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An [REDACTED] in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an [REDACTED] in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition and results of operations. In any such case, the market price of our Shares could decline, and you may lose all or part of your [REDACTED]. These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as at the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in “Forward-looking Statements” in this document.

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) key risks relating to our business, financial position and need for additional capital, and general operations, (ii) other risks relating to our business, comprising (a) risks relating to our financial position and need for additional capital; (b) risks relating to our business; (c) risks relating to extensive government regulations; (d) risks relating to our intellectual property rights; (e) risks relating to our reliance on third parties; (f) risks relating to our general operations; (g) risks relating to our doing business in China; and (h) 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 harm our business, financial condition, results of operations and prospects. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

KEY RISKS RELATING TO OUR BUSINESS, FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL, AND GENERAL OPERATIONS

The actual market size of our drug candidates might be smaller than expected and our future approved drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Our future approved drug candidates may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our drug candidates that are in clinical trials for the same or similar cancer indications. In addition, physicians, patients and third-party payors may prefer other novel products to ours. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drug candidates are approved;

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- physicians, hospitals, cancer treatment centers and patients considering 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 regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and
- the effectiveness of our sales and marketing efforts.

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

Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain relevant regulatory approvals or achieve their commercialization, or if we experience significant delays in any of the foregoing, our business and profitability may be adversely affected.

Our ability to generate revenue and realize profitability is dependent on the successful completion of the development of our drug candidates, obtaining necessary regulatory approvals, and manufacturing and commercializing our drug candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our drug candidates.

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The success of our drug candidates will depend on several factors, including but not limited to:

- successful enrollment of patients in, and completion of, clinical trials, as well as completion of pre-clinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- obtaining sufficient supplies of any drug products that are used in combination with our drug candidates, competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- receipt of regulatory approvals;
- establishing sufficient commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- the performance by contract research organizations (“CROs”) or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defend against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- successfully launching commercial sales of our drug candidates, if and when approved;
- obtaining and maintaining favorable reimbursement from third-party payers for drugs, if and when approved;
- competition with other drug candidates and drugs; and
- continued acceptable safety profile of our drug candidates following regulatory approval.

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In addition, our gene therapy assets are based on novel technologies and represent emerging approaches to treat rare diseases that face significant development and regulatory challenges. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in obtaining approval for and/or successfully commercializing our drug candidates, which would materially and adversely affect our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

We may not be able to identify, discover or in-license new drug candidates, and may allocate our limited resources to pursue a particular candidate or indication and fail to capitalize drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials and non-head-to-head analyses may not be predictive of future trial results. As such, we may not be able to successfully expand our drug portfolio, which could materially and adversely affect our future growth and prospects.

Historically, we have in-licensed a number of drug candidates to develop and commercialize them in the APAC region or globally. These assets are important for our portfolio and in-licensing will remain important for our portfolio strategy. We cannot guarantee that we will be able to successfully identify and in-license new drug candidates with high potential for a number of reasons, including but are not limited to:

- the research methodology used may not be successful in discovering new drug candidates or formulations or developing additional potential indications;
- 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 protocol elements;
- 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.

In addition, research programs to discover new drug candidates and new formulations or pursue the development of our drug candidates for additional indications require substantial technical, financial and human resources. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the

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clinical trial process. The results of pre-clinical studies, early clinical trials of our drug candidates and non-head-to-head analyses may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. In some instances, 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, other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Our future clinical trial results may thus not be favorable, which may materially and adversely affect our business and financial prospects.

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

The timely completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. Our products and product candidates target rare diseases, and the size and nature of the patient population for rare disease may be a challenge for us to enroll a sufficient number of patients. In addition, patient eligibility criteria defined in the protocols could be strict and it might increase the chances that we are not able to recruit and retain suitable patients for our clinical trials.

Our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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We have incurred significant net losses and net operating cash outflows since our inception, and expect to continue to incur net losses and net operating cash outflows for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability. Potential [REDACTED] are at risk of losing substantially all of their [REDACTED] in our Shares.

Investment in pharmaceutical drug development 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 continue to incur significant expenses related to our ongoing operations. We have incurred losses in each period since our inception. In 2019, 2020 and the six months ended June 30, 2021, we had a loss for the year/period of RMB217.7 million, RMB846.0 million and RMB344.2 million, respectively. As of December 31, 2019 and 2020 and June 30, 2021, we had an accumulated deficit attributable to owners of our Company of RMB1,004.1 million, RMB1,850.1 million and RMB2,194.3 million, respectively. Substantially all of our losses incurred during the Track Record Period resulted from costs incurred in connection with our research and development programs, administrative expenses and fair value loss on convertible redeemable preferred shares.

We expect to continue to incur losses for the foreseeable future, and we expect our operating losses to increase as we continue to expand our development of, and seek regulatory approvals for, our drug candidates, and continue to build up our manufacturing capability, commercialization and sales workforce in anticipation of the future roll-out of our drug candidates. Typically, it takes many years to develop one new drug from the drug-discovery stage to when it is available for treating patients. In addition, we will continue to incur costs associated with operating as a public company and in support of our growth as a development-stage or commercial-stage biopharmaceutical company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues, and the timing and amount of milestones and other payments we make or receive with or through arrangements with third parties. If any of our drug candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. In addition, we experienced a decrease in the average selling price of certain of our commercialized products during the Track Record Period due to our market expansion plan and active participation in the patient assistance programs. We may experience a decrease in average selling price of other newly-commercialized products in the future due to our marketing strategies and market condition of the region we sell in, which may have an adverse effect on our profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. A decline in the value of our Company may also cause you to lose substantially all or part of your [REDACTED].

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

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to focus our activities in China while pursuing global opportunities, particularly in the APAC region and the United States. These geopolitical areas all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes – some minor, some significant – that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in each of these regions.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Any recently enacted and future legislation may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical industry such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which would lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects. Failure to comply with the applicable requirements at any time during the drug development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include but are not limited to a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any occurrence of the foregoing could therefore materially and adversely affect our business, financial condition, results of operations and prospects. The regulatory approval processes of the NMPA, FDA, TFDA, EMA, HSA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our drug candidates in our targeted markets, our business will be substantially harmed.

The time required to obtain approval by the NMPA, FDA, TFDA, EMA, HSA, and other comparable regulatory authorities is unpredictable but typically takes 10-15 years following the commencement of pre-clinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities.

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Our drug candidates could fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a drug candidate is safe and effective or, if it is a biologic, that it is safe, pure and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

The NMPA, FDA, TFDA, EMA, HSA or a comparable regulatory authority may require more information, including additional pre-clinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. Additionally, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in various jurisdictions could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. While we plan to leverage our Collaboration Partners' data and FDA approvals to obtain approvals in other jurisdictions, we cannot assure you that we can also satisfy all regulatory requirements. If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and

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generate related revenues for that drug candidate. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Any of these occurrences may materially and adversely affect our business, financial condition and prospects.

Uncertainties or failures of the clinical trials of our product candidates may have a material and adverse effect on our business operations.

Situations surrounding clinical trials are dynamic and subject to changes. 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 product candidates, including but not limited to:

- regulators or ethics committees may not authorize us or our investigators to commence a clinical trial;
- our inability to reach agreements on acceptable terms with prospective CROs/SMOs and hospitals as trial centers, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs/SMOs and hospitals as trial centers;
- clinical trials of our product candidates may fail to demonstrate the efficacy and safety as anticipated, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our product development programs;
- our third-party contractors 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 product candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics, a finding that participants are being exposed to unacceptable health risks or reasons outside of our control, such as occurrences of epidemics like the outbreak of COVID-19; and
- the initial or interim results of the clinical trial may not be predictive of the final results.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates if applicable, the commercial prospects of that product candidate will be harmed, and our ability to generate product sales revenues from any of those product candidates will be weakened. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly.

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Our rights to develop and commercialize some of our drug candidates are subject to the terms and conditions of licenses granted to us by others.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development, manufacture or commercialization of our drug candidates and certain of these third parties from which we have been granted licenses themselves rely on licenses from other third parties. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use or in all territories in which we may wish to develop or commercialize our future approved drugs. As a result, we may not be able to develop, export or sell our drug products outside of the fields or territories as stipulated by the collaboration agreements or prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the drug candidates that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensing partners fail to prosecute, maintain, enforce or defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject to such licensed rights could be adversely affected.

Our licensing partners may have relied on third-party consultants or collaborators or on funds from third parties, or on upstream licenses from third parties, such that our licensing partners are not the sole and exclusive owners of the intellectual property rights we in-license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensing partners might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize drug products covered by these license agreements. If any of our licensing partners goes bankrupt, some or all of our rights under the licensing agreements may be terminated during the bankruptcy proceeding. For details, see “Business–Collaboration and Licensing Arrangements.” As such, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensing partners in a manner that may be more favorable to the licensing partners, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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Even if we are able to commercialize any approved drug candidates, the drugs may become subject to national or other third-party reimbursement practices or unfavorable pricing regulations, which could materially and adversely affect our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug or negatively impact our revenues.

Our ability to commercialize any approved drug candidates successfully will also depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

For example, in China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from China's National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, the NRDL, or provincial or local medical insurance catalogues for the Provincial Reimbursable Drug List, the PRDL, regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our future approved drug candidates will be included in the NRDL or the PRDL.

If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL or the PRDL, our revenue from commercial sales would be highly dependent on patient self-payment, which can make our products less competitive. Additionally, even if the Ministry of Human Resources and Social Security of the PRC or any of its local counterparts were to accept our application for the inclusion of products in the NRDL or the PRDL, our potential revenue from 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 the NRDL or the PRDL.

Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any approved drug candidate that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug 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 in-license or successfully develop.

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There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the NMPA, FDA, TFDA, EMA, HSA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any future approved drug candidates could have a material adverse effect on our business, operating results and financial condition.

We intend to seek approval to market our drug candidates in China and other jurisdictions. In China the pricing of drugs is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Market acceptance and sales of any of our future approved drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for drugs, and may be affected by existing and future health care reform measures.

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

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in China and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. In particular, we have sought patents in China and Hong Kong for our Core Product. For further information on our patent portfolio, see “Business – Intellectual Property.” If we or our licensors are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

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The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive drugs in all such fields and jurisdictions.

The requirements for patentability differ in certain jurisdictions, particularly developing countries. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired and our business, financial condition, results of operations and prospects may be adversely affected.

