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, as well as our financial statements and the related notes, and the "Financial Information" section, before deciding to* [**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, results of operations and growth prospects. In any such an event, 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 of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed "Forward-Looking Statements" in this document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to the research and development of our drug candidates; (ii) risks relating to manufacturing of our drug candidates; (iii) risks relating to commercialization of our drug candidates; (iv) risks relating to our intellectual property rights; (v) risks relating to our financial position and need for additional capital; (vi) risks relating to our operations; (vii) risks relating to our reliance on third parties; (viii) risks relating to government regulations; and (ix) 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 and operating results. You should consider our business and prospects in light of the challenges we face, including those discussed in this section.

RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR DRUG CANDIDATES

Our business and financial prospects depend substantially on the success of our clinical stage and preclinical stage drug candidates. In particular, among our product candidates, IAP0971, IAE0972 and IBB0979 are with first-in-class potential, and IAH0968 is with best-in-class potential. However, if we are unable to successfully complete their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.

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

- favorable safety, immunogenicity and efficacy data from our clinical trials and other studies;

- successful enrollment of patients in, and completion of, clinical trials, as well as completion of preclinical studies;

- sufficient resources to acquire or discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;

- competition with other drug candidates and marketed drugs;

- obtaining sufficient supplies of any drug products or marketed drugs that are used in combination with our drug candidates, competitor drugs, or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;

- the performance by CROs or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;

- receipt of regulatory approvals from the National Medical Products Administration ("**NMPA**"), the Food and Drug Administration ("**FDA**") or other comparable regulatory authorities for our drug candidates;

- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;

- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;

- establishing sufficient commercial manufacturing capabilities;

- successfully launching commercial sales of our drug candidates, if and when approved;

- obtaining and maintaining favorable governmental and/or private reimbursement from third-party payers for our drugs, if and when approved;

- continued acceptable safety profile of our drug candidates following regulatory approval, if and when received; and

- stable and supportive domestic policies, favorable international environment and good relationships among nations.

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

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods, which carries inherent development risks and could result in delays in clinical development, regulatory approval or commercialization. Any modification to the protocols related to the demonstration of safety or efficacy of our drug candidates may delay the clinical program, regulatory approval and/or commercialization, and we may be required to supplement, modify, or withdraw and refile our applications for the regulatory approval. This may have a material impact on our ability to generate revenue from our drug candidates, which in turn may materially and adversely affect our business, financial condition and results of operations.

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

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

The success of our business depends upon our ability to identify, discover, develop and commercialize drug candidates. Although we have developed proprietary technology platforms such as AIC™, AIM™, AEA™ which we believe enable us to discover, design, evaluate and select optimal candidates and continue to enrich our pipeline, we cannot guarantee that we will be successful in identifying potential new drug candidates. Furthermore, drug candidates that we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Some drug candidates such as Immunocytokine and BsAb drug candidates for oncology that we intend to identify could also be technically challenging to develop and manufacture. Research programs to identify new drug candidates and drug targets or to pursue the development of our drug candidates for additional indications require substantial technical, financial and human resources. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including but not limited to the following factors:

- the research methodology used may not be successful in identifying potential indications and/or new drug candidates;

- there may be a lack of transferability of experimental results obtained in the laboratory testing in cells or from animals into clinical treatment and safety outcomes in human subjects, including unexpected toxicities in humans;

- potential drug candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired safety and efficacy;

- it may take greater resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates, thereby limiting our ability to diversify and expand our drug portfolio; or

- we may not be able to manufacture the right dosage form to match the appropriate route of administration during the development of our drug candidates.

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

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

The global biologics market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2021 and 2022 and for the three months ended March 31, 2023, our research and development expenses were RMB64.0 million, RMB53.2 million and RMB14.6 million, respectively. We need to continue to invest in human resources and technologies that will allow us to enhance the scope and quality of our research and development. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital-and-time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or innovative drugs to market, obtain sufficient or any patent or other intellectual property protection for such new or innovative drugs, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such drugs are introduced to the market, that those drugs will achieve market acceptance. Any failure to do so may make our technologies obsolete, which could harm our business and prospects.

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

The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological changes. Major pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions have commercialized or are commercializing or pursuing the development of drugs competing with our drug candidates.

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

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

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

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

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

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

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

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

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

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

- the design of the trial;
- the patient eligibility criteria defined in the protocol;
- the severity of the disease under investigation;
- the size and demographics of the patient population;
- the size of the study population required for analysis of the trial's primary endpoints;
- our ability to obtain and maintain patient consents;
- the experience and competencies of our third-party contractors;
- our ability to select clinical trial sites and to recruit clinical trial investigators with the appropriate competencies and experience;
- the proximity of patients to trial sites;
- clinicians' and patients' perceptions of the potential advantages and side effects of the drug candidate being studied compared to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;

- the risk that patients enrolled in clinical trials will not complete a clinical trial;
- the outbreak of epidemics or pandemics; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

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

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

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

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

- regulatory authorities could interrupt, delay or halt pending clinical trials;
- regulatory authorities may order us to cease further development of, or delay or even 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 withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug, issue safety alerts or other communications containing warnings or other safety information of such approved drug, or impose other limitations on such approved drug;
- we may suspend, delay or alter development or marketing of our drug candidates;

- we may be required to develop a risk evaluation mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the existing strategy, or to develop a similar strategy as required by a comparable regulatory authority;

- we may be required to change the way the drug candidate is administered or conduct post-market studies;

- the patient enrollment may be insufficient or slower than we anticipate, or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;

- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;

- we could be required to recall our drug candidates and subject to litigation proceedings and regulatory investigations and held liable for harm caused to patients exposed to or taking our drug candidates; and

- our reputation may suffer.

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

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

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

In some instances, there can be significant variability in safety, immunogenicity and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and demographics of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. As drug candidates are developed through preclinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Differences in the number of clinical trial sites and countries involved may also lead to variability between earlier and later-phase clinical trials. Constantly updated standard therapies may change patient resistance, which may affect the efficacy of our medicines. Such changes carry the inherent risks that they may not necessarily

achieve the intended objectives. In addition, our future clinical trial results may differ from earlier trials and may not be favorable. Even if our future clinical trial results show favorable efficacy, not all patients may benefit. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and other than as predicted, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. If so, we would have expended a significant amount of capital to progress the relevant drug candidates to that stage, and would not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially and adversely affect our business, financial condition, results of operations and prospects.

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

Before obtaining regulatory approvals for the commercialization of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates for their proposed indications in humans. We may conduct clinical trials with larger subject sample sizes as our clinical trial plan advances, and our drug candidates may not show the promising safety, immunogenicity and efficacy results that were observed in earlier clinical trials with fewer subjects. Undesirable adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay, suspend or terminate clinical trials and result in a more restrictive label or the delay or denial of regulatory approval. Results of our clinical trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our clinical trials could be suspended or terminated and we may be required to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial, and result in potential product liability claims. In addition, our clinical trials may not generate meaningful clinical response or have other unexpected characteristics, such as the short-term duration of response and insufficient enhancement of overall survival benefits.

