing business in multiple jurisdictions.

As we operate in the PRC, the United States and Australia, our business is subject to risks associated with doing business in multiple jurisdictions. Our business and financial results in the future could be adversely affected due to a variety of factors, including but not limited:

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

RISK FACTORS

- tensions between the PRC and the United States;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management’s attention from the development of our drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic stagnation or downturn in certain jurisdictions, including those caused by inflation or political instability;
- the burden of complying with a variety of foreign laws;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- 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, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- the effects of applicable local tax regimes and potentially adverse tax consequences; or
- significant adverse changes in local currency exchange rates.

For example, in the event that the PRC or the countries from which we import raw materials impose import tariffs, trade restrictions or other trade barriers affecting the importation of such components or raw materials, we may not be able to obtain a stable supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. We may also sell our products to certain foreign countries in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. It is notable that the United States government has made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs, which have led to other countries, including the PRC and members of the EU, imposing tariffs against the United States in response. These trade disputes may further escalate and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between the PRC and other relevant foreign countries

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or regions. Tensions and political concerns between the PRC and the relevant foreign countries or regions may therefore adversely affect our business, financial condition, results of operations and prospects.

In addition, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability and changes in diplomatic and trade relationships. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially and adversely affect our business and results of operations.

Our Single Largest Group of Shareholders have substantial influence over our Company and their interests may not be aligned with the interests of our other Shareholders.

Immediately after completion of the [REDACTED], assuming the [REDACTED] is not exercised and no Share is repurchased from the ESOP Platforms before the [REDACTED], our Single Largest Group of Shareholders will collectively control approximately [REDACTED]% voting power at general meetings of our Company. Our Single Largest Group of Shareholders will, through their voting power at the Shareholders’ meetings and their delegates on the Board, have significant influence over our business, including matters relating to our management, policies and decisions regarding acquisitions, mergers, expansion plans, consolidations and sales of all or substantially all of our assets, election of Directors and other significant corporate actions. This concentration of voting power may discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their Shares as part of a sale of our Company and might reduce the [REDACTED] of our Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of our Single Largest Group of Shareholders may differ from the interests of our other Shareholders. We cannot assure you that our Single Largest Group of Shareholders will not exercise their substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as other key clinical and scientific personnel, and other key employees.

Competition for qualified employees in the biopharmaceutical industry is intense and the pool of qualified candidates is limited. In recent years, the average labor cost in the global biopharmaceutical market, particularly for highly skilled and experienced personnel, has been rising steadily. We cannot assure you that there will be no significant increase in our labor cost, especially as we continue to expand our business and operations. Despite an increase in labor cost, we may still not be able to retain the services of experienced senior management or key clinical and scientific personnel in the future. The departure of one or more of our senior management or key clinical and scientific personnel, whether or not they join a competitor or form a competing company, may subject us to risks relating to finding replacements in a timely manner or at all, which may disrupt our drug development progress and have a material and adverse effect on our business and results of operations. We will also need to hire additional employees as we expand our commercialization and manufacturing teams.

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We may be subject to disasters, health epidemics, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations.

Natural disasters, acts of war, terrorism or other force majeure events beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations, and those of our third-party research institution collaborators, suppliers and other contractors and consultants, 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, force majeure events such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or 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 the PRC or elsewhere in the world could materially disrupt our business and operations. For example, since the end of December 2019, the outbreaks of a novel strain of coronavirus COVID-19 have materially and adversely affected the global economy. Many countries and regions had been affected by the COVID-19 outbreaks and, in response, had imposed certain lockdown measures, closure of workplaces and restrictions on mobility and travel to contain the spread of the virus. The outbreak of COVID-19 has caused temporary suspension of production and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy. In December 2022, China began to modify its COVID-19 policy, and most of the travel restrictions and quarantine requirements has been lifted. However, there is no assurance that such kind of health epidemic or even a more severe pandemic will not occur again in the future.

There also could occur serious natural disasters, which may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, disaster, epidemics, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. As we rely on third parties on various services and supplies, the occurrence of any of the foregoing events could seriously harm ability to obtain services or supplies if such third parties are affected by disasters, epidemics, business interruptions and other force majeure events. In addition, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. Acts of war or terrorism may also injure our employees, 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.

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If we or our business partners fail to protect data and privacy of subjects in our clinical trials, or the medical institutions that we conduct clinical trials at or provide services to, our reputation will be damaged and we might be subject to fines or other regulatory punishments.

We need to collect and store subjects’ personal data and information in clinical trials, which require us and our business partners such as clinical trial institutions and medical institutions to maintain an effective control system to protect such personal data and information. The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every major target market in which we operate or intend to operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection. For example, the PRC regulatory and enforcement regime regarding privacy, data protection and information security is still evolving. For example, the Standing Committee of the National People’s Congress promulgated the Personal Information Protection Law (《個人信息保護法》), which became effective on November 1, 2021. The Personal Information Protection Law sets forth detailed rules on handling personal information (including but not limited to collection, storage, use, processing, transmission, provision, disclosure and deletion, etc.) and legal responsibilities, in case of any personal information processing, such individual prior consent shall be obtained, unless the Law indicates otherwise. 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 strictly protective measures have been taken. The Personal Information Protection Law also strengthens the punishment for illegal process of personal information.

Whilst we have adopted security policies and measures to protect our proprietary data and subjects’ privacy, misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of personal data might not be avoided due to human error, employee misconduct or system breakdown. We also cooperate with third parties including principal investigators, hospitals and other third parties for our clinical trials. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. 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 cause our customers to lose trust in us and could expose us to legal claims. Although we have made efforts to ensure our compliance with the applicable privacy regulations in the relevant jurisdictions, we may not be capable of adjusting our internal policies in a timely manner and any failure to comply with applicable regulations could also result in regulatory enforcement actions against us.

Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security 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, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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Our [REDACTED] may be impeded and our business operations may be adversely affected by the Measures for Cybersecurity Review or the Regulation on the Administration of Cyber Data Security (Draft for Comments).

On December 28, 2021, the Cyberspace Administration of China (“CAC”), jointly with the other 12 governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “MCR”), which became effective from February 15, 2022. Pursuant to Article 2 of the MCR, besides the procurement of network products and services by critical information infrastructure operators, any data processing activity by network platform operators that affects or may affect national security shall be subject to the cybersecurity review. In accordance with Article 7 of the MCR, network platform operators mastering personal information of more than one million users must apply to the Cybersecurity Review Office for cybersecurity review when listing abroad (國外上市).