It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, China and, recently, the U.S. have adopted the "first-to-file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the State Intellectual Property Office, or SIPO, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

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 otherwise provide us with any competitive advantage. Any patents that we hold may be challenged, narrowed, circumvented, or invalidated by third parties. In addition, the patent

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position of biopharmaceutical and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords is limited. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, 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 have a material adverse effect on any potential sales of that product. Our issued patents for our drug candidates are expected to expire on various dates as described in “Business – Intellectual Property” of this document. Upon the expiration of these patents, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Additionally, patent rights we own currently or in the future or may license in the future may be subject to a reservation of rights by one or more third parties.

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

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some non-U.S. countries can have a different scope and strength. In addition, the laws of certain non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions or from selling or importing drugs made using our inventions in all countries. 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 other countries where we have patent protection, but where enforcement rights are relatively weaker. 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.

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We currently have trademark applications pending in China, the United States and other jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the registration of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us.

We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

As a result, we may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful. Patent rights relating to our drug candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable non-U.S. authority.

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We face substantial competition and our competitors may discover, develop or commercialize competing drugs earlier or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies worldwide. There are a number of large pharmaceutical and biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of rare diseases, cancer or autoimmune diseases or other indications for which we are developing our drug candidates. Some of these competitors have greater resources and expertise than us. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

Competition in therapeutic areas such as oncology and rare diseases to which our Core Products and most of our other pipeline assets belong is fierce given the abundance of existing competing drugs and drug candidates that continue to increase competition in the market. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial, technical and human resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Competition may increase further as a result of advances in the commercial applicability of new or disruptive technologies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any of the drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA, FDA, TFDA, EMA, HSA or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our drug candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our drug candidates.

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

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RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We had net current liabilities and net liabilities during the Track Record Period, which may expose us to liquidity risk.

While we had net current assets of RMB282.9 million and RMB379.5 million as of December 31, 2020 and June 30, 2021, we had net current liabilities of RMB5.8 million as of December 31, 2019. For details, see “Financial Information.” A net current liabilities position may expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources including the [REDACTED], and/or other sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all.

We also had net liabilities of RMB990.6 million, RMB1,745.9 million and RMB2,064.8 million as at December 31, 2019, 2020 and June 30, 2021, respectively, mainly due to the convertible redeemable preferred shares which were issued through several rounds of financing arrangements and are measured at fair value as at December 31, 2019, 2020 and June 30, 2021 as liabilities in the consolidated statements of financial position. For details, see “Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Position”. Our Preferred Shares will automatically convert into ordinary shares upon [REDACTED], at which time we expect to reclassify them from liabilities to equity and, accordingly, turn into net asset position. However, there can be no assurance that we will not experience liquidity problems in the future.

Any difficulty or failure to meet our liquidity needs as and when needed may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we determine our intangible assets to be impaired, our results of operations and financial condition may be adversely affected.

As of June 30, 2021, we had intangible assets of RMB54.9 million which comprised of RMB54.6 million related to patents and licenses and RMB0.2 million related to software. Our intangible assets are primarily related to the patents and licenses we in-licensed from our collaboration partners. The value of intangible assets is based on a number of assumptions made by the management. For a detailed discussion on the intangible assets, see Note 15 to the Accountants’ Report in Appendix I to this document. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, we may be required to have a significant decrease in the value of our intangible assets and record a significant impairment loss. Furthermore, our determination on whether intangible assets are impaired requires an estimation of the carrying amount and recoverable amount of an intangible asset.

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If the carrying amount exceeds its recoverable amount, our other intangible assets may be impaired. The impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations. For more information regarding our impairment policy in relation to intangible assets, see Note 2.4 “Summary of Significant Accounting Policies – Intangible assets (other than goodwill)” and Note 3 “Significant Accounting Judgments and Estimates – Impairment of non-financial assets (other than goodwill)” to the Accountants’ Report in Appendix I to this document.

We had net operating cash outflow during the Track Record Period.

We had net cash used in operating activities of RMB126.2 million, RMB151.6 million and RMB361.2 million for the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, respectively. While we believe we have sufficient working capital to fund our current operations, we expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. If we are unable to maintain adequate working capital, we may default on our payment obligations, be unable to meet our capital expenditure requirements, be forced to scale back our operations, and/or experience other negative impacts on our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may need additional capital to meet our operating cash requirements, and financing may not be available on terms acceptable to us, or at all.

We believe our current cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED] will be sufficient to meet our anticipated cash needs for at least the next 12 months from the date of this document. We may, however, require additional cash resources to meet our continued operating cash requirements in the future, especially to fund our research and development activities. Our cash operating costs mainly consist of (i) research and development costs including employee costs, third party contracting costs, direct clinical trial expenses and others, and (ii) workforce employment costs. Employee costs consist of employees’ salaries, benefits, allowances and performance related bonus. Third-party contracting costs represent the expenses relating to our pre-clinical and clinical research and development outsourcing activities. Direct clinical trial expenses represent costs incurred directly from our clinical trials. Others mainly include experimental material costs, rental expenses, traveling expenses and expenses related to intellectual property rights. Workforce employment costs represent total non-R&D staff costs mainly including salaries and bonus. For the six months ended June 30, 2021, we incurred total cash operating costs of RMB376.8 million. We expect our cash operating costs for the rest of 2021 will increase significantly in light of our expanding clinical trial programs. If the financial resources available to us after the [REDACTED] are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. It is uncertain whether financing will be available in the amounts or on terms acceptable to us, if at all. If we were not able to obtain additional capital to meet our cash requirements in the future, our business, financial condition, results of operations and prospects could be materially and adversely affected.

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We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a China-based, rare disease-focused biopharmaceutical company committed to the research, development and commercialization of life-changing therapeutics and our predecessor CANbridge Life Sciences Limited was founded in 2012. Our operations to date have focused on organizing and staffing, business planning, raising capital, establishing our intellectual property portfolio, and conducting pre-clinical studies and clinical trials of our drug candidates. As of the Latest Practicable Date, we had three products approved for commercial sale and had started to generate revenue from product sales. Our limited operating history, particularly in light of the rapidly evolving biopharmaceutical industry, may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other business uncertainties. If we do not address these business uncertainties and difficulties successfully, our business will suffer. These risks may cause potential [REDACTED] to lose substantially all or part of their [REDACTED].

We may need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our drug candidates.

Our drug candidates will require the completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Our operations have consumed substantial amounts of cash since inception. Our operating activities used RMB126.2 million, RMB151.6 million and RMB361.2 million of net cash during the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, respectively. We expect to continue to spend substantial amounts on preclinical research, advancing the clinical development of our drug candidates, and launching and commercializing any approved drug candidates for which we receive regulatory approval. Our existing cash and cash equivalents may not be sufficient to enable us to complete all development or commercially launch all of our current drug candidates for the currently anticipated indications and to invest in additional research and development programs. Accordingly, we will require further funding through public or private offerings, debt financing, collaboration, and licensing arrangements or other sources. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the costs related to preclinical research and early development of additional drug candidates;

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- the cost and timing of development and completion of commercial-scale internal or outsourced manufacturing activities;
- the number and characteristics of drug candidates that we may develop;
- the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates;
- selling and marketing costs associated with any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the amount and timing of any profit sharing, milestone and royalty payments we receive from or pay to our current or future collaborators;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future development of other pipeline drug candidates; and
- our headcount growth and associated costs.

However, if the commercialization of our drug candidates is delayed or terminated, or if the expenses associated with drug development and commercialization increase substantially, we may need to obtain additional financing to fund our operations. 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 attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our inability to obtain additional funding when we need it could materially and adversely affect our business.

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

We adopted the 2019 Equity Incentive Plan for the benefit of our employees (including directors) and non-employees as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our Company. For further details, please see the section headed “Appendix IV – Statutory and General Information – D. [REDACTED] Equity Incentive Plan” in this document. For the years ended 2019 and 2020, and the six months ended June 30, 2021, we incurred share-based compensation of RMB16.7 million, RMB14.7 million and RMB6.7 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a negative effect on our financial performance.

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Our results of operations, financial condition and prospects may be adversely affected by fair value changes in our convertible redeemable preferred shares, convertible loan and derivative financial instruments at fair value through profit or loss.

The derivative financial instruments represented warrants issued by the Company to the holders who will be entitled to exercise the warrants in exchange for the Company’s Preferred Shares during the Track Record Period. The derivative financial instruments issued to investors were not traded in an active market and the respective fair value is determined by using valuation techniques. The prior transaction method under market approach was used to determine the fair value of the total equity value of our Company and the equity allocation model was adopted to determine the fair value of the derivative financial instruments. The Group applied the back-solve method to determine the underlying equity value of the Company and adopted the option-pricing method and equity allocation model to determine the fair value of the warrants. Key valuation assumptions used to determine the fair value of the preferred shares, the convertible loan included volatility and the exit plan of the investors. The valuation of our convertible redeemable preferred shares is subject to uncertainty due to the various assumptions, please refer to the paragraphs headed “Financial Information – Description of Selected Components of Statements of profit or loss – Fair Value Changes” and Note 25, 26 and 33 of the Accountant’s Report set out in Appendix I to this document for more details. Any change in the assumptions may lead to different valuation results and, in turn, changes in the fair value of these financial instruments issued to investors.

During the Track Record Period, we issued convertible redeemable preferred shares, which are designated as financial liabilities. For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, we realized net fair value changes in convertible redeemable preferred shares of RMB73.7 million, RMB591.4 million and RMB21.8 million, respectively. We expect to recognize additional loss from the fair value changes of the convertible redeemable preferred shares after June 30, 2021 to the [REDACTED]. After the automatic conversion of the convertible redeemable preferred shares into Shares upon the [REDACTED], which will result in a net asset position, we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares in the future. If we continue to incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

We are exposed to risks in connection with the wealth management products we purchased.