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

- regulatory approvals for our drug candidates would be delayed or denied;
- we may be required to conduct additional clinical trials or other testing of our drug candidates beyond our current development plan;
- we may be required to add labeling statements, such as a "boxed" warning or a contraindication;

- we may be required to create a medication guide outlining the risks of the side effects for distribution to patients;

- we may be required to implement a risk evaluation and mitigation strategy program, including but not limited to medication guides, doctor communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk management tools;

- we may not be able to obtain regulatory approvals for all the proposed indications as intended;

- we may be subject to restrictions on how the drug is distributed or used;

- we may be sued or held liable for injury caused to individuals exposed to or taking our drug candidates;

- we may be unable to obtain reimbursement for use of the drug; and

- conditional regulatory approval of our drug candidates may require us to conduct confirmatory studies to verify the predicted clinical benefit and additional safety studies. The results from such studies may not support the clinical benefit, which would result in the approval being withdrawn.

Having expended a significant amount of capital to progress our drug candidates, if such drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would not be able to realize any revenue on such drug candidates if they then or ultimately fail to receive regulatory approvals due to unsatisfactory clinical trial results, thereby materially and adversely affecting our business, financial condition, results of operations and prospects.

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

- we may be forced to suspend marketing of the drug;

- regulatory authorities may withdraw approvals for the commercial sales of the drug;

- regulatory authorities may require additional warnings on the label;

- we may be required to develop risk evaluation and mitigation measures for the drug or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;

- we may be required to conduct post-market studies;
- we could be required to recall our products and be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

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

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

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

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

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

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

In addition, we rely on certain third parties to monitor and manage data for some of our ongoing preclinical studies and clinical trials and control only certain aspects of their activities. If any of our CROs or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For details, see "— Risks Relating to Our Reliance on Third Parties — We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed" in this section.

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

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

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

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

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

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

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

RISKS RELATING TO MANUFACTURING OF OUR DRUG CANDIDATES

We have limited experience in manufacturing therapeutic biologic products on a large commercial scale, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.

As of the Latest Practicable Date, all of our drug candidates were in the research and development stage, and we mainly produce drugs that are used for preclinical studies and clinical trials. Moreover, the manufacturing of therapeutic biologics 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 drugs produced;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

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, and 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 regulatory standards or specifications, and maintaining consistent and acceptable production costs. We may experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the 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 drugs for commercial sales. 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 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.

We may face damage to or disruption of our facilities, which could reduce or restrict our production capacity, or interrupt our development plans or commercialization efforts.

We currently manufacture our drug candidates for research and development purposes in Nanjing, China. Any interruption in manufacturing operations at our facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. A number of factors could cause interruptions, including equipment malfunctions or failures, technology malfunctions, work stoppages, damage to or destruction of either facility due to natural disasters or other unanticipated catastrophic events, water shortages or fire, regional power shortages, product tampering or terrorist activities. Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition and results of operation.

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 of our future approved drug candidates 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 in a timely manner could materially and adversely affect our business, financial condition, results of operations and prospects.

If our manufacturing facilities fail to meet the necessary quality standards, it could harm our business and reputation, and our revenue and profitability could be adversely affected.

Our manufacturing facilities are required to obtain and maintain regulatory approvals, and ongoing, periodic inspection to ensure compliance with GMP regulations. Further, we will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any NDA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The regulations in the medical sector are relatively new and constantly evolving, and their interpretation and enforcement must be determined in accordance with the relevant laws and regulations in effect at the time. Due to the complexity of the regulatory environment and the occasional amendments to laws and regulations, we cannot assure you that our business will comply with future laws and regulations, or that we will always fully comply with applicable laws and regulations, and our failure in compliance 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 their commercialization, if approved. 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 our drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

In addition, to obtain the FDA approval for our products in the United States, we would need to undergo strict pre-approval inspections of our manufacturing facilities. When inspecting our manufacturing facilities, the FDA may cite GMP deficiencies. Remediating deficiencies can be laborious, time consuming and costly. Moreover, the FDA will generally re-inspect the facility to determine whether the deficiency was remediated to its satisfaction, and may note further deficiencies during re-inspection.

If we are unable to meet the increasing demand for our 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 and financial condition would be materially and adversely affected.

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 substantially increase, or scale up, the production process. If the scale up is delayed, 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 the commercialization of our drug candidates and market demand of our drug candidates, if approved, we may need to expand our manufacturing capacity. However, the timing and success of our capacity expansion are subject to significant uncertainty. Moreover, such plan is capital intensive and requires significant upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all. Furthermore, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence the operation. During the construction and ramp-up period, there may be significant changes in the biopharmaceutical industry, including, among others, market demand, product and supply pricing, and customer preferences. Any adverse trends in these respects could result in operational inefficiency and excess capacity in our manufacturing facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as:

- unforeseen delays due to construction, or land use rights, 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.

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 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, results of operations and prospects.

RISKS RELATING TO COMMERCIALIZATION OF OUR DRUG CANDIDATES

If we are unable to build and manage sales network, or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue.

We have not yet demonstrated an ability to launch and commercialize any of our drug candidates. Our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in launching and marketing drug candidates. We will be competing with many companies that currently have commercialization teams and extensive sales and marketing operations. With limited experience in sales and marketing, we may be unable to compete successfully against these more established companies.

In the long term, if we intend to distribute our products worldwide, we would need to develop and expand our in-house marketing organization and sales force, which will require significant expenditures, management resources and time. We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

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

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

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

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

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

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

If any approved drug candidates that we commercialize fail to achieve market acceptance among physicians, patients, third-party payers or others in the medical community, we will not be able to generate significant revenue. Even if our future approved drug candidates achieve market acceptance, we may not be able to maintain such market acceptance over time if newly introduced products or technologies are more favorably received than our drug candidates, are more cost-effective or render our drug candidates obsolete. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially and adversely affect our business, financial condition, results of operations and prospects.

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

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

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

Counterfeit pharmaceutical products are unlikely to meet our or our collaboration partners' rigorous manufacturing and testing standards and may even cause health damage to patients. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaboration partners' brand name(s). In addition, theft of inventory at warehouses, plants or while in-transit, which is not properly stored and which is sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

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

We plan to develop certain of our drug candidates for use as combination therapies. Combination therapy development carries a higher risk of failure compared to single agent development due to greater risk of combined drug toxicity as well as lower efficacy due to drug-drug interactions as well as toxicity limitations on efficacy. The development risks of failure are even higher if both agents are investigational. There are additional regulatory requirements for combination development to ensure patient safety during development, including the requirement for separate combination IND review and the trial designs which are also more complex and require close monitoring. If any regulatory agency revokes its approval of any pharmaceutical products or therapy we intend to use in combination with our drug candidates, we will be forced to terminate or re-design the clinical trials, experience significant regulatory delays, or will not be able to market our drug candidates in combination with such revoked pharmaceutical products or therapies. If safety or efficacy issues arise with these or other therapies that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the relevant clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline, or at all.

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

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

The national, provincial and other third party drug reimbursement practices and drug pricing policies or regulations are evolving from time to time, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for medical products vary widely from country to country. Our ability to commercialize any drug candidates will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payers may control costs by limiting coverage and the amount of reimbursement for particular medications.