On November 14, 2021, CAC promulgated the Regulation on the Administration of Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》) (the “**Draft Cyber Data Security Regulation**”). Given that the Draft Cyber Data Security Regulation had not come into force as of the Latest Practicable Date, the applicability of various requirements under the Draft Cyber Data Security Regulation is still subject to further official guidance and applicable implementation rules.

Our PRC Legal Advisor conducted a telephonic consultation with the China Cybersecurity Review Technology and Certification Center (the “**Center**”). The Center is authorized by the Cybersecurity Review Office of the CAC to accept public consultation and cybersecurity review submissions and is the competent authority to provide views and interpretation relating to the MCR. According to the Center, (i) the listing in Hong Kong does not fall within the scope of “listing abroad”; (ii) critical information infrastructure operators are identified by the governmental authorities of corresponding industry; (iii) Draft Cyber Data Security Regulation had not come into force as of the Latest Practicable Date, the applicability of various requirements under the Draft Cyber Data Security Regulation is still subject to applicable implementation rules.

As of the Latest Practicable Date, (i) we have not been notified of the results of any determination that we have been identified as a critical information infrastructure operator or that any of our systems have been identified as critical information infrastructure by the relevant governmental authorities; (ii) the MCR provides no further explanation or interpretation for “online platform operator” and “list abroad”, and does not stipulate that an online platform operator which intends to list in Hong Kong will be subject to cybersecurity review; (iii) Hong Kong is not a foreign country or region and does not fall within the scope of “abroad” under the MCR, and there is no specific guidance or implementation rules to indicate otherwise; (iv) the MCR provides no further explanation or interpretation for “affect or may affect national security”, which remains to be clarified and elaborated by the CAC, and we have not received any notification of cybersecurity review from relevant governmental authorities due to our impact or potential impact on national security; (v) the volume of personal information we process is far less than one million people; and (vi) we believe that our collection and handling of the personal information do not constitute any data processing activities that may affect national security under the Draft Cyber Data Security Regulation. Therefore, as advised by our PRC Legal Advisor, our Directors believe that as long as there is no material change to our current business and if no further rules are introduced and no significant changes to the enforcement of the MCR by governmental authorities, cybersecurity review under the article 2 and article 7 of the MCR shall not be applicable to us.

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Furthermore, based on the fact that (i) the MCR came into effect recently and the Draft Cyber Data Security Regulation has not been formally adopted, and their implementation and interpretation are subject to uncertainties and (ii) we have not been involved in any investigations on cybersecurity review initiated by the CAC on such basis and nor have we received any inquiry, notice, warning, or sanctions in such respect, with the support of our PRC Legal Advisor, we are of the view that we comply with such regulations in all material aspects and we believe such regulations would not have a material adverse impact on our business operations or our [REDACTED]. Considering that (a) we have not been involved in any cybersecurity review or investigation by the CAC or other authorities with respect to the MCR; (b) we have not been informed that we are recognized as a crucial information infrastructure operator by any relevant authority; (c) the data processed by us has not been included in the effective core data and important data catalogs by any authority; and (d) we have taken reasonable and adequate technical and management measures to ensure data security, we are of the view that the likelihood that our business operation or the [REDACTED] might give rise to national security risks is remote.

However, the MCR and the Draft Cyber Data Security Regulation were both released recently, certain provisions of which are still unclear and are subject to the finalization or clarifications by relevant authorities. As such, the PRC regulatory authorities may have broad discretion in the interpretation of “affect or may affect national security”. Moreover, given that the Draft Cyber Data Security Regulation was still in the draft form for comments and had not come into force as of the Latest Practicable Date, the applicability of various requirements thereunder is still subject to further official guidance and applicable implementation rules. If we were deemed as a data processor that “affects or may affect national security” by the PRC regulatory authorities under their broad discretion, we may be subject to cybersecurity review. If we fail to pass such cybersecurity review, our [REDACTED] may be impeded, our business operations may be adversely affected, and/or we may be subject to other severe penalties and/or action by the competent government authorities.

On July 7, 2022, the CAC promulgated the Measures for the Security Assessment of Data Cross-border Transfer (《數據出境安全評估辦法》), which took effect on September 1, 2022. The Measures for the Security Assessment of Data Cross-border Transfer requires the data processor providing data overseas and falling under any of the following circumstances apply for the security assessment of cross-border data transfer by the national cybersecurity authority through its local counterpart: (i) where the data processor intends to provide important data overseas; (ii) where the critical information infrastructure operator and any data processor who has processed personal information of more than 1,000,000 people intend to provide personal information overseas; (iii) where any data processor who has provided personal information of 100,000 people or sensitive personal information of 10,000 people to overseas recipients accumulatively since January 1 of the last year intends to provide personal information overseas; and (iv) other circumstances where the security assessment of data cross-border transfer is required as prescribed by the CAC. As advised by our PRC Legal Advisor, the volume of personal information we process does not meet the aforesaid trigger thresholds, and our business does not involve the aforesaid cross-border transfer of important data, the Measures for the Security Assessment of Data Cross-border Transfer is not applicable to us currently.

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On February 22, 2023, the CAC issued the Measures for the Standard Contract for Cross-Border Transfer of Personal Information (《個人信息出境標準合同辦法》), (the “**Standard Contract Measures**”), along with the formal version of the standard contractual clauses for cross-border transfer of personal information stipulated under the Personal Information Protection Law. The Standard Contract Measures will come into effect on June 1, 2023, and provide a six-month grace period. Any violation of the Standard Contract Measures shall be punished in accordance with the Personal Information Protection Law and other laws and regulations. We intend to comply with such measures within the six-month grace period in 2023. However, if we fail to comply with such measures by November 30, 2023, we may face legal liability under the Personal Information Protection Law, including being ordered to make corrections, given a warning, confiscation of illegally obtained gains, etc.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, if and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities. In addition, according to the Administration of Human Genetic Resources (《人類遺傳資源管理條例》) promulgated in May 2019 and the PRC Biosecurity Law (《生物安全法》) promulgated in October 2020, if any scientific data falls within the scope of Chinese human genetic resources, any transfer of such data outside of China will be subject to the prior approval of the PRC Ministry of Science and Technology. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all.

Our investments or acquisitions may have a material adverse effect on our business, reputation, financial condition and results of operations.