During the Track Record Period, we invested in financial products which represent wealth management products issued by banks in the PRC. Pursuant to the Guidance on Regulating Financial Institution’s Asset Management Business (《關於規範金融機構資產管理業務的指導意見》) promulgated by the People’s Bank of China, the China Banking and Insurance Regulatory Commission, the China Security Regulatory Commission and the State Administration of Foreign Exchange on April 27, 2018, financial institutions selling wealth management products shall not guarantee the returns of principal and interest of such products. As a result, the returns of our investments on the wealth management products were not guaranteed, and therefore were measured at fair value through profit or loss. We are exposed

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to credit risks in relation to these financial assets, which may adversely affect their fair value. Net changes in their fair value are recorded as our other income or losses, and therefore directly affect our results of operations. We may continue to invest in wealth management products in the future when we believe that we have surplus cash on-hand and the potential investment returns are stable and attractive. However, there can be no assurance that our internal management and investment strategy will be effective and adequate with respect to our purchased wealth management products. We cannot guarantee that we will not experience losses with respect to such investments in the future or that such losses or other potentially negative consequences due to such investments will not have material adverse effects on our business, results of operations and prospects.

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

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

RISKS RELATING TO OUR BUSINESS

Risks Relating to the Pre-Clinical and Clinical Development of Our Drug Candidates

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

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. 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, institutional review boards or

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ethics committees not authorizing us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; manufacturing issues relating to our third-party CDMOs or after we establish our own facilities, including problems with manufacturing, supply quality, compliance with good manufacturing practice, or GMP, or obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; clinical trials of our drug candidates producing negative or inconclusive results, and additional clinical trials or abandoning drug development programs being required; the number of patients required for clinical trials of our drug candidates being larger than we anticipate, enrollment being insufficient or slower than we anticipate, or patients dropping out at a higher rate than we anticipate; our third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; our having to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks; the cost of clinical trials of our drug candidates being greater than we anticipate; and the supply or quality of our drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates being insufficient or inadequate.

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

Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may materially and adversely affect our business and results of operations.

Adverse events or undesirable side effects caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Drug-related adverse events and serious adverse events have been reported in our clinical trials. See “Business – Our Portfolio.” Undesirable adverse events caused by our drug candidates, or caused by our drug candidates when used in combination with other drugs, could potentially cause significant negative consequences, including but not limited to:

- regulatory authorities could interrupt, delay or halt pending clinical trials;

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

In addition, oncology and autoimmune therapies such as our CAN008 are still considered as emerging and relatively novel therapeutics for treating GBM. Their mechanisms of action are yet to be thoroughly understood, and side effects have been observed in clinical studies and reported by medical practitioners in connection with their usage in patients. For example, the NMPA, FDA, TFDA, EMA, HSA or other comparable authorities could order us to suspend or terminate our studies or to cease further development of or deny approval of our drug candidates. Any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete trials or may result in potential product liability claims, which could prevent us from obtaining regulatory approvals or achieving or maintaining market acceptance of a particular drug candidate, and could materially and adversely our business, results of operations and prospects.

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Our drug development progress may be affected by the clinical development progress of our collaboration partners, including but not limited to Apogenix, GC Pharma, Mirum, WuXi Biologics, Privus, UMass and LogicBio (collectively, our “Collaboration Partners”). If the collaboration partners are unable to successfully complete clinical development, obtain relevant regulatory approvals or achieve commercialization, or if they experience significant delays in any of the foregoing, our business and profitability may be adversely affected.

We have entered into collaboration agreements with our Collaboration Partners granting us exclusive licenses to our three clinical-stage assets. See “Business – Collaboration and Licensing Arrangements.” The success of our collaborations with our Collaboration Partners and drug development may be affected by our Collaboration Partners to the extent they are responsible for performance of collaboration activities or their clinical development activities may facilitate or accelerate our drug development process. Each Collaboration Partner may not be successful in the performance of such activities, including, for example, obtaining approvals for the product candidates developed under the collaboration or in marketing, or arranging for necessary supply, manufacturing, or distribution relationships for, any approved products. Our Collaboration Partners may change their strategic focus or pursue alternative technologies in a manner that results in reduced, delayed, or no additional costs to us under the collaboration agreements. Our Collaboration Partners have a variety of marketed products and product candidates under collaboration with other companies, possibly including some of our competitors, and our Collaboration Partners’ own corporate objectives may not be consistent with our interests. If any of our Collaboration Partners experiences significant delays in or fail to develop, obtain regulatory approval for, or ultimately commercialize any product candidate under our collaborations, our business, financial condition, results of operations and prospects could be materially and adversely affected.

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

We must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, our research and development costs were RMB55.4 million, RMB109.6 million and RMB274.8 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We intend to continue to enhance our technical capabilities in drug research, development and manufacturing, which are capital-and-time- intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could materially and adversely affect our business and prospects.

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

We face an inherent risk of product liability as a result of the clinical trials and any future commercialization of our drug candidates inside and outside China. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. As of the Latest Practicable Date, we had not been subject to any such product liability claim. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our drug candidates; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals, or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any approved drug candidate; and a decline in the market price of our Shares.

To cover such liability claims arising from clinical studies, we have purchased clinical trial insurance in the conduct of our clinical trials and also maintain product liability insurance. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claims or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

Our business and reputation may be adversely affected by negative publicity involving us, our Shareholders, Directors, officers, employees, Collaboration Partners, suppliers or other third parties that we work with or rely on.

We, our Shareholders, Directors, officers, employees, Collaboration Partners, suppliers, or other third parties we cooperate with or rely on may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our employees, Collaboration Partners, suppliers or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Any negative publicity regarding our industry could also affect our reputation

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and commercialization. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity that may or may not directly related to us, and may not be able to diffuse them to the satisfaction of our current or future investors, customers, patients and business partners.

Risks Relating to Extensive Government Regulations

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, and results of operations or prospects.

Such data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects’ private or medical records without their consent, they will be held liable for damage caused thereby. We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring our employees to maintain the confidentiality of our subjects’ medical records. However, these measures may not be always effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials frequently also involve professionals from third party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including hospitals, CROs and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. In particular, certain industry-specific laws and regulations may affect the collection and transfer of personal data in China, including Administrative Regulations on

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Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) issued by the State Council. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our clinical trial practices, potentially resulting in the confiscation of human genetic resources samples and associated data and administrative fines. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

Even after we obtain regulatory approval for the marketing and distribution of our drug candidates, our products will continue to remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our future approved drugs.

If any of our drug candidates is approved in the future, it will be subject to ongoing or additional regulatory requirements for manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including requirements of regulatory authorities in China and other jurisdictions.

Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug’s commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidates. The NMPA, FDA, TFDA, EMA, HSA or a comparable regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or following approval. In addition, if the NMPA, FDA, TFDA, EMA, HSA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements, including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and good clinical practice (“GCP”), for any clinical trials that we conduct post-approval.

The NMPA, FDA, TFDA, EMA, HSA and other regulatory authorities strictly regulate the marketing, labelling, 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, TFDA, EMA, HSA and other 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.

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If we fail to comply with our obligations in the agreements under which we in-license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into license agreements with third parties providing us with rights to various intellectual properties, including rights in patents and patent applications that relate to our drug assets. See “Business – Collaboration and Licensing Arrangements.” These license agreements impose diligence obligations in development or commercialization of the licensed intellectual properties, payment obligations when certain development, commercialization or regulatory milestones and sales are achieved and other obligations on us. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our business. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

In addition, the agreements under which we license intellectual properties or technologies from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, or if our licensors fail to fully perform their obligations or meet or expectations under the such in-licensing agreements or terminate their relationship with us, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Pursuant to the relevant laws, regulations and relevant regulatory practice by governmental, we and/or other parties related to our operations, such as landlords or managers of premises on or local science parks in which we operate, are required to obtain and maintain various approvals, licenses, permits and certificates (e.g. drainage permits) from relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations

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

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

If we participate in compassionate-use programs or expanded access programs, current regulatory discrepancies among competent authorities of different countries may lead to increased risk of adverse drug reactions and serious adverse events arising from the use of our products.

Expanded access programs are regulatory programs that facilitate access to investigational drugs for the treatment of patients with serious or immediately life-threatening diseases or conditions that lack therapeutic alternatives. Currently, there is no unified approach or standard practice to regulate expanded access programs among competent authorities in different countries for access to investigational drugs. In China, currently there is no officially approved regulation to oversee expanded access programs. In the U.S., expanded access programs are limited to patients who have a life-threatening disease or serious disease or condition, who may gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

The regulatory discrepancy for expanded access programs among competent authorities in different countries may lead to uneven patient entry criteria and protocols for expanded access programs. This may create increased risk of serious adverse events because of enrolled patients' advanced disease or comorbidities. In addition, because the products in expanded access programs are investigational drugs, many of which are still in experimental stages and have not received marketing approval, patients in expanded access programs may exhibit adverse drug reactions from using these products. If we participate in expanded access programs, we may be subject to the risk of enrolled patients exhibiting adverse drug reactions or serious adverse events arising from the use of our products. These occurrences can potentially lead to clinical holds of our ongoing clinical trials or complicate the determination of the safety profile of a drug candidate under regulatory review for commercial marketing. Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, including healthcare reform in China, and compliance with new regulations may result in additional costs.

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If safety, efficacy or other issues arise with any drug or medical product used in combination with or to facilitate the use of our drug candidates, we may be unable to market such drug candidate or may experience significant regulatory delays.

Our strategy to develop combination therapies depends on the safety and efficacy of each component drug within each combination therapy. If the NMPA, FDA, TFDA, EMA, HSA or another comparable regulatory agency revokes or denies its approval of a component therapeutic, in either the clinical design, clinical administration, therapy approval or commercialization stage, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts. In addition, we may fail our commercialization effort because products that facilitate the use of our drug candidates incur safety, efficacy or availability issues. For example, the regulations in China on the companion diagnostic test used in conjunction with our drug candidates for patient identification are still developing and the definition of diagnostic companion in the U.S. may not be the same as that of China. The lack of regulations presents uncertainties to our commercialization efforts and may have an adverse effect on our business and results of operations.

Adverse drug reactions and negative results from off-label use of our products could materially and adversely affect our business reputation, product brand name and financial condition and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA, FDA, TFDA, EMA, HSA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and materially and adversely our business reputation, product brand name, commercial operations and financial condition, including our Company’s share price. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates.

The illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in China and other countries where we commercialize our products. Unapproved foreign imports of prescription drugs are illegal under current laws of China. However, illegal

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imports may continue to occur or even increase as the ability of patients to obtain these lower-priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers’ ability to import lower-priced versions of our future approved products or competing products from outside China or other countries where we operate. Any future legislation or regulations that increase consumer access to lower-priced medicines from outside China or other countries where we operate could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future approved drug candidates. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators’ brand name(s). In addition, thefts of inventory at warehouses or plants or while in transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

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), or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any relevant 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 pre-clinical studies or clinical trials conducted within China) abroad. 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.