The national or local medical insurance catalogs, as well as drug reimbursement lists are reviewed and updated regularly, which affects the amounts reimbursable to program participants for their purchases of drugs. There can be no assurance that any of our future approved drugs will be included in the national, provincial or local medical insurance catalogs. Drugs or medical products included in the national, provincial or local medical insurance catalogs are generally generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in such medical insurance catalogs. Even if our drug candidates have already obtained regulatory approval, any adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effective data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drugs. Patients are unlikely to use any of our future approved drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs. Because some of our drug candidates have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

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

There may be delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is

used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced or rebates required by government healthcare programs or private payers. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

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

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

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

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies or defects in the patent applications or lack of novelty or an inventive step of the underlying invention or technology. As of the Latest Practicable Date, we owned four issued patents and 102 pending patent applications. We cannot assure you that all of these patent applications will be granted. For further information on our patent portfolio, see "Business – Intellectual Property" in this document. It is also possible that we will fail to identify patentable subject matter of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable subject matter of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, 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 or our collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we or our collaborators were the first to file for patent protection of such inventions. Furthermore, China and the 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. If a third party can establish that we were not the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable, and third parties may be granted a patent relating to a technology which we invented.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged. We may be subject to a third-party pre-issuance submission of prior art, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or drug candidates and compete directly with us. Moreover, we may have to participate in interference proceedings declared by the intellectual property offices to determine priority of invention or in post-grant challenge proceedings, such

as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or drug candidates will be protectable or remain protected by valid and enforceable patents globally. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights with respect to our drug candidates in all other jurisdictions throughout the world would be prohibitively expensive for us. Our intellectual property rights in certain jurisdictions may have a lessor or different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of our target markets. Consequently, in some cases, we may not be able to obtain issued patents or other intellectual property rights covering our drug candidates in jurisdictions outside our target markets and, as a result, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions in and into our target markets or other jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent and other intellectual property protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patents or other intellectual property protection. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

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

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

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

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. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing drugs and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Competitors or other third parties may challenge the ownership, validity and enforceability of our patents, infringe, misappropriate or otherwise violate our other intellectual property rights. To counter infringement, misappropriation or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Litigation and other proceedings

in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can. Accordingly, 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 litigation proceeding could put our patent, 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 uncover infringement against our patents. Even if we uncover infringement by a third party of any of our patents, we may choose not to pursue litigation against or settlement with such third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first uncovered and when the suit was brought. Such legal defenses may make it impossible for us to enforce our patents against such third party.

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 partner, our or their patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates, leave our technology or drug candidates without patent protection, allow third parties to commercialize our technology or drug candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our drug candidates without infringing third party patent rights. Even if a defendant does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

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

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

Our commercial success depends in part on our ability to avoid infringing, misappropriating, or otherwise violating intellectual property rights of third parties. However, our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Defending ourselves against third parties' intellectual right infringement allegations, meritorious or not, would be expensive and time consuming, and would be a substantial diversion of our resources and our management team's attention. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

In the event that third parties assert infringement claims against us, there is no assurance that the outcome would be in our favor, as whether a drug candidate or technology infringes on third parties' intellectual property rights involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and the burden of proof required to successfully challenge or invalidate a third-party intellectual property right may be high. If we were found by courts or other competent authorities to have infringed on the patent or other intellectual property rights of third parties, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing our drug candidates, or at least delay the development or commercialization process. Even if the litigations or other proceedings are resolved in our favor, our involvement in such proceedings may attract publicity, thereby having a substantial adverse effect on our reputation and brand name.

We may not be able to enjoy additional protection over drug-related patents in the U.S.

In the United States, the Federal Food Drug and Cosmetic Act, as amended by the law generally referred to as "Hatch-Waxman", provides the opportunity for limited patent term extension. Hatch-Waxman permits a patent-term restoration that provides a patent term extension of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. However, 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. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. 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. 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 period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we fail to obtain patent term extensions or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and thus our revenue could be reduced.

Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Moreover, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, Hatch-Waxman provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity 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 U.S. 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. However, we may not be able to enjoy those benefits if we fail to apply for them according to the FDA's relevant requirements.

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

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

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

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

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

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

Furthermore, our employees, consultants and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisors, including each member of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. 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. 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.

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 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.

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

Our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property rights, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biopharmaceutical industry involves technological and legal complexity and is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretations may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

Under the America Invents Act, enacted in 2011, the United States moved to first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Publications of discoveries in the scientific literatures often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. The Standing Committee of the National People's Congress revised the Patent Law of the PRC on October 17, 2020, which entered into force on June 1, 2021. Comparison with the Patent Law of the PRC revised on December 27, 2008 and effective October 1, 2009, the major changes in the Patent Law of the PRC (revised in 2020) are focused on the following: (i) clarification of the incentives for inventors or designers of subject inventions; (ii) extension of the term for industrial designs; (iii) establishment of a new "open license" system; (iv) improve the allocation of the burden of proof in patent infringement cases; and (v) improve damages for patent infringement. We cannot guarantee that any other changes to intellectual property laws would not have a negative impact on our intellectual property protection.

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

Our pipeline portfolio includes an acquired drug candidate IBC0966, and may involve additional drug candidates that require the use of proprietary rights held by third parties, and we have obtained and may need to further acquire and maintain licenses or other rights to use these proprietary rights. However, we may be unable to acquire or in-license any compositions, methods of use or other intellectual property rights from third parties that we identify. We also face risks relating to disputes or claims from the contracting parties, including with the local government, if we do not invest in such projects in a timely manner in accordance with the terms of the aforementioned agreements, which may adversely impact our research and development progress, reputation, financial conditions and results of operations.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, USPTO and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and other similar 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.

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

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

- others may be able to make products that are similar to any of our drug candidates or utilize similar or alternative technology that are not covered by the claims of the patents that we own or have exclusively licensed now or in the future;

- we or our current or future collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;

- we or our current or future collaboration partners might not have been the first to file patent applications covering certain of our or their inventions, which could result in the patent applications not issuing or being invalidated after issuing;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;

- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;

- patents that may be issued from our pending patent applications may not provide us with any competitive advantages, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sales of the related product, the commercial value of our patents may be limited;

- the proprietary technologies on which we rely may not be patentable;

- the patents of others may materially and adversely affect our business; and

- we may choose not to file a patent for certain trade secrets or know-how, yet a third party may subsequently file a patent covering such intellectual property.

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

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have a limited operating history and have incurred net losses since inception. We expect to continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability.

Investment in the development of pharmaceutical products is highly speculative as it requires substantial upfront capital expenditures and involves significant risks that a drug candidate may fail to demonstrate efficacy or safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we had financed our operating activities primarily through capital contributions from our shareholders, private equity financing and loans.

While we have other sources of income, we had not generated any revenue from commercialization of our drug candidates during the Track Record Period, and had incurred, and may continue to incur, significant research and development expenses and other expenses related to our ongoing operations. For the years ended December 31, 2021 and 2022 and for the three months ended March 31, 2023, we had loss and total comprehensive expenses of RMB70.6 million, RMB52.0 million and RMB15.3 million, respectively. Our ability to generate revenue will depend primarily on the success of the regulatory approval, manufacturing, and commercialization of the drug candidates, which is subject to significant uncertainty. Even if we obtain regulatory approval to market our drug candidates, our future revenue will depend upon other factors such as the market size for the proposed indications of our drug candidates, and our ability to achieve sufficient market acceptance.

We expect to continue to incur significant expenses and losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue to advance the clinical trials and preclinical studies of our drug candidates;
- initiate preclinical, clinical or other studies for new drug candidates;
- construct new manufacturing facilities;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- commercialize our drug candidates for which we have obtained marketing approvals;
- attract and retain skilled personnel, and grant equity-settled awards to our employees under our share incentive schemes;

- develop and expand our commercialization team to commercialize any drug candidates in our pipeline for which we may obtain regulatory approval;
- maintain, protect, expand and enforce our intellectual property portfolio;
- enforce and defend any intellectual property-related claims; and
- acquire or in-license other drug candidates, intellectual property assets and technologies.