We may in the future evaluate and consider a wide array of investments and acquisitions that we believe can augment our overall business strategy. We may be engaged in discussions or negotiations with respect to one or more of these types of transactions. These transactions involve significant challenges and risks, including but not limited to:

- difficulties integrating into our operations the personnel, operations, products and services;

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- technology, internal controls and financial reporting of companies we acquire;
- disrupting our ongoing business, distracting our management and employees and increasing our expenses;
- losing skilled professionals as well as established client relationships of the businesses we invest in or acquire;
- for investments over which we do not obtain management and operational control, we may lack influence over the controlling partner or shareholder, which may prevent us from achieving our strategic goals in such investment;
- new regulatory requirements and compliance risks that we become subject to as a result of acquisitions in new industries or otherwise;
- actual or alleged misconduct or non-compliance by any company we acquire or invest in (or by its affiliates) that occurred prior to our acquisition or investment, which may lead to negative publicity, government inquiry or investigations against such company or against us;
- unforeseen or hidden liabilities or costs that may adversely affect us following our acquisition of such targets;
- regulatory hurdles including the anti-monopoly and competition laws, rules and regulations of the PRC and other countries in connection with any proposed investments and acquisitions;
- the risk that any of our pending or other future proposed acquisitions does not close;
- the costs of identifying and consummating investments and acquisitions;
- the use of substantial amounts of cash and potentially dilutive issuances of equity securities;
- the occurrence of significant goodwill impairment charges and amortization expenses for other intangible assets; or
- challenges in achieving the expected benefits of synergies and growth opportunities in connection with these acquisitions and investments.

Any such negative developments described above could disrupt our existing business and have a material adverse effect on our business, reputation, financial condition and results of operations.

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If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including but not limited to:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- 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;
- retention of key employees, the loss of key 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 products and pipeline products and regulatory approvals; and/or
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

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

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In addition, if we undertake acquisitions, we may assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals materials, and may produce hazardous wastes. We may contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials and wastes, whether arising from our own operations or those of our CROs, CDMOs or other contractors and business partners, now or in the future. In the event of such contamination or injury, we could be held liable for any resulting damages, and such liabilities could exceed our resources. We could also incur significant costs associated with civil or criminal fines and penalties.

In addition, we may incur substantial costs to ensure compliance 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 subject, directly or indirectly, to 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 other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians and others, play a primary role in the recommendation and prescription of products for which we may seek regulatory approval. If we obtain approval from the NMPA, FDA, EMA, TGA or other regulatory authorities for any of our drug candidates and if we then begin to market those drugs in the United States or in the PRC, our operations may be subject to federal and state fraud and abuse laws in the United States, PRC and other countries, including the federal Anti-Kickback Statute and the False Claims Act, as well as physician payment transparency laws and regulations, including the Federal Physician Payment Act. Our current and future operations also may be subject to regulation by U.S. federal, state and local authorities including, among others, the Centers for Medicare and Medicaid Services and other divisions within the U.S. Department of Health and Human Services such as the Office of the Inspector General and the Office for Civil Rights. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirements, we could be subject to applicable penalties.

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Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or 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 participation in governmental healthcare programs, contractual damages, reputational damage, 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 material adverse effect on our business and results of operations.

If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations. We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees or other third parties.

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages. In addition, although currently our primary business operations are in China, we are subject to the Foreign Corrupt Practices Act of the United States, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Although we have policies and procedures designed to ensure that we, our employees, agents and intermediaries comply with anti-bribery laws, there is no assurance that such policies or procedures will always effectively prevent our employees, agents 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 significantly affect our business, financial condition, and results of operations. We could also be adversely affected by any allegation that we violated such laws.

Any failure to comply with applicable laws and regulations and industry standards or obtain various licenses and permits or any change to the applicable laws and regulations could harm our reputation and business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the PRC and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our business partners' failure to comply with such regulations could result in the termination of ongoing

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research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects and results of operations.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or impose fines and penalties which could materially and adversely affect our business, financial condition and results of operations. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we will be able to meet new criteria that may be imposed. If the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect results of operations and prospects.

Any government investigation of alleged violations of laws could require us to expend significant time and resources in response and generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our results of operations will be adversely affected.

If we become a party or are subject to litigation, legal or contractual disputes, governmental investigations or administrative proceedings, our management’s attention may be diverted and we may incur substantial costs and liabilities.

We may also from time to time become a party to various litigation, legal disputes, claims, administrative proceedings or other administrative measures arising in the ordinary course of our business. On-going litigation, legal disputes, claims, administrative proceedings or other administrative measures may divert our management’s attention and consume their time and our other resources. Furthermore, any litigation, legal disputes, claims, administrative proceedings or other administrative measures which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. Negative publicity arising from litigation, legal disputes, claims, administrative proceedings or other administrative measures may damage our reputation and adversely affect the image of our brands and products. In addition, if any verdict or award is rendered against us or we are imposed any fines or penalties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business ventures or projects. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

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Failure to make social insurance and housing provident fund contributions for some of our employees timely as required by PRC laws and regulations may subject us to late payments and fines imposed by relevant governmental authorities.

During the Track Record Period, we had not made full contributions to the social insurance plan and housing provident fund based on the actual salary level of some of our employees as prescribed by relevant laws and regulations. As of the Latest Practicable Date, we had not received any notice from the local authorities or any claim or request from the relevant employees that require us to make payments or impose upon us administrative penalties for insufficient contributions. Pursuant to relevant PRC laws and regulations, the under-contribution of social insurance within a prescribed period may subject us to a daily overdue charge of 0.05% of the delayed payment amount. Although we had made timely payments for the full amount of social insurance and housing provident fund contribution since May 2022, we cannot assure you that the relevant government authorities will not require us to pay the outstanding amount within a prescribed time and impose late charges or fines on us, which may affect our business, financial condition and results of operations.

During the Track Record Period, Shenzhen HighTide entrusted a third-party human resource agency, Shanghai HighTide and Shanghai Fusion to pay social insurance premium and housing provident funds for three of our employees. Pursuant to the agreement entered into between such third-party human resources agency and us, the third-party human resources agency have the obligation to pay social insurance premium and housing provident funds for only one employee. These three employees have accepted this arrangement and will not pursue any claims against us with the competent authorities. However, if the local governments determine the use of third-parties to pay social insurance and housing provident funds to be non-compliant in the future or such human resource agency fail to pay the social insurance premium or housing provident funds for and on behalf of our employees as required by applicable PRC laws and regulations, we may be subject to additional contribution, late payment fee or penalties imposed by the relevant PRC authorities for failing to discharge our obligations in relation to payment of social insurance and housing provident funds as an employer or be ordered to rectify. This in turn may affect our financial condition and results of operations.

We have enhanced our internal control measures requiring social insurance and housing provident fund contributions to be made in compliance with relevant PRC laws and regulations. We will review and monitor the reporting and contributions of social insurance and housing provident fund and we will consult our PRC legal counsel on a regular basis for advice on relevant PRC laws and regulations to keep us abreast of relevant regulatory developments.