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Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results.

International market conditions and the international regulatory environment have historically been affected by competition among countries and geopolitical frictions. Changes to trade policies, treaties and tariffs, or the perception that these changes could occur, could adversely affect the financial and economic conditions in the jurisdictions in which we operate, as well as our overseas expansion, our financial condition and results of operations. The U.S. administration under President Donald J. Trump has advocated greater restrictions on international trade generally and significant increases on tariffs on certain goods imported into the U.S., particularly from China, and has taken steps toward restricting trade in certain goods. For example, in 2018, the United States announced three finalized tariffs that applied exclusively to products imported from China, totaling approximately US\$250 billion, and in May 2019, the U.S. increased the rate of certain tariffs previously levied on Chinese products from 10% to 25%. In addition, in August 2019, President Donald J. Trump threatened to impose additional tariffs on remaining Chinese products, totaling approximately US\$300 billion. Although on January 15, 2020, the U.S. and China signed an agreement on the phase one trade deal, under which both parties made certain concessions and agreed not to proceed with additional tariffs against one another, the 25% tariffs on US\$250 billion of Chinese imports are still in place. These concerns and threats to impose new tariffs or sanction on China, have resulted in increased tensions in China’s international relations. Moreover, the bilateral relationship is an ongoing matter, evolving sometimes from day to day, and we cannot predict how the relationship will further evolve or what impact any subsequent developments in the relationship may have on our business.

In addition, China and other countries have retaliated, and may further retaliate, in response to new trade policies, treaties and tariffs implemented by the U.S. government. Such retaliation measures may further escalate the tensions between the countries or even lead to a trade war. Any escalation in trade tensions or a trade war, or the perception that such escalation or trade war could occur, may have negative impact on the economies of not merely the two countries concerned, but the global economy as a whole. In addition, if China were to increase the tariff on any of the items imported by our suppliers and contract manufacturers from the U.S., we might not be able to find substitutes with the same quality and price in China or from other countries.

Furthermore, during the Track Record Period, we formed licensing agreements with entities in foreign countries and regions, such as Puma, based in the United States. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. As a result, China’s political relationships with those foreign countries and regions may affect the prospects of maintaining existing or establishing new collaboration partnerships and licensing agreements, and the communication and transfer of know-how.

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There can be no assurance that such licensing partners or potential collaborators or licensing partners in the future will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. It also remains unclear what actions, if any, the U.S. government will take with respect to other existing international trade agreements. As a result of the above and if the U.S. were to withdraw from or materially modify certain international trade agreements to which it is a party, especially with respect to intellectual properties transfer, our business, financial condition and results of operations could be negatively impacted. For further details, please see the section headed “Business – Collaboration and License Arrangements” in this document.

Risks Relating to Manufacturing and Commercialization of Our Drug Candidates

We have limited experience in manufacturing pharmaceutical products on a large commercial scale, which is a highly exacting and complex process, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.

We have limited experience in large-scale manufacturing of our products for commercial use. Moreover, the manufacturing of pharmaceutical products is highly complex. 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;
- delays in the construction of new facilities or the expansion of our existing manufacturing facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of products produced;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

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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. We face additional manufacturing risks in relation to the CDMOs that we may engage from time to time. See “– Risks Relating to Our Reliance on Third Parties – We rely on third parties to manufacture and import our clinical drug supplies and expect to rely on third parties to supply raw materials for manufacturing and/or manufacture our drugs when approved, and our business could be harmed if those third parties fail to provide us with sufficient quantities of the raw materials or the drug product or fail to do so at acceptable quality levels or prices.”

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.

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

In addition, the quality of our products, including drug candidates manufactured by us for research and development purposes and, in the future, drugs manufactured by us for commercial use, depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. We are, however, working on improving our documentation procedures for quality control and quality assurance activities. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, jeopardize any GMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

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If we are unable to meet the increasing demand for our existing drug candidates and future drug products by ensuring that we have adequate manufacturing capacity, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business could suffer.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel and compliance with strictly-enforced regulations. If our manufacturing facilities encounter unanticipated delays and expenses as a result of any of these difficulties, or if construction, regulatory evaluation and/or approval of our new facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates in the time frame we expect or at all, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could also require us to raise additional funds from other sources.

To produce our drug candidates in the quantities that we believe will be required to meet anticipated market demand of our drug candidates, if approved, we will need to increase, or "scale up," the production process by a significant factor over the initial level of production. If we are unable or delayed to do so, the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our approved drug candidates in a sufficient quantity to meet future demand.

In anticipation of commercialization of our drug candidates, we aim to establish our manufacturing capacity, mainly through the construction of new manufacturing facilities. However, the timing and success of these plans are subject to significant uncertainty. Moreover, such plans are capital intensive and require significant upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all.

Furthermore, given the size of our new facilities, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence operation. During the construction and ramp up period, there may be significant changes in the macroeconomics of the pharmaceutical and biopharmaceutical industry, including, among other things, market demand, product and supply pricing trends and customer preferences. Any adverse trends in these respects could result in operational inefficiency and unused capacity in our facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as:

- unforeseen delays due to construction, land use rights or regulatory issues, which could result in loss of business opportunities;
- construction cost overruns, which may require diverting resources and management's attention from other projects; and
- difficulty in finding sufficient numbers of trained and qualified staff.

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The success of our business expansion also depends on our ability to advance drug candidates through the development, regulatory approval and commercialization stages. Any delay, suspension or termination in such respects would harm our ability to generate satisfactory returns on our investment in manufacturing expansion, if at all, which in turn could have a material adverse effect on our business, financial condition and results of operations.

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

We successfully received marketing approval from China’s NMPA for Hunterase[®] (CAN101) in September 2020, following the submission of the NDA in July 2019, followed by NDAs of our other drug candidates in the future as their clinical development progress. To obtain regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in pre-clinical studies and well-controlled clinical trials, and, with respect to approval in China, to the satisfaction of the NMPA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to pre-clinical and clinical data, the NDA or biologics license application must include significant information regarding the chemistry, manufacturing and controls for the drug candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA to the NMPA, the NMPA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the NMPA.

We have limited experience in filing for regulatory approval for our drug candidates, and we have not yet demonstrated the ability to receive regulatory approval for our internally developed drug candidates. As a result, our ability to successfully obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals.

We also plan to commercialize our products in other markets such as United States and Taiwan. Regulatory authorities outside of China, such as the NMPA, FDA, TFDA, EMA, HSA, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements and approval processes can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Seeking foreign regulatory approval could require additional nonclinical studies or clinical trials, which could be costly and time- consuming. The foreign regulatory approval process may include all of the risks associated with obtaining the NMPA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

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The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly, and approval is never guaranteed. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target markets will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

We have limited experience in launching and marketing drug candidates. If we are unable to maintain sufficient marketing and sales capabilities, we may not be able to generate product sales revenue as planned.

Although we launched the first product in 2018, our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with rich experience launching and marketing drug candidates.

We will have to compete with other pharmaceutical and biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our drug candidates, we will likely pursue collaborative arrangements regarding the sales and marketing of our drug candidates. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates.

We may fail to effectively manage our network of distributors. Actions taken by our distributors in violation of the relevant agreements or taken by the distributors with whom we have not entered into distribution agreements could materially and adversely affect our business, prospects and reputation.

We have limited control over the operations and actions of our distributors, all of whom, to the best of our Directors’ knowledge, are Independent Third Parties during the Track Record Period. We rely on the distribution agreements and the policies and measures we have in place to manage our distributors, including their compliance with laws, rules, regulations and our policies. See “Business – Sales and Marketing – Our Marketing Model and Sales Arrangements – Distribution and Direct Sale.” We cannot guarantee that we will be able to effectively manage

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our distributors, or that our distributors would not breach our agreements and policies. If our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected:

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

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

Moreover, some of our distributors engage sub-distributors to distribute our products. Historically, we did not require our distributors to seek our approval before engaging such sub-distributors. We do not engage these sub-distributors directly or maintain contractual relationships with them, and mainly rely on our distributors to manage and control their sub-distributors in accordance with regulatory requirements, the terms of the distribution agreements we entered into with our distributors and our policies and measures that our distributors agree to comply with. As a result, we have a more limited control over these sub-distributors. Although we are currently in compliance with the Two-Invoice System, there is no assurance that the sub-distributors will comply with the geographical restrictions we have agreed with our distributors, or comply with other distribution requirements under our distribution agreements and policies. Furthermore, we cannot assure you that we will be able to identify or correct all the sub-distributors' practices that are detrimental to our business in a timely manner or at all, which may adversely affect our results of operations and reputation. As there is no contractual relationship between us and these sub-distributors, we have no direct legal recourse against them if their activities cause harm to our business or reputation.

The market opportunities for our drugs and drug candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Subsequently, for those drugs that prove to be sufficiently beneficial, if any, we may seek approval as a first-line therapy, but there is no guarantee that our drug candidates, even if approved, would be approved for second-line or first-line therapy.

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Our projections of both the number of people who have the neuromuscular and lysosomal storage or rare disease or cancers we are targeting, as well as the subset of people with these cancers in a position to receive later-stage therapy and who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates and may prove to be inaccurate or based on imprecise data.

Further, new studies may change the estimated incidence or prevalence of these cancers and rare diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our drugs and drug candidates may be limited or may not be amenable to treatment with our drugs and drug candidates. Even if we obtain significant market share for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first-or second-line therapy.

We intend to manufacture at least a portion of our approved drug candidates ourselves in the future. Delays in completing and receiving regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.

We do not have manufacturing experience previously, but we plan to build manufacturing facilities in Suzhou, China and Greater Boston, U.S.. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction, regulatory evaluation and/or approval of our new facility is delayed, we may not be able to manufacture sufficient quantities of our drug candidates and our drugs, if approved, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources.

In addition to the similar manufacturing risks described in “– Risks Relating to Our Reliance on Third Parties,” our manufacturing facilities may be subject to ongoing, periodic inspection by the NMPA, FDA, TFDA, EMA, HSA or other comparable regulatory agencies to ensure compliance with cGMP. Our failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our drugs, if approved. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet NMPA, FDA, TFDA, EMA, HSA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the NMPA, FDA, TFDA, EMA, HSA or other comparable regulatory agencies.

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Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could materially and adversely our business.