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

We incurred deficit and recorded net current liabilities during the Track Record Period and may continue to have deficit going forward, which can expose us to liquidity risk.

We had a total deficit of RMB131.6 million, RMB1.5 million and RMB16.6 million as of December 31, 2021 and 2022 and March 31, 2023, respectively, and we had net current liabilities of RMB36.7 million, RMB51.5 million and RMB62.9 million as of December 31, 2021 and 2022 and March 31, 2023, respectively. A total deficit can expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources such as external debt or issuance of our equity interest, which may not be available on terms favorable or commercially reasonable to us or at all. While we believe we have sufficient working capital to fund our current operations, we may have net liabilities for the foreseeable future. If we are unable maintain adequate working capital or obtain sufficient equity or debt financings to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale back our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We had net cash outflow from operating activities during the Track Record Period and may continue to experience net operating cash outflow for the foreseeable future.

During the Track Record Period, our operations have consumed a substantial amount of cash, and accordingly our net cash used in operating activities was RMB52.7 million, RMB34.6 million and RMB6.4 million for the years ended December 31, 2021 and 2022 and for the three months ended March 31, 2023, respectively. While we believe we have sufficient working capital to cover at least 125% of our costs, for at least the next 12 months from the

date of this document, 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 such as the milestone payments to CROs, 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 to obtain additional financing to fund our operations even if we consummate the [REDACTED], and if we fail to obtain such financing, we may be unable to complete the development and commercialization of our primary drug candidates.

We may 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 costs relating to R&D of our product candidates, including contract research expenses, staff costs, material consumed, application fees and others. For details of our cash operating costs, see "Financial Information — Cash Operating Costs" in this document. We expect to continue to spend substantial amounts of cash on drug discovery, advancing the clinical development of our drug candidates, and launching and commercializing any drug candidates for which we receive regulatory approval. 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.

Our results of operations, financial condition, and prospects may be adversely affected by fair value changes and credit risk associated with our financial assets at fair value through profit or loss.

During the Track Record Period, we had certain financial assets at fair value through profit or loss. We are exposed to risks in relation to the financial assets, which may adversely affect our net changes in their fair value. The financial assets at fair value through profit or loss are stated at fair value, and net changes in their fair value are recorded as other income or losses, and therefore directly affect our results of operations. We cannot assure you that market conditions and regulatory environment will create fair value gains and we will not incur any fair value losses on our financial assets at fair value through profit or loss in the future. If we incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

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

We implemented share incentive plans during the Track Record Period. For the years ended December 31, 2021 and 2022 and the three months ended March 31, 2023, we incurred share-based payment expenses of RMB8.3 million, RMB2.0 million and RMB0.2 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. We established Sunho Stellar, an incentive platform, to provide incentives to certain eligible employees and directors. For details, see "History, Reorganization and Corporate Structure — Adoption of RSU Scheme" in this document. 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.

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

The change in the value of currencies may fluctuate and is affected by, among other things, changes of the relevant political and economic conditions and foreign exchange policies. Most of our costs, our assets (including cash and cash equivalents) will be denominated in a different currency from Hong Kong dollars, the currency that denominates our [**REDACTED**] from the [**REDACTED**]. Any significant change in the related exchange rates may adversely affect the value of and any dividends payable on, our Shares in Hong Kong dollars.

RISKS RELATING TO OUR OPERATIONS

Any failure to comply with applicable regulations and industry standards or obtain or renew certain approvals, various licenses and permits could harm our reputation and our business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the PRC, the U.S. and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our CROs' failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations. For example, if we or our CROs were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. 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 may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations. During the Track Record Period, the owner of our leased property did not obtain the sewage disposal drainage license because the industrial park where our lease property is located was under construction which resulted in the application review and approval process being temporarily put on hold. As of the Latest Practicable Date, we had not received any order of correction or any fines or penalties from the competent authority as a result of any such failure. Furthermore, as confirmed by the competent authorities, we will not be subject to penalties or encounter business suspension due to the leased property owner's failure to timely obtain such license. As advised by our PRC Legal Adviser, the likelihood that we are subject to penalties or orders to suspend or shutdown operations by the competent authority due to the leased property owner's failure to timely obtain such license during the Track Record Period is relatively low, based on the interviews with competent authorities. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect results of operations and prospects.

The loss of any key members of our senior management team or our inability to attract and retain highly skilled scientists, clinical and sales personnel could adversely affect our business.

Our commercial success depends significantly on the continued service of our senior management. For more details of our senior management, see "Directors and Senior Management" in this document. The loss of any of our senior management could have a material adverse effect on our business and operations. 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.

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

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

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

We are a rapidly growing company working on a rich and expanding pipeline of drug candidates. Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

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

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

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

We may engage in acquisitions or strategic partnerships, which may increase our capital requirements, cause dilution for our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions, joint ventures and strategic partnerships, including licensing or acquiring drug products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

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

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

We face risks related to natural disasters, health epidemics and outbreaks of contagious diseases, and other factors beyond our control.

Any future occurrence of force majeure events, natural disasters or outbreaks of other epidemics and contagious diseases, including avian influenza, severe acute respiratory syndrome, swine influenza caused by the H1N1 virus, or H1N1 influenza or the Ebola virus, may materially and adversely affect our business, financial condition and results of operations. Moreover, the world has experienced natural disasters such as earthquakes, floods and droughts in the past few years. Any future occurrence of severe natural disasters may materially and adversely affect its economy and our business. We cannot assure you that any future occurrence of natural disasters or outbreaks of epidemics and contagious diseases or the measures taken in response to such contagious diseases will not seriously disrupt our operations or those of our customers, which may materially and adversely affect our business, financial condition and results of operations.

We are subject to the risks of doing business globally. Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

We primarily operate and currently conduct all our clinical trials in China. As we may further our development efforts for our drug candidates in the United States in the future, 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;
- differences between national and local practice with respect to laws and regulatory requirements in a specific jurisdiction;
- difficulty of effective enforcement of contractual provisions in certain jurisdictions;

- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;

- the occurrence of economic weakness, including inflation or political instability;

- inadequate intellectual property protection in certain jurisdictions;

- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;

- the enforcement of anti-corruption and anti-bribery laws against us;

- trade protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;

- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, and greater difficulty in accounts receivable collection;

- non-compliance with tax, employment, immigration and labor laws;

- the effects of applicable local tax regimes and potentially adverse tax consequences;

- significant adverse changes in local currency exchange rates; and

- business interruptions resulting from geo-political actions and cultural climate or economic condition, including war and acts of terrorism, natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or the impact of public health pandemics or epidemics.

Furthermore, global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors, including extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

We may become involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation.

We may become subject, from time to time, to legal proceedings and claims that arise in breach of related laws and regulations in our ordinary course of business or pursuant to governmental or regulatory enforcement activity. 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 that may initially not appear to be 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. We believe that our have maintained adequate insurance to cover our key liabilities arising from such proceedings. For more details of our insurance, see "Business — Insurance" in this document. 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. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our financial condition, results of operations or reputation.

We 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 and that we believe are in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our insurance policies cover adverse events in our clinical trials. We also maintain social welfare insurance for our employees in accordance with relevant PRC laws and regulations. However, 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.