Our Directors believe that such non-compliance would not have a material adverse effect on our business and results of operations, considering that: (i) as advised by our PRC Legal Advisor and based on the written confirmations issued by the competent government authorities of our Company and its subsidiaries, we had not been subject to any administrative penalties during the Track Record Period and up to the Latest Practicable Date; (ii) we were neither aware of any employee complaints filed against us nor involved in any labor disputes with our employees with respect to social insurance and housing provident funds during the Track Record Period and up to the Latest Practicable Date; (iii) as of the Latest Practicable Date, we had not received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges with respect to social insurance and housing provident funds; and (iv) the amount of

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shortfalls is low and such non-compliance will not have a material adverse effect on our financial condition or results of operations taken as a whole. As a result, we did not make any provisions in connection with these non-compliances during the Track Record Period and up to the Latest Practicable Date.

Our business significantly depends on our reputation, and any negative publicity on us or failure to maintain and enhance our recognition and reputation may materially and adversely affect our business, financial condition and results of operations.

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may engage various third parties, such as contract sales organizations, to expand our commercialization network and increase market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties.

Any negative publicity, including disputes concerning us, our business partners or our affiliates, even if untrue, could adversely affect our reputation and prospects. Moreover, if we are unable to maintain a good reputation, our ability to attract and retain key employees and business partners could be harmed which, in turn, may materially and adversely affect our business, results of operations and prospects.

Our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. Negative publicity about us, such as alleged misconduct or improper activities, or negative rumors relating to us, our management, employees, business partners or affiliates, can harm our business and results of operations, even if they are unsubstantiated or are later satisfactorily addressed. Any regulatory inquiries or investigations or other actions against our management, any perceived unethical, fraudulent, or inappropriate business conduct by us or perceived wrong doing by any key member of our management team or other employees, our business partners or our affiliates, could harm our reputation and materially and adversely affect our business. Regardless of the merits or final outcome of such regulatory inquiries, investigations or actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talent and business partners and grow our business.

Moreover, any negative media publicity about the pharmaceutical industry in general, including issues and allegations solely involving other companies in the industry, may also negatively impact our reputation.

In the event that such negative publicity relates to our own products and business, the adverse impact on our financial condition or results of operations might be more significant. Any such negative publicity may undermine the public confidence in our products, reputation, brand image, business prospects, and impair the development and commercialization of our drug candidates, all of which may adversely affect our business operations and financial performance. Investigations and increasingly stringent regulations arising from such negative publicity, if any, may draw time and attention from our management team, which would have otherwise been devoted into our business operations, or may incur additional compliance expenses.

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Our information technology systems, or those of our CROs, CDMOs or other contractors and business partners, may fail or suffer security breaches.

Despite the implementation of security measures, our information technology systems and those of our CROs, CDMOs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, 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.

If we fail to maintain effective internal controls, we may not be able to accurately report our financial results or prevent fraud, and our business, financial condition, results of operations and reputation could be materially and adversely affected.

We will become a public company upon completion of the [REDACTED], and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our management, operational and financial resources and systems in the foreseeable future. In order to address our internal controls issues and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including establishing a compliance program for data storage and transmission, adopting new policies, and providing training on our controls, procedures and policies to our employees. In addition, in preparation for the [REDACTED], we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

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

We maintain insurance policies that are required under the PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. Our principal insurance policies cover employee benefits liability and adverse events in clinical trials. We currently do not maintain insurance for environmental liability or property loss. According to CIC, our insurance policy is in line with the industry practice. Our insurance coverage may be insufficient to cover any claims that we may have. 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 and may negatively impact our product development and overall operations.

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We are subject to risks relating to leased properties.

As of the Latest Practicable Date, the actual usage of one leased property was inconsistent with the usage set out in its title certificate and lease agreement. As advised by our PRC Legal Advisor, it is primarily the lessor’s responsibility to ensure the actual usage is consistent with the approved usage, and to the extent necessary, to complete the relevant “change of registration” procedures with the competent authorities to register the changed usage; we as the tenant will not be subject to any administrative punishment or penalties. But our use of the leased property may be affected by third party claims or challenges against the lease. If the lessor does not have the requisite rights to lease the defective leased property to us for our intended usage, the relevant lease agreement may be deemed invalid, and as a result we may be required to vacate the defective leased property. In the event that we are required to relocate, there is no assurance that we will be able to identify comparable locations in a timely manner or at all, and that we will secure a lease on comparable terms. We may also incur substantial reinstatement, relocation and renovation costs. Further, the establishment of our offices, manufacturing or residential facilities at new location involves regulatory approvals and reviews by various PRC governmental authorities, and we may need to complete of relevant environmental assessment, construction permits and fire prevention inspection of the new premises by relevant PRC governmental authorities.

Moreover, nine of our lease agreements for properties in China have not been registered with relevant authorities in China. As advised by our PRC Legal Advisor, according to the PRC Civil Code, failure to complete the registration and filing of lease agreements will not affect the validity of the lease agreements. However, the relevant PRC authorities may impose a fine on us ranging from RMB1,000 to RMB10,000 for each unregistered lease. We have used our commercially reasonable efforts to register the relevant leases. However, the registration of these relevant lease agreements requires additional steps to be taken by the lessors which are beyond our control. We cannot assure you that the lessors will be cooperative and that we can complete the registration of these lease agreements.

We have enhanced our internal control measures in connection with property rentals. We should obtain the valid title certificates and other necessary documentation from all of our lessors, before we enter into lease agreements with them. Before entering into any new lease agreements, we will carefully review the relevant documents provided by the lessors, to ensure that we will not inadvertently lease any property with title defects. All the lease agreements as well as the relevant documents provided by the lessors need to be approved by our legal department.

Our Directors believe that the non-registrations of leases described above will not, individually or in the aggregate, materially affect our business and results of operation, on the grounds that: (i) no penalty had been imposed on us for our failure to register and file the relevant lease agreements during the Track Record Period and up to the Latest Practicable Date, (ii) the maximum potential penalty for the non-registration of the leases will be approximately RMB90,000, so even if we were penalized by the competent authorities, it would not materially and adversely affect our business or financial position, (iii) as advised by our PRC Legal Advisor, if the lease registration can be completed in accordance with the relevant laws and regulations within a reasonable time from the date of application or the prescribed time limit ordered by the competent governmental authorities, the risk of governmental authorities imposing a penalty on us with respect to these leased properties is remote, and (iv) we have enhanced our internal control measures and procedures to prevent the re-occurrence of such incidents.

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Difficult conditions and turbulence in the global economic, political and financial environment may adversely affect our business.