To produce our drugs in the quantities that we believe will be required to meet anticipated market demand of our drug candidates if approved, we will need to increase, or “scale up,” the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our drugs in a sufficient quantity to meet future demand.

In addition to the similar manufacturing risks described in “– Risks Relating to Our Reliance on Third Parties,” if our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales if and when we are able to successfully commercialize one or more of our drug candidates. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates or drugs in a timely manner could materially and adversely our business, financial condition and operating results.

We may be subject, directly or indirectly, to applicable anti-kickback, false-claim, physician payment transparency, or fraud and abuse laws, or similar healthcare and security laws and regulations in the U.S., 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, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain the NMPA or the FDA or other comparable regulatory authorities’ approval for any of our drug candidates and begin commercializing those drugs in China, the U.S., Taiwan, Australia or markets, our operations may be subject to various PRC, U.S. federal and state and other applicable jurisdictions’ fraud and abuse laws, including, without limitation, the PRC Anti-Unfair Competition Law, the PRC Criminal Law, the Federal Anti-Kickback Statute and the Federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business.

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If any of the physicians or other providers or entities with whom we expect to do business are 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 are subject to the anti-bribery laws of various jurisdictions. As our business has expanded, the applicability of the applicable anti-bribery laws to our operations has increased. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

Risks Relating to Our Intellectual Property Rights

Our current or any future patents may be challenged and invalidated even after issuance, which would materially adversely affect our ability to successfully commercialize any product or technology.

The patent position of pharmaceutical and biopharmaceutical companies is generally highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future owned and licensed patent applications may not issue as patents at all, and even if such patent applications do issue as patents, they may not issue in a form, or with a scope of claims, that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, its scope can be reinterpreted after issuance and changes in either the patent laws or interpretation of the patent laws in China, the U.S. and other jurisdictions may diminish the value of our patent rights or narrow the scope of our patent protection. Any patents that we own or in-license may be challenged, narrowed, circumvented or invalidated by third parties. 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 issued patents will provide sufficient protection from competitors or other third parties.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S. and other jurisdictions. We may be subject to a third-party submission of prior art to the United States Patent and Trademark Office (“USPTO”) challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a

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patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We may become involved in opposition, derivation, revocation, re-examination, post-grant review, inter partes review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. In addition, a third party may claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. An adverse determination in any such submission, proceeding or litigation could put one or more of our owned or licensed patents at risk of being interpreted narrowly, invalidated, or ruled unenforceable and could allow third parties to commercialize products similar or identical to our technology or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges and proceedings may result in loss of patent rights or freedom to operate, loss of exclusivity, or patent claims being narrowed, invalidated, or held unenforceable, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or could limit the duration of the patent protection of our technology and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Despite measures we take to obtain patent protection with respect to our major drug candidates and technologies, any of our issued patents could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the U.S., for example, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in China, the U.S. or in other jurisdictions, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, inter partes review, post-grant review, interference proceedings, derivation, invalidation, revocation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer adequately cover and protect our drug candidates.

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Additionally, patent rights we may own or license currently or in the future may be subject to a reservation of rights by one or more third parties. For example, under U.S. law, when new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may also permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology that was developed using U.S. government funding. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, or if it determines that action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government or other third parties of such rights could harm our competitive position, business, financial condition, results of operations, and prospects. Furthermore, the recipient of such U.S. government funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. If we fail to meet these obligations, it may lead to a loss of rights or the unenforceability of relevant patents or patent applications. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our in-licensed patents and intellectual property relating to our self-developed drug candidates may be subject to priority disputes or to inventorship disputes and similar proceedings. If we or our licensing partners are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture and commercialization of one or more of the drug candidates we may develop, which could have a material adverse impact on our business.

We or our licensing partners may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property. If we or our licensing partners are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which our or the in-licensed intellectual properties are subject to, 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 or our licensing partners are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership. If we or our licensing partners are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our drug candidates. The loss of exclusivity or the

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narrowing of our or our licensing partners' patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

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

Competitors or other third parties may challenge the validity and enforceability of our patents and/or those of our licensing partners, infringe, misappropriate or otherwise violate our other intellectual property rights. To counter infringement, misappropriation or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any such litigation proceeding could put our and/or in-licensed patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. Moreover, we may not be able to detect infringement against our and/or in-licensed patents. Even if we detect infringement by a third party of any of our or in-licensed patents, we or our licensing partners may choose not to pursue litigation against or settlement with such third party. If we and/or our licensing partners later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce our patents against such third party.

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

Moreover, if the breadth or strength of protection provided by our patents, patent applications and in-licensed patents is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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"), USPTO and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. 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 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 failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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Changes in patent law of China, the U.S. or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

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

In China, the recent amendment to the Chinese Patent Law, which was promulgated by the SCNPC in October 2020 and became effective in June 2021, introduced patent extensions to eligible innovative drug patents, but lacks operational details. According to the Chinese Patent Law, the patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products (if approved) without facing infringement risks. The adoption of this amendment may enable the patent owner to submit applications for a patent term extension. The extension may not exceed five years, and the total effective term of the patent after the new drug approved for marketing shall not exceed 14 years. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our products non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Recently enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the U.S. and the enforcement or defense of our issued patents, each of which could have a material adverse effect on our

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business, financial condition, results of operations and prospects. Recent U.S. Supreme Court rulings have also changed the law surrounding patent eligibility and narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights all of which could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial conditions, results of operations and prospects.

FIRMA Pilot Program may restrict our ability to acquire technologies and assets in the U.S. that are material to our commercial success.

The U.S. Congress has passed legislation that will expand the jurisdiction and powers of the Committee on Foreign Investment in the U.S. (“CFIUS”), the U.S. interagency committee that conducts national security reviews of foreign investment. President Trump signed the Foreign Investment Risk Review Modernization Act (“FIRMA”) in August 2018. Pursuant to the FIRMA, investments in companies that deal in “critical technology” are subject to filing requirements and, in some instances, review and approval by the CFIUS. The term “critical technology” includes, among others, technology subject to U.S. export controls and certain “emerging and foundational technology,” a term that is still being defined but that is expected to include a range of U.S. biotechnology. If an investment by a foreign entity in a U.S. business dealing in “critical technology” meets certain thresholds, a filing with the CFIUS is mandatory. While the FIRMA currently grants CFIUS jurisdiction on only controlling and certain non-controlling investments made by foreign persons in U.S. businesses in research and development in biotechnology, the CFIUS’s jurisdiction may be further expanded in the future, which may place additional limitations on strategic collaborations with our current U.S. partners, which could detrimentally affect our capacity to acquire foreign assets in the U.S. that may be material to our commercial success.

The absence of patent linkage, patent term extensions and data and market exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition with our products in China.

In the U.S., the Federal Food, Drug and Cosmetic Act, the FDCA, as amended by the law generally referred to as “Hatch-Waxman,” provides the opportunity for patent term restoration that provides a patent term extension of up to five years to reflect patent time period lost during certain portions of product development and the FDA regulatory review process. Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications for a period of up to 30 months if, within 45 days of receiving notice of a follow-on application, we file a patent infringement suit against such applicant.

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Finally, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity (as defined by the FDCA) and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the United States Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

Depending upon the timing, duration and specifics of any FDA marketing approval process for any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under Hatch-Waxman. Hatch-Waxman permits a patent extension term of up to five years as compensation for patent time period lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval; only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In China, the recent amendment to the Chinese Patent Law, which was promulgated by the SCNPC in October 2020 and took effect in June 2021, describes the general principles of patent term extension and patent linkage, but lacks operational details. The patent term extension provided by the amended Chinese Patent Law is similar to that under the Hatch Waxman Amendments. Since the second half of 2020, several draft measures have been published by NMPA, CNIPA, and Supreme Court (SPC) for public comments, proposing frameworks for patentees to defend their patent exclusivity and apply for patent term extension. As of the date of this document, the final versions of these draft measures have not been published, and uncertainties remain with respect to how the Chinese government will implement the patent term extension or patent linkage system. As a result, the patents we have in-licensed or own in China may not be eligible to be extended for any patent term lost during the regulatory review process. In addition, an extension may not be granted because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

In addition to our issued patents and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisers and other third parties that have access to them. However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach or violate the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, consultants, and advisers, including our senior management, may currently be, or were previously employed at other pharmaceutical or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisers, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors 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 these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such

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intellectual property rights would materially and adversely our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates and technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management. In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar drug candidates or technology, without payment to us, or could limit the duration of the patent protection covering our drug candidates and technology. Such challenges may also result in our inability to develop, manufacture or commercialize our drug candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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If we fail to comply with our obligations in the agreements under which we obtain or in-license intellectual property rights from third parties, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into and may in the future enter into additional license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents, patent applications and copyrights. These license agreements may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under any of our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our business. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under such agreements to important intellectual property or technology or our rights to develop and commercialize our drug candidates. In addition, such an event may cause us to experience significant delays in the development and commercialization of our drug candidates or incur liability for damages. If any such license is terminated, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our drug candidates.

In addition, we may need to obtain additional licenses from licensors and others to advance our research or allow commercialization of drug candidates we may develop. In connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our drug candidates and technology. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our drug candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could materially and adversely affect our business, financial condition, results of operations, and prospects significantly.

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Disputes may arise regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation-related issues;

- our or our licensors' obligation to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, drug candidates and processes infringe, misappropriate or otherwise violate intellectual property of the licensors that is not subject to the license agreements;
- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, financial or other obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and the priority of invention of patented technology; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are, and any such future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our diligence, financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed or any other dispute described above related to our license agreements prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

Because our programs may involve additional drug candidates that require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, or other intellectual property rights from third parties that we identify. The licensing and acquisition of third-party

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intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects for growth.

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

The registered or unregistered trademarks or trade names that we own or license may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our products. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names.

Claims that our drug candidates or the sale or use of our future products infringes, misappropriates or otherwise violates the patent or other intellectual rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends upon our ability to develop, manufacture, market and sell our drug candidates without infringing, misappropriating or otherwise violating the intellectual property rights of others. We cannot guarantee that our drug candidates or any uses of our drug candidates do not and will not in the future infringe third-party patents or other intellectual property rights. It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

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Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, use or manufacture of the compounds we have developed or are developing. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing future approved drugs, or be forced, by court order or otherwise, to cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement, including treble damages and attorneys’ fees if we are found to willfully infringe a third party’s patent.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could 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 adverse impacts on our business.