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

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees, including management, technical, research and development, sales and marketing, production, quality control and other personnel. We face intense competition in recruiting and retaining qualified personnel, as competitors are competing for the same pool of qualified personnel and our remuneration packages may not be as competitive as those of our competitors. Increasing market competition may cause market demand and competition for qualified employees to intensify. If we face labor shortages or significant increases in labor costs, higher employee turnover rates or changes to labor laws and regulations, our operating costs could increase significantly, which could materially and adversely affect our results of operations. In addition, we could face labor disputes with our employees, which could lead to fines by governmental authorities and settlement costs to resolve the disputes. Labor disputes could also make it more difficult to recruit new employees due to the reputational damage caused. Any of the foregoing changes could have a material adverse effect on our business, results of operations and prospects.

If we or our CROs fail to comply with environmental, health and safety laws and regulations, we could be 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 in China and the United States, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties for the disposal of these materials and wastes. We cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facilities during the process of discovery, testing, development and manufacturing of our drug candidates. In the event of such accidents, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could harm our business. 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 adverse impact on our business, financial condition, results of operations and prospects.

We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our drug candidate R&D program efforts. Moreover, there is increasing stakeholder pressure on companies to diligence environmental, social, and governance matters in the supply chain. Negative publicity regarding production methods, alleged practices or workplace or related conditions of any of our suppliers, CROs or other third parties who perform services for us could adversely affect our reputation and force us to locate alternatives, which could increase our costs and result in delayed supply of components for, and manufacturing of, our drug candidates, or other disruptions to our operations.

We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees, principal investigators, consultants and commercial partners.

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other third parties that had any material adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

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

According to the Social Insurance Law of the PRC, the Regulations on Management of Housing Provident Fund and other applicable PRC regulations, any employer operating in China must contribute social insurance premium and housing provident funds for its employees. Any failure to make timely and adequate contribution of social insurance premium or housing provident funds for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium or housing provident funds within a specified period of time, otherwise the competent authority may further impose fines or penalties. We make contributions of social insurance premiums for our employees to provide for retirement, medical, work-related injury, maternity and unemployment benefits, as well as the housing provident funds. During the Track Record Period, we were not in strict compliance with the requisite contribution requirements in relation to some of our PRC employees, which will not bring any material adverse effect to our operations or financial position. Based on the relevant rules and regulations, the under provision of social insurance and housing provident fund contributions amounted to approximately RMB1.9 million, RMB2.8 million and RMB0.8 million in 2021, 2022 and the three months ended March 31, 2023, respectively. As of the Latest Practicable Date, we had not received any order of correction or any fines or penalties from the competent authority as a result of any such failure. We have obtained certain confirmation letters issued by the relevant competent social insurance and housing provident fund authorities confirming that there is no record of any member of our Group that hires employees being imposed administrative penalties by the relevant authorities for violation of the relevant laws and regulations. As advised by our PRC Legal Adviser, the likelihood that we will be required to settle all historical social insurance premiums and housing provident funds and be subject to material administrative penalties due to our failure to make full contributions of social insurance premium and housing provident funds for some of our employees during the Track Record Period is relatively low, provided that there are no material adverse changes in the current regulatory policies and environment and no material employee complaints occur. However, we cannot assure you that the competent authority will not require us to rectify any non-compliance by making contribution of overdue social insurance premium or housing provident funds or to pay any overdue fine or penalty related thereto.

We do not own the real property for our current major operation sites and are subject to risks associated with leasing space.

We lease premises in China. The lessors of the leased properties may not have valid title or the legal rights to such leased properties or may not have complied with all the necessary property leasing procedures. In addition, as our leases expire, we may fail to obtain renewals, either on commercially acceptable terms or at all, which could compel us to close such offices or manufacturing facilities. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition. Pursuant to PRC laws, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases.

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

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 data utilizing on-site systems. Such data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information technology systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions pose increasing risks. Despite the implementation of security measures, our internal information technology systems and those of our current and any future third-party vendors, collaboration partners, consultants, and third parties performing services for us, as well as our clinical sites and regulatory authorities, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, and telecommunication and electrical failures.

Although we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our drug candidate development and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions.

For example, the loss of clinical trial data from our current or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in the theft or destruction of intellectual property, data, or other misappropriation of assets, financial loss, or otherwise compromise our confidential or proprietary information and disrupt our operations, our competitive position could be harmed, and the further development and commercialization of our drug candidates could be delayed.

We could 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 clinical sites, including personal information of our employees and, potentially, our clinical study patients and confidential data. In addition, third parties may attempt to penetrate our systems or fraudulently induce our personnel to disclose sensitive information in order to gain access to data and systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems 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 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 is 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 engage in more electronic transactions with clinical sites and collaboration partners, 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. In addition, there can be no assurance that our internal information technology systems, or those of third parties with which we conduct business, will be sufficient to protect us against breakdowns, service disruption, data deterioration, or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks, or insider threat attacks, which could result in financial, legal, business, or reputational harm.

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

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

Our risk management and internal control systems may not fully protect us against various risks inherent in our business.

We have established risk management and internal control systems consisting of the relevant organizational framework policies, risk management policies and risk control procedures to manage our risk exposures, primarily credit risk, operational risk and legal risk as well as liquidity risk. However, we may not be successful in implementing our risk management and internal control systems. While we seek to continue to enhance our risk management and internal control systems from time to time, we cannot assure you that our risk management and internal control systems are adequate or effective notwithstanding our efforts, and any failure to address any potential risks and internal control deficiencies could materially adversely affect our business, financial condition and results of operations.

Since our risk management and internal control systems depend on their implementation by our employees, we cannot assure you that all of our employees will adhere to such policies and procedures, and the implementation of such policies and procedures may involve human errors or mistakes. Moreover, our growth and expansion may affect our ability to implement stringent risk management and internal control policies and procedures as our business evolves. If we fail to timely adopt, implement and modify, as applicable, our risk management and internal control policies and procedures, our business, financial condition and results of operations could be materially adversely affected.

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.

We have worked with and plan to continue to work with third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We work with these parties to execute our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCP, which are regulations and guidelines enforced by the NMPA, the FDA, 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 GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA, 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 products 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 or to do so on commercially reasonable terms or in a timely manner. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, or 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. If our CROs err in their experimental operations, the development projects of our drug candidates may be delayed or adversely affected. 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 additional CROs involves additional costs 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.

Our future revenues are dependent on our ability to work effectively with collaboration partners to develop our drug candidates, including to obtain regulatory approval. Our arrangements with collaboration partners will be critical to successfully bringing drug candidates to market and commercializing them. We rely on collaboration partners 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 collaboration partners; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaboration partners and if any of our collaboration partners 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.

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.

We depend on a stable and adequate supply of quality materials and research and development and manufacturing equipment from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.

Our business operations require a substantial amount of raw materials as well as equipment and other materials needed for research and development and manufacturing purposes, and are therefore exposed to various supply chain risks. During the Track Record Period, we relied on third parties to supply certain materials. We expect to continue to rely on third parties to supply such materials and equipment for the research, development, manufacturing and commercialization of our drug candidates. For details, see "Business – Suppliers and Raw Materials" in this document.

Currently, the materials and equipment are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, we may not be able to find alternative supplies in a timely and commercially reasonable manner, or at all, and it would materially harm our business. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates.

Moreover, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter commercial production of drugs upon receipt of marketing approval, but there is no assurance that current suppliers have the capacity to meet our demand. Any delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical trials, regulatory approval of our drug candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us at any time.