Geopolitical, economic and market conditions, including factors such as the liquidity of the global financial markets, the level and volatility of debt and equity prices, interest rates, currency and commodities prices, investor sentiment, inflation and the availability and cost of capital and credit have been and will continue to affect the countries where we operate. The stress experienced by the global financial markets in 2020 due to the COVID-19 pandemic, the series of measures taken by major economies in response and the consequences of such measures continue to impact the global economy in varying degrees in different regions over the years. The financial markets continue to be impacted by general uncertainty, and growth rates have declined recently. In addition, tighter monetary policy in the United States could further undermine financial stability in emerging market economies. Central banks around the world, including in the United States and several large emerging markets, have tightened monetary policy and have indicated that they would continue to do so in the near future. The financial conditions of banking institutions have come under severe pressure and deterioration, as exemplified by the proposed restructuring of Credit Suisse Group AG and the failures of Silicon Valley Bank and Signature Bank in the first quarter of 2023, driven by bank runs or simultaneous withdrawals by depositors due to various reasons, including lack of confidence in the banking system. The slow economic recoveries around the world, the Ukraine-Russia military conflict and the high inflation, high interest environment have contributed to higher global volatility. These developments may adversely impact global liquidity, heighten market volatility and increase U.S. dollar funding costs resulting in tightened global financial conditions and fears of a recession. A prolonged period of extremely volatile and unstable market conditions would likely increase our funding costs and could also adversely affect the countries where we operate, which could in turn affect our business.

RISKS RELATING TO DOING BUSINESS IN THE PRC

PRC economic, political, social conditions, government policies and political relationships between the PRC and other jurisdictions may adversely affect our business operations, and any changes in the United States and international trade policies particularly with regard to the PRC, may adversely impact our business, financial condition, results of operations and prospects.

Substantially all of our assets and operations are located in the PRC. Accordingly, our business, financial condition, results of operations and prospects may be influenced to a significant degree by economic, political and social conditions in the PRC generally. The PRC economy differs from the economies of most developed countries in many respects, including the level of development, growth rate, level of government involvement and control of foreign exchange and allocation of resources. The PRC government exercises significant control over China’s economic growth through allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, and providing preferential treatment to particular industries or companies. In addition, the PRC government continues to play a significant role in regulating industry development by imposing relevant industrial policies.

While the PRC economy has experienced significant growth over the past decades, growth has been uneven, both geographically and among various sectors of the economy. In addition, the rate of growth has been slowing since 2012, and COVID-19 adversely affected the Chinese and

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global economies in recent years. Any adverse changes in economic conditions in China, in the policies of the PRC government or in the laws and regulations in China could have a material adverse effect on the overall economic growth of China. Such developments could adversely affect our business and operating results, lead to reduction in demand for our solutions and services and adversely affect our competitive position. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations. In addition, in the past the PRC government has implemented certain measures, including interest rate adjustment, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations.

Furthermore, there is no assurance that the substantial growth in the PRC economy in the previous decades will continue or continue at the same pace. In 2017, Moody’s Investors Service downgraded China’s sovereign credit rating for the first time since 1989 and changed its outlook from stable to negative, citing concerns on the country’s rising levels of debt and expectations of slower economic growth. In recent years, the U.S.-China relations also give rise to uncertainties on the PRC economy as well as the global economy. Since 2018, the United States government imposed several rounds of tariffs on Chinese products. In retaliation, the PRC government responded with tariffs on U.S. products. The trade tensions were accompanied with escalating economic restrictions and sanctions, which created further uncertainties and volatilities to the PRC economy and global markets. Since 2019, the United States government has imposed increasing restrictions on Chinese technology companies exporting sensitive U.S. goods. In 2021, the United States government blacklisted over 40 Chinese technology companies, citing activities contrary to the national security or foreign policy interests of the United States. The United States government also approved the Strategic Competition Act of 2021, signaling bipartisan consensus on orienting policy towards being more aggressive in efforts to counter China. The PRC government also imposed sanctions on several United States citizens and entities. The future development and lasting impact of the U.S.-China relations on China’s economy and the online chronic disease management industry remain uncertain. Should the U.S.-China relations materially impact the PRC economy, the purchasing power of our customers may decrease and procurement costs of the imported drugs sold on our platforms may increase, which will have an adverse effect on our business operation and financial performance. Moreover, if the PRC government, in response to the escalating U.S.-China tension, enacts additional laws and regulations that may affect our business, our compliance costs may increase and our results of operations will be adversely affected.

The legal protections available to you under the PRC legal system may be limited. It may be difficult to effect service of legal process and enforce judgments against us and our management.

A significant portion of our assets and the majority of our Directors and senior management are located in the PRC. As a result, it may not be possible to effect service of process within certain jurisdictions outside the PRC upon us or most of our Directors and senior management. Furthermore, the PRC does not have treaties providing for the reciprocal enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the

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United States. As a result, recognition and enforcement in Mainland China or Hong Kong of judgments of a court obtained in the United States or any of the other jurisdictions mentioned above may be difficult or impossible. On July 3, 2008, the Supreme People’s Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by Courts of the Mainland and the Hong Kong Special Administration Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “**Arrangement**”). Under 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 pursuant to 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. It is not possible to enforce a judgment rendered by a Hong Kong court in Mainland China if the parties in dispute have not agreed to enter into a choice of court agreement in writing. In addition, the Arrangement has expressly provided for “enforceable final judgment”, “specific legal relationship” and “written form.” On January 18, 2019, the Supreme People’s Court and the government of the 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 (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “**New Arrangement**”), which seeks to establish a mechanism with further clarification on and certainty for reciprocal recognition and enforcement of judgments in a wider range of civil and commercial matters between Mainland China and Hong Kong. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court and the completion of the relevant legislative procedures in Hong Kong. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in Mainland China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

Under the New Arrangement, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the effective judgments in civil and commercial cases subject to the conditions set forth in the New Arrangement. Although the New Arrangement has been signed, the outcome and effectiveness of any action brought under the New Arrangement may still be uncertain. We cannot assure you that an effective judgment that complies with the New Arrangement can be recognized and enforced in a PRC court.

There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.

A majority of our operations are conducted in China, and are hence governed by PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In the late 1970s, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of

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economic activities in China. However, China has not developed a fully-integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to the significant interpretation discretion by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulators significant discretion in how to enforce them, and because of the limited number of published decisions and the non-binding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based in part on government policies, some of which are not published timely or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Additionally, the NMPA’s recent reform of the drug approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our drug candidates in a timely manner. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we may enjoy. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

Future changes in laws, regulations or enforcement policies in the PRC could adversely affect our business.