Intellectual property rights do not necessarily address all potential threats.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents and trademarks of our tradename. As of the Latest Practicable Date, we own or otherwise have exclusive rights to 17 granted patents and 47 pending patent applications worldwide. See “Business – Intellectual Property” for more details. 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. For example:

- others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;
- we or any future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;

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- we or any future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- patents that may be issued from our pending patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may materially and adversely affect our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Relating to Our Reliance on Third Parties

We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, we may not realize the benefits of such alliances or licensing arrangements, and disputes may arise between us and our Collaboration Partners which could harm our business.

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

Our strategic collaboration with partners involves numerous risks. We may not achieve the revenue and cost synergies expected from the transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve

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the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that these synergies will be achieved.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biopharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

Disputes may arise between us and our Collaboration Partners. Such disputes may cause delay or termination of the research, development or commercialization of our drug candidates, or may result in costly litigation or arbitration that diverts management attention and resources. Global markets are an important component of our growth strategy. If we fail to obtain licenses or enter into collaboration arrangements with third parties in other markets, or if third-party collaborator is not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- decisions of our collaborators, especially those in combo therapy trials, to delay any clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing, or not to pursue development and commercialization of our drugs and drug candidates, continue or renew development or commercialization programs based on clinical trial results or other external factors;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- third parties obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;

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- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;
- unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements;
- economic weakness, including inflation;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest;
- failure of our employees and contracted third parties to comply with United States Department of the Treasury’s Office of Foreign Assets Control rules and regulations and the United States Foreign Corrupt Practices Act of 1977, as amended (“FCPA”); and
- business interruptions resulting from geopolitical actions, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

We rely on third parties to conduct a certain number of our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates, or experience delay in doing any of the foregoing, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to generate, monitor or manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on 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 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 applicable GCPs, the clinical

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data generated in our clinical trials may be deemed unreliable and the NMPA or 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 product produced under GMP regulations. Our 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 terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. In addition, our CROs are not our employees. 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 non-clinical programs. If CROs do not successfully carry out their contractual duties or 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 approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including obtaining regulatory approval. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them. 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. Therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If third parties fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We cannot guarantee 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 licensed drug which could materially and adversely affect our business, financial condition, cash flows and results of operations.

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We rely on third parties to manufacture and import our clinical drug supplies and expect to rely on third parties to supply raw materials for manufacturing and/or manufacture our drugs when approved, and our business could be harmed if those third parties fail to provide us with sufficient quantities of the raw materials or the drug product or fail to do so at acceptable quality levels or prices.

We currently use third parties for our manufacturing process and for the clinical supply of our drug candidates, some of which are among our five largest suppliers during the Track Record Period. We expect to continue to rely on third-parties to supply raw materials for us to manufacture or manufacture the approved drugs in the future. 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, TFDA, EMA, HSA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and cGMP-compliance inspections by the NMPA, FDA, TFDA, EMA, HSA or other comparable regulatory authorities;
- 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 by the regulatory authorities to ensure strict compliance with cGMP and other government regulations. 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;
- 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 critical reagent suppliers may be subject to inclement weather, as well as natural or human-made disasters.

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Each of these risks could delay or prevent R&D activities, result in higher costs, or adversely impact commercialization of our future approved drug candidates. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm, and regulatory authorities could place significant restrictions on our Company until deficiencies are remedied.

Manufacturers of drug and pharmaceutical products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced regulations. Furthermore, if contaminants are discovered in our supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future, either relating to our third-party CDMOs or on our manufacturing facilities we plan to build in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any future approved drug candidates for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs, and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

We had a limited number of suppliers during the Track Record Period and the loss of one or more of our key suppliers could disrupt our operations.

In 2019 and 2020 and the six months ended June 30, 2021, our purchases from our five largest suppliers in the aggregate accounted for 63.1% and 83.7% and 69.3% of our total purchases, respectively. During the Track Record Period, we had a small number of suppliers, and the largest purchase amounts related to upfront payments for drug in-licensing and acquisition arrangements, which were not recurring in nature. Our other major purchases were fees paid to CROs we engaged to manage, conduct and support our preclinical research and clinical trials. We expect to continue our purchases from these suppliers as we fund the continuing research and development activities of our Core Products and other drug candidates in our pipeline. We believe that we have long and stable relationships with our existing large third-party suppliers. However, the stability of operations and business strategies of our suppliers are beyond our control, and we cannot assure you that we will be able to secure a stable relationship and high-quality outsourced services with our large suppliers. If any of our large suppliers terminates its business relationship with us, we may encounter difficulty in finding a replacement that can provide services of equal quality at a similar price. If this occurs, our operations may be significantly disrupted.

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Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, vendors and CROs may engage in misconduct or other improper activities.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- NMPA regulations, including those laws requiring the reporting of true, complete and accurate information to the NMPA;
- manufacturing standards; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. We may not be able to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from the NRDL, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations.

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RISKS RELATING TO OUR OPERATIONS

Our future success depends on our ability to retain key executives and to attract, train, retain and motivate qualified and highly skilled personnel especially R&D and clinical related staff.

We are highly dependent on Dr. Xue, our Founder, Chairman and CEO and other principal members of our management and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain key-person insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Our clinical activities might be delayed if any key member of R&D team leaves. To incentivize valuable employees, especially these R&D and clinical related staff that are key to our R&D efforts, to remain at our Group, in addition to salary and cash incentives, we have provided share incentives that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the market price of our Shares that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified scientific, technical, clinical, manufacturing, and sales and marketing personnel in the future will also be critical to our success. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executive officers, key employees, experienced R&D staff or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biopharmaceutical companies for similar personnel. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. In addition, we may not be successful in training our professionals to keep pace with technological and regulatory standards. Any inability to attract, motivate, train or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

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Our reputation is key to our business success. Negative publicity may adversely affect our reputation, business and growth prospect.

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

We have significantly increased the size and capabilities of our organization, and we may experience difficulties in managing our growth.

We had 173 employees as of the Latest Practicable Date. As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals.

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We may be involved in lawsuits, claims, administrative proceedings or other legal proceedings against us, which could be costly and time-consuming to defend and therefore adversely affect our business, financial conditions, results of operations and reputation.

We may be involved in lawsuits claims, administrative proceedings or other legal proceedings arising in the ordinary course of business or pursuant to governmental or regulatory enforcement activity from time to time. Litigation and governmental proceedings can be expensive, lengthy and disruptive to normal business operations, and can require extensive management attention and resources, regardless of their merit. While we do not believe that the resolution of any lawsuits against us will, individually or in the aggregate, have a material adverse effect on our business, financial condition and results of operations, litigation to which we subsequently become a party might result in substantial costs and divert management’s attention and resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake, and the parties involved. In July 2020, Puma Biotechnology, Inc. (Nasdaq: PBYI) (“Puma”) initiated an arbitration proceeding against us in connection with the license agreement between Puma and us signed in 2018. We have reached a settlement with Puma in February 2021 to settle such arbitration. For details, please see “Business – Legal Proceedings and Compliance”. We have implemented heightened measures to monitor our other license agreements, including but not limited to periodic check of performance under the agreements by our business development team and enhanced compliance review by our internal counsel.

Although we maintained various insurances including the product liability insurance, our insurance might not cover claims brought against us, might not provide sufficient payments to cover all of the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. In particular, any claim could result in unanticipated liability to us if the claim is outside the scope of the indemnification arrangement we have with our collaborators, our collaborators do not abide by the indemnification arrangement as required, or the liability exceeds the amount of any applicable indemnification limits or available insurance coverage. While we intend to defend the aforementioned matters vigorously, we cannot predict the results of complex legal proceedings and an unfavorable resolution of a lawsuit or proceeding could materially adversely affect our business, results of operations, financial conditions and reputation.

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If we engage in acquisitions, joint ventures or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, may have a material adverse effect on our ability to manage our business and may not be successful.

From time to time, to pursue our growth strategy, we may evaluate various acquisitions, joint ventures 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:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- 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 drugs or drug candidates and regulatory approvals; and
- 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.

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

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recruit key employees away from companies during the integration phase of an acquisition. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors, or the M&A Rules, and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. Moreover, according to the Anti-Monopoly Law of PRC and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, or the “Prior Notification Rules” issued by the State Council, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the anti-monopoly enforcement agency of the State Council when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors, or the “Security Review Rules,” issued by the MOFCOM specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns, and mergers and acquisitions through which foreign investors may acquire the de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval and filing processes, including obtaining approval or filings from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

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

Our growth strategies aim to develop potential therapies for rare oncology and rare diseases in china and globally. For more information, see “Business – Our Strategies.” Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global and Chinese biopharmaceutical market, effective coordination and integration of our facilities and teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute on our growth strategies or realize our anticipated growth could adversely affect our business, financial condition, results of operations and prospects.

RISK FACTORS

If we or our CROs or CDMOs 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 but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in the process of our business operations. In addition, our construction projects can only be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety have examined and approved the relevant facilities in certain jurisdictions. We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our construction projects may affect our abilities to develop, manufacture and commercialize our pipeline products as we plan. As requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may not be able to comply with, or accurately predict any potential substantial cost of complying with, these laws and regulations. If we fail to comply with environmental protection, and health and safety laws and regulations, we may be subject to rectification orders, substantial fines, potentially significant monetary damages, or production suspensions in our business operations. As a result, any failure by us to control the use or discharge of hazardous substances could have a material and adverse impact on our business, financial condition, results of operations and prospects.

In addition, we cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facilities during the process of research, testing, development and manufacturing of biopharmaceuticals. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could materially and adversely our business. Other adverse effects could result from such liability, including reputational damage. We may also be forced to close or suspend operations at certain of our affected facilities temporarily, or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material and adverse impact on our business, financial condition, results of operations and prospects. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

RISK FACTORS

We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control. Natural disasters, epidemics, pandemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business.

Our operations may be under the threat of natural disasters such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, or other events, such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks.