We are also exposed to the risk of increased costs, which we may not be able to pass on to customers and, as a result, lower our profitability. In the event of significant price increases for such materials, we cannot assure you that we will be able to raise the prices of our future drug products sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability.

Additionally, our suppliers may also fail to maintain adequate quality of the services, materials and equipment we need. Although we have implemented quality inspection on the materials before using them in the manufacturing process, we cannot assure you that we will be able to identify all of the quality issues. Suboptimal or even deficient supplies of services, materials and equipment may hinder the research and development of our drug candidates, subject us to product liability claims or otherwise have a material adverse effect on our operations.

In addition, we cannot assure you that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Their failure to do so may lead to interruption in their business operations, which in turn may result in shortage of the materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or recall of our products. The non-compliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of non-compliance, which may have a material adverse effect on our business, financial condition and results of operations.

We have entered into collaboration with our partner and may seek further collaboration opportunities and strategic alliances or enter into licensing arrangements in the future, but we may not realize the benefits of such collaboration, alliances or licensing arrangements.

Historically we have entered into the collaboration arrangement with ImmuneOnco Biopharmaceuticals (Shanghai) Inc. ("**ImmuneOnco**") in relation to the development of our drug candidate IBC0966. For details, see "Business – Collaboration Arrangement" in this document. We may in the future seek and form additional 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 such relationships may require us to incur non-recurring and other charges, increase our short- and long-term capital expenditures, issue securities that dilute our existing shareholders, or divert the attention of our management from our normal course of business. Moreover, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early 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 the development and commercialization of a drug candidate, we may relinquish some or all of the control over the future success of that drug candidate to the third party. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Collaborations involving our drug candidates are subject to a number of risks, which may include but are not limited to the following:

- our collaboration partners have significant discretion in determining the efforts and resources that they will allocate to such collaborations or strategic alliances;

- our collaboration partners may not pursue development and commercialization of drug candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- our collaboration partners may delay their drug development plan, including clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;

- our collaboration partners could independently develop, or develop with other third parties, drugs that compete directly or indirectly with our drug candidates;

- our collaboration partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigations that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- collaboration partners may not always be cooperative or responsive in providing their services in a clinical trial;

- disputes may arise between us and our collaboration partners that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated if we or our collaboration partners fail to comply with our or their obligations in the collaboration agreements;

- termination of collaborations may result in a need for additional capital to pursue further development or commercialization of the relevant drug candidates;

- our collaboration partners may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and

- our collaboration partners with marketing and distribution rights to one or more of our drug candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such drug candidates.

We cannot be certain that, following a strategic transaction, we will be able to generate the target level of revenue or profit that can justify such a transaction. If we are unable to reach agreements with suitable collaboration partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition, results of operations and prospects.

We are exposed to risks related to concentration of suppliers.

Purchases from our five largest suppliers accounted for 75.4%, 54.1%, and 76.1% of our total purchase amount, respectively, in each 2021, 2022 and the three months ended March 31, 2023. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material shortage of supplies or services. However, we cannot assure you that these suppliers will continue to provide supplies and services at prices and on terms and conditions acceptable to us. Our reliance on our top five suppliers may also expose us to the risk of unexpected price increases for purchases, or shortage in supply of raw materials and services. In such a situation, our business, financial condition and results of operations may be materially and adversely affected.

RISKS RELATING TO GOVERNMENT REGULATIONS

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

All jurisdictions in which we intend to develop and commercialize our drug candidates and conduct other pharmaceutical-industry activities regulate these activities in great depth and detail. We adopt a global development strategy and intend to focus our activities in the major markets including China and the United States. These jurisdictions all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of the development and approval, manufacturing, marketing, sales and distribution of pharmaceutical products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions. Our or our CROs' failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations.

We are also subject to the laws and regulations as amended from time to time in all jurisdictions in which we intend to develop and commercialize our drug candidates and conduct other pharmaceutical-industry activities. For example, on September 12, 2022, the President of the United States issued "Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy" (the "Executive Order"), launching a national biotechnology and biomanufacturing initiative in the United States. This initiative will be comprised of various efforts by the U.S. government, including investments, programs and partnerships to advance research and development in biotechnology and biomanufacturing, as well as efforts to secure and protect the U.S. bioeconomy. The Executive Order may lead to potential changes to U.S. policies affecting the biotechnology and biomanufacturing industries. Substantially all of our operations and all of our clinical trials are conducted in China. We plan to conduct clinical trials for certain drug candidates and explore development and/or commercialization opportunities in the United States in the future. We therefore expect that the Executive Order will have no immediate

impact on our research and development activities in the United States. However, it is unknown at this time whether and what specific policies and actions will be adopted by the U.S. government. If the U.S. government were to adopt any policies that adversely impact foreign companies conducting research and development activities in the United States, our business, financial condition and results of operations could be adversely affected.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the drug development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include 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. Failure to comply with these regulations could therefore materially and adversely affect our business, financial condition, results of operations and prospects.

Moreover, the regulatory framework regarding the pharmaceutical industry is continuing to change and evolve, and we cannot guarantee that changes to the laws and regulations with regard to pharmaceutical industry in jurisdictions where we operate would not adversely affect our business and prospects. Any such changes or amendments may result in increased compliance difficulty and costs or cause delays in, or prevent the successful development or commercialization of, our drug candidates and reduce the current benefits we believe are available to us from developing and manufacturing our drug candidates. 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.

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

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

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

We are subject to risks associated with obtaining regulatory approvals. Difficulties and failures in doing so may expose us to various harms. Significant time, effort and expense are required to bring our drug candidates to market in compliance with the regulatory process, and we cannot assure you that any of our drug candidates will be approved for sale. The time required to obtain approvals from the NMPA, the FDA, and other comparable regulatory authorities is unpredictable but typically takes 10 to 15 years following the commencement of preclinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities. In addition, regulations, approval policies and requirements for clinical data may change during the clinical development process of a drug candidate and may vary among jurisdictions. It is not uncommon that the NMPA, the FDA or a comparable regulatory authority may require more information, including additional analysis, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may increase our costs, prolong, delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our drug candidates will be approved for sale in those jurisdictions. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes.

Our drug candidates could fail to receive regulatory approval in a timely manner for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities in the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and potent for its proposed indications or, if it is a biologic, that it is safe, pure and potent for its proposed indication;
- failure to demonstrate that the clinical and other benefits of a drug candidate outweigh its safety risks;
- failure of clinical trial results to meet the level of statistical and medical significance required for approval;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;

- insufficiency of data from clinical trials of our drug candidates to support the filing of the submission or to obtain regulatory approval;

- failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;

- 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 resulting in failure to pass audits carried out by the NMPA, the FDA or other comparable regulatory authorities and a potential invalidation of our research data;

- failure of our clinical trial process to keep abreast with any scientific or technological advancements required by regulations or approval policies; and

- findings by the NMPA, the FDA or other comparable regulatory authorities of deficiencies related to our manufacturing processes or the manufacturing facilities of third-party manufacturers from whom we procure clinical and commercial supplies.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to competent regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, the FDA and other comparable regulatory authorities may also change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Moreover, 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.

We may experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates. 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 generate related revenues for that candidate. 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, and may cause reputational damage.