Laws, regulations or enforcement policies in China, including those regulating the healthcare and pharmaceutical industry, are evolving and subject to frequent changes. The PRC pharmaceutical industry is heavily regulated and many aspects of our business depend on the receipt of the relevant government authorities’ approvals and permits. Further, regulatory agencies in China may periodically change their enforcement practices. Therefore, prior enforcement activities, or lack of enforcement activities, are not necessarily predictive of future actions. Any enforcement actions against us could have a material adverse effect on us.

Any litigation or governmental investigation or enforcement proceedings in China may be protracted and may result in substantial costs and diversion of resources and management attention, negative publicity, and damage to reputation. In addition, such changes may be applied retroactively and thus subject our business and operations to increased uncertainties and risks.

Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.

Certain of our cash and cash equivalents, with original maturity less than one year, trade payables and convertible redeemable preferred shares are denominated in foreign currencies, and are exposed to foreign currency risk. We recognized net foreign exchange gains of RMB0.6 million and net exchange loss of RMB7.5 million for the year ended December 31, 2021 and 2022, respectively. The fair value change of convertible redeemable preferred shares take into account exchange gains or losses. As of December 31, 2021 and 2022, RMB765.3 million and RMB412.3 million of our cash and bank balances were denominated in U.S. dollars, respectively, primarily representing proceeds from our [REDACTED] Financing. The exchange rate of the Renminbi against the

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U.S. dollar and other foreign currencies fluctuates and is affected by, among other things, the policies of the PRC Government and changes in China’s and international political and economic conditions, as well as supply and demand in the local market. It is difficult to predict how market forces or government policies may impact the exchange rate between the Renminbi and the Hong Kong dollar, the U.S. dollar or other currencies in the future. In addition, the People’s Bank of China regularly intervenes in the foreign exchange market to limit fluctuations in Renminbi exchange rates and achieve policies goals.

There remains significant international pressure on the PRC Government to adopt a more flexible currency policy, which, together with domestic policy considerations, could result in a significant appreciation of Renminbi against the U.S. dollar, the Hong Kong dollar or other foreign currencies.

The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Any 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.

More stringent restrictions on the remittance of Renminbi into and out of the PRC and governmental control over currency conversion may limit our ability to pay dividends and other obligations, and affect the value of your [REDACTED].

The Renminbi is not currently a freely convertible currency, as the PRC Government imposes controls on the convertibility of Renminbi into foreign currencies and in certain cases, the remittance of currency out of China. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under China’s current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from China’s State Administration of Foreign Exchange (“SAFE”), but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government 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. The PRC Government may also at its discretion restrict access in the future to foreign currencies for current account transactions. Since 2015, in response to China’s declining foreign currency reserves, the PRC Government has placed increasingly stringent restrictions on the convertibility of the Renminbi into foreign currencies. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay

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dividends in foreign currencies to our Shareholders. Further, there is no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.

We may be deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law and our global income may be subject to PRC corporate tax under the PRC Enterprise Income Tax Law.

The PRC Enterprise Income Tax (“EIT”) Law provides that enterprises established outside of China whose “*de facto* management bodies” are located in the PRC are considered “resident enterprises” and are generally subject to the uniform 25% enterprise income tax rate on their global income. “*De facto* management body” is defined as the body that has the significant and overall management and control over the business, personnel, accounts and properties of an enterprise. In April 2009 and July 2011, the SAT issued several circulars to clarify certain criteria for determining location of the “*de facto* management bodies” of foreign enterprises controlled by PRC enterprises; however, no official implementation rules have been issued for determining the location of the “*de facto* management bodies” of foreign enterprises that are not controlled by PRC enterprises. Being regarded as a PRC resident enterprise may materially and adversely affect our profit and hence our retained profit available for distribution to our Shareholders.

Dividends paid by us to our foreign [REDACTED] and gains on the [REDACTED] of our Shares may be subject to withholding taxes under PRC tax laws.

Under the EIT law, PRC withholding tax at a rate of 10% is normally applicable to dividends from a PRC source paid to investors that are “non-resident enterprises”, which do not have an establishment or place of business in China, or which have an establishment or place of business in China but whose relevant income is not effectively connected with the establishment or place of business in China. Any gain realized by non-resident enterprise investors on the transfer of shares is generally subject to a 10% PRC income tax if such gain is regarded as income derived from sources within China.

Under the PRC Individual Income Tax Law and its implementation rules, dividends from sources within China paid to foreign individual investors who are not PRC residents are generally subject to a PRC withholding tax at a rate of 20% and gains from PRC sources realized by such investors on the transfer of shares are generally subject to PRC income tax at a rate of 20% for individuals. Any PRC tax may be reduced or exempted under applicable tax treaties or similar arrangements.

If we are treated as a PRC resident enterprise as described under the risk factor headed “— We may be deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law and our global income may be subject to PRC corporate tax under the PRC Enterprise Income Tax Law”, dividends we pay with respect to our Shares, or the gain realized from the [REDACTED] of our Shares, may be treated as income derived from sources within China and as a result be subject to the PRC income taxes described above. However, owners of our Shares who are not PRC tax residents and seek to enjoy preferential tax rates under relevant tax treaties may apply to the PRC tax authorities to be recognized as eligible for treaty benefits in accordance with the Announcement of the State Taxation Administration on Promulgating the Administrative Measures for Tax Convention Treatment for Non-resident Taxpayers (《國家稅務總局關於發佈非居民納稅

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人享受稅收協定待遇管理辦法的公告》) (the “**Circular 60**”). If any PRC tax is imposed on distributions on, or dispositions of, our Shares, the value of your [REDACTED] in our Shares may be materially and adversely affected.

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

We have adopted the Incentive Plans to, among others, attract and retain outstanding individuals to serve as directors, officers, employees, consultants, and advisors to the Company. We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based compensation to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under our currently effective share incentive plans and any subsequently adopted share incentive plans from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges in the reporting periods following the [REDACTED].

Any failure to comply with PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (“**SAFE Circular 7**”), repealing the previous rules issued by SAFE in March 2007. Under SAFE Circular 7 and other relevant rules and regulations, PRC residents who participate in a stock incentive plan in an overseas publicly listed company are required to register with SAFE or its local branches and complete certain other procedures. Participants in a stock incentive plan who are PRC residents must retain a qualified PRC agent, which could be a PRC subsidiary of the overseas publicly listed company or another qualified institution selected by the PRC subsidiary, to conduct the SAFE registration and other procedures with respect to the stock incentive plan on behalf of its participants. The participants must also retain an overseas entrusted institution to handle matters in connection with their exercise of stock options, the purchase and sale of corresponding stocks or interests and fund transfers. In addition, the PRC agent is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan, the PRC agent or the overseas entrusted institution or other material changes. We and our PRC employees who have been granted share options will be subject to these regulations upon the completion of this [REDACTED]. Failure of our PRC share option holders to complete their SAFE registrations may subject these PRC residents to fines of up to RMB300,000 for entities and up to RMB50,000 for individuals, and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries, limit our PRC subsidiaries’ ability to distribute dividends to us, or otherwise materially and adversely affect our business.