The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in China or elsewhere in the world could materially disrupt our business and operations. For example, since the end of December 2019, the outbreak of COVID-19 has affected many people in and outside of China, caused temporary suspension of productions and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy generally. The exacerbation, continuance or reoccurrence of COVID-19 has already caused and may continue to cause an adverse and prolonged impact on the economic, geopolitical and social conditions in China and other affected countries, which may potentially delay our progress in the expected commercialization of CAN008. Although, the existing clinical trials and the commencement of new clinical trials have not been obviously affected by the COVID-19 pandemic, it could be substantially delayed or prevented by any delay or failure in patient recruitment or enrollment in our or our collaborators' trials as a result of the outbreak of COVID-19 or other outbreaks and relevant vaccination schedule. These factors could cause delay of clinical trials, regulatory submissions, and required approvals of our drug candidates, and could cause us to incur additional costs. If our employees or employees of our business partners are suspected of being infected with an epidemic disease, our operations may be disrupted because we or our business partners must quarantine some or all of the affected employees or disinfect the operating facilities. If we are not able to effectively develop and commercialize our drug candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, and/or failure to recruit and conduct patient follow-up, we may not be able to generate revenue from sales of our drug candidates as planned.

Our internal computer systems, or those used by our partners or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our partners and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

RISK FACTORS

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or vendors that provide information systems, networks or other services to us pose increased risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial-of-service attacks, and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of our Company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyberattacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes are costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

RISK FACTORS

We are subject to the risks of doing business globally.

Because we operate in China and other countries, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: changes in a specific country’s or region’s political and cultural climate or economic condition; unexpected changes in laws and regulatory requirements in local jurisdictions; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in certain countries; 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; the effects of applicable local tax regimes and potentially adverse tax consequences; and significant adverse changes in local currency exchange rates.

We have historically received government grants and subsidies for our research and development activities. Expiration of, or changes to, these incentives or policies or our failure to satisfy any condition for these incentives would have an adverse effect on our results of operations.

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. We recorded government grants of RMB0.2 million, RMB0.4 million and RMB0.2 million for the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, respectively. The local governments have the discretion in deciding the timing, amount and criteria of government financial incentives and thus we cannot predict with certainty whether or how much financial incentive will be granted to us even if we apply for such funding. We generally do not have the ability to influence local governments in making these decisions. Government authorities may also decide to reduce or eliminate incentives or may amend or terminate the relevant financial incentive policies at any time. In addition, some of the government financial incentives are granted to us on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

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

The change in the value of RMB against the Hong Kong dollar and other currencies may fluctuate and is affected by, among other things, changes in China’s political and economic conditions and China’s foreign exchange policies. Substantially all of our costs are denominated in RMB and US dollars, most of our assets are cash and bank balances primarily denominated in US dollars, and our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. Any significant change in the exchange rates of the Hong Kong dollar against RMB or US dollars against RMB may materially and adversely affect the value of and any dividends payable on, our Shares in Hong Kong dollars.

RISK FACTORS

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, including insurance for our new facilities. Although we have maintained clinical trial insurance, product liability insurance, property loss insurance, business interruption insurance and public liability insurance. We expect our employer liability insurance to be effective upon [REDACTED], 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 drug development and overall operations.

We do not own the real property for our current major operation sites and may be subject to risks relating to leased properties.

We do not own any real property for our operations. As of the Latest Practicable Date, we lease an aggregate area of over 4,000 sq.m. in Greater China and Greater Boston area. Upon expiration of the leases, we will need to negotiate for renewal of the leases and may have to pay increased rent. We cannot assure you that we will be able to renew our leases on terms which are favorable or otherwise acceptable to us, or at all. If we fail to renew any of our leases or if any of our leases are terminated or if we cannot continue to use any of our leased property, we may need to seek an alternative location and incur expenses related to such relocation, and our operation and businesses may also be disrupted or even suspended if we are not able to complete the relocation, including the reconstruction of relevant facilities in the new location, in a timely manner.

We are subject to other risks related to our leased properties. For example, our landlords failed to provide valid title certificates with respect to some of our leased properties to us. If our landlords are not the owners or not authorized by the real owners to sign the lease agreements, the validity and enforceability of the lease agreements may be adversely affected. Since we only use these leased properties for registration purposes, such risk will not have a material adverse impact on our business in the PRC as confirmed by our PRC Legal Advisor.

Pursuant to the applicable PRC laws and regulations, property lease agreements must be registered with the local branch of the Ministry of Housing and Urban-Rural Development of the PRC. As of the Latest Practicable Date, we had not completed the relevant property leasing registrations for some of our leased properties. According to our PRC Legal Advisers, the failure to complete the registration process does not affect the validity of the property lease agreements but a maximum penalty of RMB10,000 may be imposed on us for the non-registration of each lease. We cannot assure we will not be subject to any penalties arising from the non-registration of lease agreements in the future. As advised by our PRC Legal Advisor, such non-compliance does not affect the validity of the property lease agreement according to PRC Civil Code and will not have a material adverse effect on the [REDACTED].

RISK FACTORS

RISKS RELATING TO OUR DOING BUSINESS IN CHINA

The pharmaceutical industry in China is highly regulated and such regulations are subject to change, which may affect approval and commercialization of our drug candidates.

We currently conduct most of our operations in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the benefits we believe are available to us from developing and manufacturing drugs in China.

Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth over the past 30 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development 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 that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, 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 operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

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

A large portion of our operations are conducted in China through our PRC subsidiaries, and are governed by PRC laws, rules and regulations. Our PRC subsidiaries are subject to laws, rules and regulations applicable to foreign investment in China. 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.

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In 1979, 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 foreign investment 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 significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the nonbinding 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 and internal rules, some of which are not published on a timely basis 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 and clinical trial 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.

On July 2, 2021, the NMPA released the Draft of Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (以臨床價值為導向的抗腫瘤藥物臨床研發指導原則(徵求意見稿)), or the Draft Guiding Principles. The Draft Guiding Principles emphasize the clinical value-oriented and patient-centered research and development concept and encourage Best Support Care to be utilized as a control in randomized controlled trials. Although we believe our trial design of ongoing and planned clinical trials are in compliance with the current version of Draft Guiding Principles, as the CDE is collecting opinions towards the Draft Guiding Principles, there exists uncertainties as to the enactment, interpretation and application thereof. We will pay close attention to the development of the Draft Guiding Principles and if necessary, make adjustments to our oncology drugs clinical trials according to the latest development of this Draft Guiding Principles to ensure our compliance when they are promulgated and come into force in the future. We do not expect any potential material adverse impact of the Draft Guiding Principles on our business operations. However, as the laws and regulations regarding clinical trials are generally evolving, we cannot assure you that if we will at all times fully comply with the relevant laws and regulations in the future. Failure to comply with such laws and regulations could adversely affect our business and results of operation.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than we would in more developed legal systems. 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.

RISK FACTORS

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 after-tax 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. At its discretion, our PRC subsidiaries may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in China, up to the amount of net assets held in each operating subsidiary.

In response to the persistent capital outflow in China and RMB’s depreciation against the U.S. dollar, People’s Bank of China, or PBOC, 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 investors or other obligations to our suppliers, or otherwise fund and conduct our business.

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

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

Pursuant to the Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), the withholding tax rate on dividends paid by our PRC subsidiary to our

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Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of the PRC-sourced income and we have obtained the approval of the competent tax authority. On February 3, 2018, the State Taxation Administration, or the SAT issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement (《關於稅收協定中“受益所有人”有關問題的公告》), also known as Circular 9, which provides guidance for determining whether a resident of a contracting state is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to Circular 9, 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 holds any equity interest in a PRC subsidiary and does not engage in any substantive business activity in the future, based on the abovementioned principles, PRC tax authorities would not consider our Hong Kong subsidiary as the “beneficial owner” of any dividends paid from our PRC subsidiaries and would deny the claim for the reduced rate of withholding tax. Under the current PRC tax law, if our Hong Kong subsidiary is not considered as a “beneficial owner,” dividends from our PRC subsidiaries to our Hong Kong subsidiary being subject to PRC withholding tax at a 10% rate instead of a 5% rate. This would negatively impact us and it would impact our ability to pay dividends in the future.

Uncertainties exist with respect to the interpretation and implementation of the PRC Foreign Investment Law, which may impose new burdens on us.

The PRC Foreign Investment Law, or the FIL, was enacted by the NPC on March 15, 2019 and became effective on January 1, 2020, which replaces a trio of previous laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. This law has become the legal foundation for foreign investment in the PRC. The FIL embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Implementation Rules to the Foreign Investment Law were promulgated by the State Council on December 26, 2019 and became effective on January 1, 2020. However, uncertainties exist with respect to interpretation and implementation of the FIL and its Implementation Rules, which may adversely impact our corporate governance practice and increase our compliance costs. For instance, we might be required by government interpretations or implementing rules of the FIL to adjust the corporate governance of certain of our PRC subsidiaries in a five-year transition period. In addition, the FIL imposes information reporting requirements on foreign investors or foreign-invested enterprises. Failure to take timely and appropriate measures to cope with any of these or other regulatory compliance requirements under the FIL may lead to rectification obligations, penalties or other regulatory sanctions on us.

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

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

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

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. We recorded government grants of RMB0.2 million, RMB0.4 million and RMB0.2 million for the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, respectively. The local governments have the discretion in deciding the timing, amount and criteria of government financial incentives and thus we cannot predict with certainty whether or how much financial incentive will be granted to us even if we apply for such funding. We generally do not have the ability to influence local governments in making these decisions. Government authorities may also decide to reduce or eliminate incentives or may amend or terminate the relevant financial incentive policies at any time. In addition, some of the government financial incentives are granted to us on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

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We are subject to PRC tax laws and regulations.

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. Although we believe that in the past we had acted in compliance with the requirements under the relevant PRC tax laws and regulations in all material aspects and had established effective internal control measures in relation to accounting regularities, we cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC government from time to time adjusts or changes its tax laws and regulations. Such adjustments or changes, together with any uncertainty resulting therefrom, could have an adverse effect on our business, financial condition and results of operations.

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

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

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 recognition and enforcement of judgments in a wider range of civil and commercial matters between Hong Kong Special Administrative Region and the China. The New Arrangement discontinued the requirements for a choice of

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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 the Hong Kong Special Administrative Region. 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 China if the parties in the dispute do not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors to effect service of process against our assets or management in China in order to seek recognition and enforcement of foreign judgments in China.