We cannot assure you that we can satisfy all regulatory requirements to obtain regulatory approvals in a timely manner, or at all, or to obtain regulatory approvals with an ideal scope of indications, which may have an adverse impact on our reputation and the commercial prospects of our drug candidates, and eventually may harm our business, financial condition and prospects significantly.

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

Adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, or a significant change in our clinical protocol or our development plan and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or could result in limitations or withdrawal following approvals.

If results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events, our trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications.

Adverse events caused by our drug candidates, including when used in combination therapy, which may involve unique adverse events that could be exacerbated compared with adverse events from monotherapies, and off-label use of our drug candidates could potentially cause significant negative consequences for our Company, including:

- regulatory authorities could delay or halt pending clinical trials;
- we may suspend, delay or alter development or marketing of the 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;

- we may be required to develop a risk evaluation and mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the risk evaluation and 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 subjects or patients;

- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;

- the costs of clinical trials of our drug candidates may be substantially higher than anticipated; and

- our reputation may suffer.

We primarily conduct clinical trials for our drug candidates in China, while FDA or comparable foreign regulatory authorities may not accept data from such trials.

We primarily conduct clinical trials for our drug candidates in China. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application for marketing approvals on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice, or GCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There is no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming and delay our business plan, and may result in product candidates that we may develop not receiving approval for commercialization in the relevant jurisdiction.

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

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

The PRC authorities promulgated a series of laws and regulations governing the various aspects of information security, data collection and privacy protection, including, among others, the Cybersecurity Law of the PRC, the Provisions on Protection of Personal Information of Telecommunication and Internet Users, the Cybersecurity Review Measures, the Data Security Law of the PRC, and the Personal Information Protection Law of the PRC. Under the Personal Information Protection Law of the PRC, in case of any personal information processing, such individual prior consent shall be obtained, unless otherwise specified. Further, any data processing activities that are in relation to the sensitive personal information such as biometrics, medical health and personal information of teenagers under fourteen years old, are not allowed, unless such activities have a specific purpose, are highly necessary and strictly protective measures have been taken. In addition, the Measures for the Security Assessment of Outbound Data Transfer took effect on September 1, 2022, which apply to the security assessment of data processors' provision of important data and personal information collected and generated in their operations within the territory of the PRC to overseas recipients, and require relevant data processors to submit a data security assessment to the regulatory authority for review prior to the outbound data transfer activities in order to prevent illegal data transfer activities. In addition, certain industry-specific laws and regulations affect the collection and transfer of data in China. The Regulations on the Administration of Human Genetic Resources of the PRC or the HGR Regulation, was promulgated by the State Council in May 2019 and came into effect in July 2019. It stipulates that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and export China's human genetic resources. Foreign organizations and the entities established or actually controlled by foreign organizations or individuals may only utilize and be provided with China's human genetic resources after satisfaction of all regulatory requirements, such as (i) China's human genetic resources being utilized only in international cooperation with Chinese scientific research institutions, universities, medical

institutions, and enterprises for scientific research and clinical trials after completion of requisite approval or filing formalities with competent governmental authorities, and (ii) China's human genetic resources information being provided after required security review, filing and information backup procedures have been gone through. In October 2020, the SCNPC promulgated the Biosecurity Law of the PRC, which became effective in April 2021. The Biosecurity Law of the PRC reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China's human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. The interpretation and implementation of the HGR Regulation and the related laws and regulations may vary from time to time. Given such circumstance, although we have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC and other applicable laws in our utilizing of and dealing with China's human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation and the Biosecurity Law of the PRC and the applicable laws and regulations.

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

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to

significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, our clinical trials also frequently involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including principal investigators, hospitals, CROs, and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Noncompliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could have a material adverse effect on our business, financial condition and results of operations.

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

Under the Regulations on Administration of Imports and Exports of Technologies promulgated by the State Council, which were amended in November 2020, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approvals by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts, issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology. We may in the future enter into agreements with CROs in the United States for their technical support to assist us with the development of individual drug candidates, which may be deemed to constitute the import of technology under the regulations. As a result, such transfers are may be required to be registered with applicable governmental authorities. We are

also subject to regulatory supervision over genetics and data-related operations. To carry out clinical trials, as a foreign-invested enterprise, we are required to obtain approval from the Office of Human Genetic Resources Management under the Ministry of Science and Technology who will conduct genetics and data safety review. There is no assurance that we will be able to obtain such approval in a timely manner, or at all. In addition, we may also be subject to similar requirements of overseas regulatory authorities.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data, or the Scientific Data Measures, which provides that enterprises in China must seek governmental approval before any scientific data involving a state secret or individual privacy may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the government authority 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 preclinical 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.

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

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

Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug candidates, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on our clinical trials;
- refusal by the regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- refusal by the regulatory authorities to accept any of our other IND approvals, NDAs or BLAs;
- suspension or revocation of existing drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

Regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of drugs that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations.

In addition, we are subject to anti-bribery laws that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Moreover, although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

The pharmaceutical industry is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs.

The pharmaceutical industry where our business located 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 been revolving. Any such changes or amendments may cause changes in compliance costs on our business, the successful development or commercialization of our drug candidates and the benefits we believe are available to us from developing and manufacturing drugs. For example, the Clinical Value-oriented Guiding Principles on the Clinical Study for Antineoplastic Drugs ("**Clinical Guidelines**") issued by the CDE on November 19, 2021, states that the fundamental purpose of the drug market is to address the needs of patients, and emphasizes that drug research and development should be based on patient needs and clinical value. The Clinical Guidelines discourage repetitive research and development of "me-too drugs" (drugs with identical mechanisms of actions) and disorderly waste. If we are unable to comply with, or are deemed to be in violation of the Clinical Guidelines' detailed provisions and principles, our clinical development activities and overall business operations may be adversely impacted.

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

Due to our extensive operations in the PRC, our business, financial condition, results of operations and prospects are affected by economic, political, and legal developments in the PRC. The overall economic growth is influenced by the governmental regulations and policies in relation to resource allocation, monetary policies, regulations of financial services and institutions, preferential treatment to particular industries or companies and others. Any of the foregoing would affect our business, financial condition, results of operations and prospects.

Laws, rules and regulations in relation to economic matters are promulgated from time to time, including those related to such as foreign investment, corporate organization and governance, commerce, taxation, finance, foreign exchange and trade, so as to develop a comprehensive system of commercial law. In addition, the interpretation and implementation of the laws and regulations relating to pharmaceutical industry also evolve from time to time. The NMPA's recent reform of the drug approval system could has impacts on our commercialization of drug candidates in a timely manner. For example, the NHC issued the Administrative Measures for Clinical Use of Oncology Drugs (Trial), effective from March 1, 2021, requiring the oncology drugs, as classified into the "restricted-use" and "normal-use" categories, to be rationally used or prescribed by the medical institutions and medical practitioners. In June 2021, the NHC further issued the Administrative Measurements for Rational Clinical Use of Oncology Drugs, which specifies the calculation formula for the administrative measurements used for gauging the rational use of restricted-use oncology drugs, while not yet setting any numeric limits on the measurements. We currently do not experience or foresee any potential material adverse impact of these regulations on our business operations. However, as such administrative regulations are newly released and relevant measures are generally evolving, we cannot assure you if our business operations will not be adversely affected in the future.

Changes in U.S. and international trade policies may cause significant disruptions to our drug candidate manufacturing and other operations.

The U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as imposing several rounds of tariffs. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry.