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The STA has also issued relevant rules and regulations concerning employee share incentives. Under these rules and regulations, our employees working in the PRC will be subject to PRC individual income tax upon exercise of the share options. Our PRC subsidiaries have obligations to file documents with respect to the granted share options or restricted shares with relevant tax authorities and to withhold individual income taxes for their employees upon exercise of the share options or grant of the restricted shares. If our employees fail to pay or we fail to withhold their individual income taxes according to relevant rules and regulations, we may face sanctions imposed by the competent governmental authorities.

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

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

In response to the persistent capital outflow in China and RMB’s depreciation against the U.S. dollar, the People’s Bank of China, and the SAFE promulgated a series of capital control measures, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments. The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by the SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our [REDACTED] or other obligations to our suppliers, or otherwise fund and conduct our business.

Our dividend income from our foreign-invested PRC subsidiaries may be subject to a higher rate of withholding tax than that which we currently anticipate.

Under the EIT Law, if a foreign entity is deemed to be a “non-resident enterprise”, a PRC withholding tax at the rate of 10% will be applicable to any dividends for earnings accumulated since January 1, 2008 payable to the foreign entity, unless the foreign entity is entitled to reduction or elimination of such tax, including by tax treaties or agreements. According to the Arrangement between the Mainland of China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Incomes (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), dividends paid by a PRC

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foreign-invested enterprise to its shareholder(s) incorporated in Hong Kong will be subject to withholding tax at a rate of 5% if the Hong Kong company directly holds a 25% or more interest in the PRC foreign-invested enterprise. The STA promulgated the Circular of the State Taxation Administration on Relevant Issues relating to Beneficial Owner under Tax Treaties (《國家稅務總局關於稅收協定中“受益所有人”有關問題的公告》) (the “**Circular 9**”) on February 3, 2018, which addresses the methods for determining the “beneficial owners” under tax treaties’ articles on dividends, interest and royalties. According to Circular 9, the PRC tax authorities must evaluate whether an applicant qualifies as a “beneficial owner” on a case-by-case basis, and a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner.

If our Hong Kong subsidiary is not considered as a “beneficial owner” under PRC tax law, dividends from our PRC subsidiaries to our Hong Kong subsidiary will be subject to PRC withholding tax at a 10% rate instead of a 5% rate. This would negatively impact us and our ability to pay dividends in the future.

The heightened scrutiny over acquisitions from the PRC tax authorities may has an adverse impact on our business, acquisitions or restructuring strategies.

On February 3, 2015, the STA promulgated the Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》) (the “**Circular 7**”), which provides comprehensive guidelines relating to, and heightened the PRC tax authorities’ scrutiny on indirect transfers, by a non-resident enterprise, of assets (including equity interests) of a PRC resident enterprise.

The application of the Circular 7 is uncertain. Tax authorities may determine that Circular 7 applies to our offshore restructuring transactions or sale of the shares of our offshore subsidiaries, where non-resident enterprises are transferors. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with the Circular 7 or to establish that we and our non-resident enterprises should not be taxed under the Circular 7 for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial conditions and results of operations.

PRC regulations relating to the establishment of offshore special purpose vehicles by PRC residents may subject our PRC resident Shareholders to personal liability, limit our PRC subsidiaries’ ability to distribute profits to us, or otherwise adversely affect our financial position.

The SAFE promulgated the Circular of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by Domestic Residents in China via Special-Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the “**Circular 37**”) on July 4, 2014. According to Circular 37, PRC residents (including PRC citizens and PRC enterprises) shall apply to the SAFE or its local bureau to register foreign exchange for overseas investments before contributing to special purpose vehicles (the “**SPVs**”) with legitimate domestic and overseas assets or rights and interests. In the event of any alteration in the basic information of the registered SPVs, such as the change of a PRC citizen

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shareholder, name and operating duration; or in the event of any alternation in key information, such as increases or decreases in the share capital held by PRC citizens, or equity transfers, swaps, consolidations, or splits, the registered PRC residents shall timely submit a change in the registration of the foreign exchange for overseas investments with the foreign exchange bureaus. SAFE promulgated the Notice on Further Simplifying and Improving the Administration of the Foreign Exchange Concerning Direct Investment (《關於進一步簡化及改進直接投資外匯管理政策的通知》) (the “**Simplifying and Improving Notice**”) in February 2015, which took effect on June 1, 2015. The Simplifying and Improving Notice amended Circular 37 requiring PRC residents or entities to register with qualified banks rather than SAFE or its local branch in connection with the establishment or control of an offshore entity established for the purpose of overseas investment.

We may not at all times be fully aware or informed of the identities of our beneficiaries who are PRC nationals, and may not be able to compel our beneficiaries to comply with the requirements of the Circular 37. As a result, we cannot assure you that all of our Shareholders or beneficiaries who are PRC nationals will at all times comply with, or in the future make or obtain any applicable registrations or approvals required by the Circular 37 or other related regulations. Under the relevant rules, failure to comply with the registration procedures set forth in the Circular 37 may result in restrictions on the foreign exchange activities of the relevant PRC enterprise and may also subject the relevant PRC resident to penalties under the PRC foreign exchange administration regulations.

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

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of SAFE. Additionally, our capital contributions must be filed with or approved by the MOFCOM or its local counterpart and registered with the SAIC or its local branch. We cannot assure you that we will be able to obtain these government registrations or approvals or to complete filing and 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 conditions and results of operations.

The approval, filing or other requirements of the China Securities Regulatory Commission or other PRC government authorities may be required under PRC laws.

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”) and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures will comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and will regulate both direct and indirect overseas

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offering and listing of PRC domestic companies’ securities. Any domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

As advised by our PRC Legal Advisor, our [REDACTED] will be considered an indirect overseas [REDACTED] under the Overseas Listing Trial Measures. Pursuant to the Overseas Listing Trial Measures, where an issuer submits an application for [REDACTED] to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted.

Accordingly, our PRC Legal Advisor is of the view that we will be required to complete the filing procedures with the CSRC in connection with the [REDACTED] within three business days after our application for [REDACTED] is submitted. As the Overseas Listing Trial Measures are new, there remain substantial uncertainties as to their interpretation and implementation. We cannot assure you that we could meet such requirements or complete such filing in accordance with the Overseas Listing Trial Measures in a timely manner. Any failure may restrict our ability to complete the [REDACTED] or any future equity capital raising activities, which would have a material adverse effect on our business and financial position.