Furthermore, China does not have treaties or agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the U.S., the United Kingdom, or most other western countries. Hence, the recognition and enforcement in China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

On January 9, 2021 the MOFCOM promulgated the Measures for Blocking Improper Extraterritorial Application of Foreign Laws and Measures (阻斷外國法律與措施不當域外適用辦法), or Order No.1, pursuant to which, where a citizen, legal person or other organization of China is prohibited or restricted by foreign legislation and other measures from engaging in normal economic, trade and related activities with a third State (or region) or its citizens, legal persons or other organizations, he/it shall truthfully report such matters to the MOFCOM within 30 days. Upon assessment and being confirmed that there exists unjustified extra-territorial application of foreign legislation and other measures, the MOFCOM could issue a prohibition order to the effect that, the relevant foreign legislation and other measures are not accepted, executed, or observed, but such a citizen, legal person or other organization of China may apply to the MOFCOM for an exemption from compliance with such prohibition order. However, since the Order No.1 is relatively new, the enforcement of it involves uncertainty in practice.

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

The SAFE has promulgated several regulations requiring PRC residents to register with local qualified banks before engaging in direct or indirect offshore investment activities, including Circular of the State Administration of Foreign Exchange on Issues Relating to the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by Domestic Residents (國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通告), or SAFE Circular 37, issued and effective on July 4, 2014. SAFE Circular 37 requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment

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and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle.” SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC citizen or resident does not complete the registration with the local SAFE branches, the PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be restricted to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including but not limited to (1) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (2) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

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

On February 13, 2015, SAFE promulgated the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知), or SAFE Circular 13, which came into effect on June 1, 2015, pursuant to which local banks shall review and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration under SAFE Circular 37 and SAFE Circular 30, while the application for remedial registrations shall still be submitted to, reviewed and handled by the relevant local branches of SAFE.

There remains uncertainty as to the interpretation and implementation of the latest SAFE rules at practice level. We are committed to complying with and to ensuring that our Shareholders who are subject to the regulations will comply with the relevant SAFE rules and other regulations; however, due to the inherent uncertainty in the implementation of the regulatory requirements by PRC authorities, such registration might not be always practically available in all circumstances as prescribed in those regulations. In addition, we may not

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

We face uncertainty relating to PRC laws and regulations relating to transfers by a non-resident enterprise of assets of a PRC resident enterprise.

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

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

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

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inadequate in their ability to perform their intended functions and withstand risks as their alleged organization forms suggest; or (iv) the income tax from the indirect transfer of PRC Taxable Assets payable abroad is lower than the income tax in China that may be imposed on the direct transfer of such PRC Taxable Assets.

Circular 7 contains certain exemptions, including (i) the Public Market Safe Harbor described below; and (ii) where there is an indirect transfer of PRC Taxable Assets, but if the non-resident enterprise had directly held and disposed of such PRC Taxable Assets, the income from the transfer would have been exempted from enterprise income tax in the PRC under an applicable tax treaty or arrangement. However, it remains unclear whether any exemptions under Circular 7 will be applicable to the transfer of our Shares that do not qualify for the Public Market Safe Harbor or to any future acquisition by us outside of the PRC involving PRC Taxable Assets, or whether the PRC tax authorities will reclassify such transactions by applying Circular 7. Therefore, the PRC tax authorities may deem any transfer of our Shares that do not qualify for the Public Market Safe Harbor by our Shareholders that are non-resident enterprises, or any future acquisition by us outside of the PRC involving PRC Taxable Assets, to be subject to the foregoing regulations, which may subject our Shareholders or us to additional PRC tax reporting obligations or tax liabilities.

Provisions of Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to “non-resident enterprise acquiring and disposing of the equity interests of the same offshore listed company in a public market,” or the Public Market Safe Harbor, which is determined by whether the parties, number and price of the shares acquired and disposed are not previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to the Several Issues Relating to the Administration of Income Tax on Non-resident Enterprises (關於非居民企業所得稅管理若干問題的公告). In general, transfers of the Shares by Shareholders on the Stock Exchange or other public market would not be subject to the PRC tax liabilities and obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. As stated in “Information about this Document and the [REDACTED]” in this document, potential [REDACTED] should consult their professional advisors if they are in any doubt as to the tax implications of subscribing for, purchasing, holding, disposing of and dealing in the Shares.

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

Under China’s Enterprise Income Tax Law, or the “EIT Law,” an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it can be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. Notice on Issues about the Determination of Chinese-Controlled Enterprises Registered Abroad as Resident Enterprises on the Basis of Their Body of Actual Management (關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知), which was issued by the SAT on April 22, 2009, or Circular 82, regarding the standards used to classify resident enterprises clarified that dividends and other distributions

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

Currently, most of the members of our management team as well as the management team of some of our offshore holding companies are located in China. However, Circular 82 and Bulletin 45 only apply to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreign corporations like us. In the absence of detailed implementing regulations or other guidance determining that offshore companies controlled by PRC individuals or foreign corporations like us are PRC resident enterprises, we do not currently consider our Company or any of our overseas subsidiaries to be a PRC resident enterprise.

Despite the foregoing, the SAT may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules and Bulletin 45 dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax, as the PRC foreign-exchange control authorities and tax authorities have not yet issued guidance

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with respect to the processing of outbound remittances to entities that are treated as resident enterprises for PRC enterprise income tax purposes but not controlled by a PRC enterprise or enterprise group like us. Finally, under the EIT Law and its implementing rules issued by PRC tax authorities dividends paid by us to our non-PRC shareholders may be subject to a withholding tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders, and gains recognized by our non-PRC shareholders may be subject to PRC tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders. Any PRC tax liability on dividends or gain described above may be reduced under applicable tax treaties. However, it is unclear whether, if our Cayman Islands holding company is considered a PRC resident enterprise, non-PRC shareholders might be able to claim the benefit of income tax treaties entered into between PRC and their countries. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise.

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

The PRC government imposes controls on the convertibility of foreign currencies into Renminbi. Under China’s existing foreign-exchange regulations, foreign-exchange transactions under capital accounts continue to be subject to significant foreign-exchange controls and require the registration with, and approval of, PRC governmental authorities. In particular, if one subsidiary receives foreign-currency loans from us or other foreign lenders, these loans must be registered with SAFE or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be filed with or approved by certain government authorities, including the MOFCOM or its local counterparts.

In August 2018, the SAFE promulgated the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Exchange Capital Funds of Foreign Invested Enterprises (國家外匯管理局綜合司關於完善外商投資企業外匯資本金支付結算管理有關業務操作問題的通知), or SAFE Circular 142, providing that the Renminbi capital converted from foreign exchange capital funds of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investment within the PRC.

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

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on the settlement of foreign exchange capital of foreign-invested enterprises. Under SAFE Circular 19 and SAFE Circular 16, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, SAFE Circular 19 and SAFE Circular 16 also reiterate that the settlement of foreign exchange shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity. Under SAFE Circular 19 and SAFE Circular 16, we may still not be allowed to convert foreign-currency-registered capital of our PRC subsidiaries which are foreign-invested enterprises into RMB capital for securities investments or other finance and investment except for principal-guaranteed bank products. Further, SAFE Circular 19 and SAFE Circular 16 restrict a foreign-invested enterprise from using Renminbi converted from its registered capital to provide loans to a its non-affiliated company.

Violations of SAFE Circular 19 and SAFE Circular 16 could result in severe monetary or other penalties. We cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries, and conversion of such loans or capital contributions into Renminbi. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business. On October 23, 2019, the SAFE released the Circular on Further Promoting Cross-border Trade and Investment Facilitation (國家外匯管理局關於進一步促進跨境貿易投資便利化的通知), or SAFE Circular 28, according to which a non-investment foreign-invested enterprise is permitted to make domestic equity investments with its capital funds provided that such investments do not violate the Negative List and the target investments are genuine and in compliance with laws. On April 10, 2020, the SAFE promulgated the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (關於優化外匯管理支持涉外業務發展的通知), or SAFE Circular 8, under which eligible enterprises are allowed to make domestic payments by using their capital funds, foreign loans and the income under capital accounts of overseas listing, without providing the evidentiary materials concerning authenticity of each expenditure in advance, provided that their capital use shall be authentic, and conform to the prevailing administrative regulations on the use of income under capital accounts. Considering that SAFE Circular 28 and SAFE Circular 8 are often principle-oriented and subject to the detailed interpretations by the enforcement bodies to further apply and enforce such laws and regulations in practice, it is unclear how they will be implemented, and there can be high uncertainties with respect to its interpretation and implementation by government authorities and banks.

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The political relationships between China and other countries or regions may affect our business operations.

During the Track Record Period, we have formed partnerships with entities in foreign countries and regions and initiated or plan to initiate clinical trials, in the U.S., Australia, South Korea, Taiwan and certain Asia countries and territories. Establishing new collaboration partnerships globally is key to our future growth. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. As a result, China's political relationships with those foreign countries and regions may affect the prospects of maintaining existing or establishing new collaboration partnerships.

There can be no assurance that such collaborators or customers will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Since mid-2018, political tension has increased between China and the U.S. and has escalated into a tariff war and deteriorating political and diplomatic relationships. There can be no assurance that potential collaboration partners will not alter their perception of us or their preferences as a result of such adverse changes between China and relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. It also remains unclear what actions, if any, the U.S. government will take with respect to other existing international trade agreements. If the U.S. were to withdraw from or materially modify certain international trade agreements to which it is a party, especially with respect to intellectual properties transfer, our business, financial condition and results of operations could be negatively impacted.

RISKS RELATING TO THE [REDACTED]

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

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

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

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

The [REDACTED] of our Shares sold 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 price 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 sale and the time trading begins.

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

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

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You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future, including pursuant to the share incentive schemes.

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 in [REDACTED] net tangible asset value. 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 which is lower than the net tangible asset value per Share at that time. Furthermore, we may issue Shares pursuant to the share incentive schemes, which would further dilute Shareholders’ interests in our Company.

We do not expect to pay dividends in the foreseeable future after the [REDACTED].

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

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

We have significant discretion as to how we will use the net [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the net [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return to our shareholders. We plan to use the net [REDACTED] from the [REDACTED] to conduct clinical trials in China and other APAC regions on our most promising drug candidates and to expand our sales and marketing staff in preparation for the approval and commercialization of those drug candidates. For details, see “Future Plans and Use of [REDACTED] – Use of [REDACTED].” However, our management will have discretion as to the actual application of our net [REDACTED]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net [REDACTED] from this [REDACTED].

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

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

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

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the [REDACTED], the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the pharmaceutical industry in and outside China may be inaccurate and you should not place undue reliance on them. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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You should read the entire document carefully, and we 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 when 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.