While we have not started commercialization of any of our drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our future drug products, the competitive position of our future drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or may prevent us from selling our future drug products in certain countries. If any new tariffs, legislation and regulations are implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition and results of operations.

The evolving trade disputes may escalate going forward and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships among the relevant countries or regions. Trade disputes, tensions and political concerns among the relevant countries or regions may therefore adversely affect our business, financial condition, results of operations, cash flows and prospects.

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

The State Administration of Foreign Exchange has promulgated several regulations requiring PRC residents to register before engaging in direct or indirect offshore investment activities, including the Circular on Relevant Issues Concerning the Administration of Foreign Exchange on Domestic Residents' Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, issued and effective on July 4, 2014. SAFE Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities as well as foreign individuals that are deemed as PRC residents for foreign exchange administration purpose) to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with onshore or offshore assets or equity interests held by the PRC residents, referred to in SAFE Circular 37 as a "special purpose vehicle." SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC resident does not complete

the required registration or update the previously filed registration, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be subject to restrictions when making additional capital contributions to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including (1) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (2) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

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

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

We are committed to complying with and to ensuring that our Shareholders who are subject to the regulations will comply with the relevant SAFE rules and other regulations. However, we may not always be fully aware or informed of the identities of our beneficiaries who are PRC 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. 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.

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

The PRC Enterprise Income Tax Law ("**Enterprise Income Tax Law**") and its implementation rules provide that China-sourced income of 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. As a result, dividends paid to us by our PRC subsidiaries are expected to be subject to the PRC withholding tax at a rate of 10%.

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

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

Under the Enterprise Income Tax Law, an enterprise established outside the PRC with "de facto management bodies" within China is considered a "resident enterprise," meaning that it is treated in a manner similar to a Chinese enterprise for the PRC enterprise income tax ("**EIT**") purposes. The implementing rules of the Enterprise Income Tax Law define "de facto management bodies" as "management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties" of the enterprise. In addition, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following 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. State Administration of Taxation of the PRC has subsequently provided further guidance on the implementation of Circular 82.

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

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

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

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

The PRC tax authorities make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment under Bulletin 7. If the PRC tax authorities make adjustments to the taxable income of the transactions under Bulletin 7, our income tax costs associated with such potential acquisitions or disposals may increase.

We may face risks from transferring our scientific data.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data, or the Scientific Data Measures, which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, if the provision of scientific data involving "state secrets" is required in foreign exchanges and cooperation, Chinese enterprises should clarify the type, scope and purpose of the data to be used, and report to the competent authority for approval in accordance with relevant procedures of confidentiality management regulations. When publishing a paper in a foreign academic journal requires the author to submit the relevant scientific date, the author should, prior to the publication, submit such scientific data to the belonged institution for unified management if such scientific data are generated with the government funding. We cannot assure you that we can always obtain relevant approvals for sending scientific data. If we are unable to obtain necessary approvals in a timely manner, or at all, our R&D of drug candidates may be hindered, which could materially and adversely affect our business, financial condition, results of operations 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 rectification and other administrative penalties imposed by those government authorities.

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

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

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

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

On January 18, 2019, the Supreme People's Court and the Hong Kong SAR Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region, or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong SAR and the mainland China. The New Arrangement does not include the requirement for a choice of court agreement in writing by the parties. 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 SAR. The New Arrangement will, upon its effectiveness, supersedes the Arrangement. Therefore, before the New Arrangement becomes effective, it may be difficult 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.

RISKS RELATING TO THE [REDACTED]

There has been no prior [REDACTED] market for our Shares and there can be no assurance that an active market would develop, especially taking into account that certain of our existing shareholders may be subject to a lock-up period, and the [REDACTED] and [REDACTED] of our Shares may be volatile.

Prior to this [**REDACTED**], there has been no [**REDACTED**] market for our Shares. The [**REDACTED**] for our [**REDACTED**] was the result of negotiations among us and the [**REDACTED**] (on behalf of the [**REDACTED**]) and the [**REDACTED**] may differ significantly from the market price for our Shares following this [**REDACTED**]. We have applied for [**REDACTED**] of and permission to [**REDACTED**] in our [**REDACTED**] on the [**REDACTED**]. A [**REDACTED**] on the [**REDACTED**], however, does not guarantee that an active and liquid [**REDACTED**] for the Shares will develop, especially during the period when a certain portion of our Shares may be subject to lock-up, or if it does develop, that it will be sustained following the [**REDACTED**], or that the [**REDACTED**] of the Shares will not decline following the [**REDACTED**].

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

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

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

There will be a time gap between pricing and [REDACTED] of our Shares, and the price of our Shares when [REDACTED] 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 [**REDACTED**] until they are delivered, which is expected to be several Business Days after the [**REDACTED**]. As a result, [**REDACTED**] may not be able to sell or otherwise [**REDACTED**] in the Shares before the commencement of [**REDACTED**]. Accordingly, holders of our Shares are subject to the risk that the [**REDACTED**] of the Shares when [**REDACTED**] begins could be lower than the [**REDACTED**] as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time [**REDACTED**] begins.

Future sales or perceived sales of a substantial number of our Shares in the [**REDACTED**] market following the [**REDACTED**] could materially and adversely affect the price of our Shares and our ability to raise additional capital in the future, and may result in dilution of your shareholding.

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

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

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

Our Controlling Shareholders have substantial control over our Company and their interests may not be aligned with the interests of the other Shareholders.

Upon the completion of the Share Subdivision and the [**REDACTED**], our Controlling Shareholders will be interested in approximately [**REDACTED**]% of our total issued share capital, assuming that the [**REDACTED**] is not exercised. Our Controlling Shareholders, who will remain as the Controlling Shareholders upon completion of the Share Subdivision and the [**REDACTED**], will continue to have significant influence on us on various important corporate actions requiring the approval of Shareholders, such as mergers, disposal of assets, election of Directors, and timing and amount of dividends and other distributions. There may be a conflict between the interests of our Controlling Shareholders and your interests. Control by our Controlling Shareholders of a substantial percentage of our Shares may have the effect of delaying, discouraging or preventing a change in control of us, which may deprive you of opportunities to receive premiums for your Shares and may reduce the price of the Shares. If our Controlling Shareholders causes us to pursue strategic objectives that would conflict with your interests, you may also be left in a disadvantaged position.

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

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

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 with which you may not agree or which do not yield a favorable return to our shareholders. We plan to use the net [**REDACTED**] from the [**REDACTED**] to continue the research and development activities of our drug candidates to commercialization. For details, see "Future Plans and Use of [**REDACTED**] — Use of [**REDACTED**]" in this document. 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**].

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

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

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

Facts, forecasts and statistics in this document relating to the pharmaceutical markets 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 Sole Sponsor, 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 industry statistics in this document may be inaccurate and you should not place undue reliance on it. 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.

Forward-looking statements contained in this document are subject to risks and uncertainties.

This document contains certain future plans and forward-looking statements about us that are made based on the information currently available to our management. The forward-looking information contained in this document is subject to certain risk and uncertainties. Whether we implement those plans, or whether we can achieve the objectives described in this document, will depend on various factors including the market conditions, our business prospects, actions by our competitors and the global financial situations.

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

Subsequent to the date of this document but prior to the completion of the [**REDACTED**], there may be press and media coverage regarding us and the [**REDACTED**], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [**REDACTED**]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, [**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, [**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 purchase our Shares in the [**REDACTED**], you will be deemed to have agreed that you will not rely on any information other than that contained in this document.