RISKS RELATING TO THE [REDACTED]

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

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED], and the [REDACTED] may differ significantly from the market price of the Shares following the [REDACTED]. As a result, a listing on the Hong Kong Stock Exchange does not guarantee that an active and liquid trading market for our Shares will develop, especially during the period when a significant portion of our Shares are subject to lock-up undertakings, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will rise following the [REDACTED].

The [REDACTED] and [REDACTED] of our Shares may be volatile, which could lead to substantial losses to [REDACTED].

The [REDACTED] and [REDACTED] of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the [REDACTED] and [REDACTED] of our Shares. In addition to market and industry factors, the [REDACTED] and [REDACTED] of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting the biopharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in price not directly related to our performance.

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There will be a gap of several days between [REDACTED] and [REDACTED] of our [REDACTED], and the price of our Shares when trading begins could be lower than the [REDACTED].

The initial [REDACTED] to the public of our Shares [REDACTED] in the [REDACTED] is expected to be determined on the [REDACTED]. However, the Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be five Business Days after the [REDACTED]. As a result, [REDACTED] may not be able to sell or otherwise deal in the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the [REDACTED] of the Shares when [REDACTED] begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of [REDACTED] and the time [REDACTED] begins.

Future sales or perceived sales of a substantial number of our Shares in the public market following the [REDACTED] could materially and adversely affect the [REDACTED] 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 public market 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.

In addition, our Shareholders would experience dilution in their shareholdings upon offer or sale of additional share capital or share capital-linked securities by our Company in future offerings. If additional funds are raised through our issuance of new share capital or share capital-linked securities other than on a pro rata basis to existing Shareholders, the shareholdings of such Shareholders may be reduced and such new securities may confer rights and privileges that take priority over those conferred by the [REDACTED].

Sales of substantial amounts of Shares in the public market after the completion of the [REDACTED], or the perception that these sales could occur, could adversely affect the market price of our Shares. Although our Single Largest Group of Shareholders are subject to restrictions on its sales of Shares within 6 months from the [REDACTED] as described in “[REDACTED]” in this document, future sales of a significant number of our Shares by our Single Largest Group of Shareholders in the public market after the [REDACTED], or the perception that these sales could occur, could cause the market price of our Shares to decline and could materially impair our future ability to raise capital through offerings of our Shares. We cannot assure you that our Single Largest Group of Shareholders will not dispose of Shares held by it or that we will not issue Shares pursuant to the general mandate to issue shares granted to our Directors, upon the expiration of restrictions set out above. We cannot predict the effect, if any, that any future sales of Shares by our Single Largest Group of Shareholders, or the availability of Shares for sale by our Single Largest Group of Shareholders, or the issuance of Shares by the Company may have on the market price of the Shares. Sale or issuance of a substantial amount of Shares by our Single Largest Group of Shareholders or us, or the market perception that such sale or issuance may occur, could materially and adversely affect the prevailing market price of the Shares.

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There may be difficulties in protecting your interests under the laws of the Cayman Islands.

Our corporate affairs are governed by, among other things, our Memorandum of Association and Articles of Association, the Companies Act and common law of the Cayman Islands. The rights of Shareholders to take action against our Directors, actions by minority shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority Shareholders may be located. See “Appendix III — Summary of the Constitution of the Company and Cayman Islands Company Law” in this document. As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management, Directors or Substantial Shareholders, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such shareholders are located.

There may be dilution because of issuance of new Shares or equity securities.

In spite of our current cash and cash equivalents and the net [REDACTED] from the [REDACTED], we may require additional funds due to changes in business conditions or other future developments relating to, inter alia, our existing operations or any future expansions. The amount and timing of such additional financing needs will vary depending on the timing investments in and/or acquisitions of new businesses from third-parties, and the amount of cash flow from our operations. If our resources are insufficient to satisfy our cash requirements, we may seek additional financing through selling additional equity or debt securities or obtaining a credit facility.

The sale of additional equity securities could result in additional dilution to our Shareholders. If additional funds are raised by way of issuance of new Shares or equity linked securities other than on a pro rata basis to existing Shareholders, the percentage of ownership of our existing Shareholders in our Company, the earnings per Share and the net asset value per Share may be reduced.

Because the initial public [REDACTED] per Share is higher than the net tangible book value per Share, [REDACTED] of our Shares in the [REDACTED] will experience immediate dilution.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution, and our existing Shareholders will receive an increase in the net tangible assets per Share of their Shares. In order to expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price that is lower than the net tangible asset value per Share at that time.

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

Our ability to declare future dividends will depend on the availability of dividends, if any, received from our operating subsidiaries. Under applicable laws and the constitutional documents of our operating subsidiaries, the payment of dividends may be subject to certain limitations. The calculation of certain of our operating subsidiaries’ profit under applicable accounting standards differs in certain respects from the calculation under HKFRSs. As a result, our operating subsidiaries may not be able to pay a dividend in a given year even if they have profit as determined under HKFRSs. Accordingly, since we derive all of our earnings and cash flows from dividends paid by our operating subsidiaries, we may not have sufficient distributable profit to pay dividends to our Shareholders.

In addition, any future dividend declaration and distribution will be at the discretion of our Directors and will depend on our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors deem relevant. Any declaration and payment as well as the amount of dividends will also be subject to our Articles of Association and PRC laws, including (where required) the approvals from our Shareholders and our Directors. Our Shareholders at a general meeting must approve any declaration of dividends, which must not exceed the amount recommended by our Board. Moreover, our Directors may from time to time pay such interim dividends as our Board considers to be justified by our profits and overall financial requirements, or special dividends of such amounts and on such dates as they think appropriate. As a result, we cannot assure you that we will make any dividend payments on our Shares in the future.

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

Under Rule 18A.10 of the Listing Rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or any series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Rule 18A.10. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

Certain statistics contained in this document are derived from a third-party report and publicly available official sources and they may not be reliable.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by CIC that we commissioned. We believe that the sources of such information is appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. The information has not been independently verified by us, the

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Joint Sponsors, the [REDACTED] or any other party involved in the [REDACTED] and no representation is given as to its accuracy. The Directors and the Joint Sponsors have exercised reasonable care in selecting and identifying the named information sources, in compiling, extracting, and reproducing the information, and in ensuring that there is no material omission of the information.

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 [REDACTED] are cautioned to make their [REDACTED] 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 in making your [REDACTED] 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 [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] 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 and the [REDACTED].