An [**REDACTED**] *in our H 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 H 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* [**REDACTED**] *of our H Shares could decline, and you may lose all or part of your* [**REDACTED**]. *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 our financial position and need for additional capital; (iii) risks relating to commercialization of our drug candidates; (iv) risks relating to manufacturing of our drug candidates; (v) risks relating to our intellectual property rights; (vi) risks relating to our reliance on third parties; (vii) risks relating to extensive government regulations; (viii) risks relating to our operations; (ix) risks relating to doing business in China; and (x) risks relating to the [**REDACTED**].

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

RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR DRUG CANDIDATES

Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain 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 are 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 designed and developed a pipeline of seven clinical-stage drug candidates. We have invested a significant portion of our efforts and resources in the development of our existing drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our drug candidates.

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 pre-clinical 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 NMPA, the FDA or other comparable regulatory authorities for our drug candidates;
- the capabilities and competence of our collaboration partners;
- 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, either by constructing new facilities ourselves and/or making arrangements with qualified CMOs;
- successfully launching commercial sales of our drug candidates, if and when approved;

- obtaining and maintaining favorable governmental and 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, which would have a material adverse effect on our business, financial condition and results of operations.

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods. For instance, patients with MA and/or MPE currently have limited treatment options and poor prognosis. Current treatments for MA have limited efficacy and certain risks, such as significant patient discomfort and declining efficacy with tumor progression, and current treatments for MPE are mainly palliative while seldom effective in increasing the survival rate. Our Core Product, M701, is designed to address the medical demands of MA and MPE patients, leveraging its mechanisms. However, there are inherent risks in the development of novel therapeutics, including M701 and our other drug candidates, which 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 pre-clinical 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 additional drug candidates. We cannot guarantee that we will be successful in identifying potential new drug candidates. Even if we succeeded in identifying new drug candidates, 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 BsAb drug candidates for oncology that we intend to identify could also be technically challenging to develop and manufacture. We may also pursue collaboration with third parties in the discovery and development of potential drug candidates, but we cannot assure you that such collaboration will be able to deliver the intended results.

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.

The development of BsAbs is a nascent field and faces many imminent risks and challenges.

BsAbs are produced through cellular expression techniques, typically incurring higher production costs than the synthesis technologies used for small molecule drugs. In addition, BsAbs cannot be administered orally, thus the less convenient administration methods of BsAbs, especially intravenous administration, increases treatment costs and safety risks associated with infusions.

Compared to monospecific antibodies, the design, research, and validation of the dual-specific binding mechanism of BsAbs, along with the molecular construction and preparation of BsAbs, are significantly more complex. This increases the difficulty and risk of developing BsAbs and the difficulty and cost of their production. Compared to cell therapies, BsAbs cannot replenish functional cells in the body. Therefore, in situations where there is a deficiency of functional cells in the body, BsAbs may not be able to achieve optimal therapeutic effects. In addition, BsAbs face intense competition from monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs), multi-specific antibodies (MsAbs), and fusion protein antibodies, which may surpass BsAbs in terms of cost, research and development difficulty, success rate, and market acceptance. For example, the advantages and distinctive characteristics of fusion protein antibodies have led to considerable commercial success. Pharmaceutical giants such as Regeneron and Roche have generated substantial sales from fusion protein antibody drugs.

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 the five months ended May 31, 2023, our research and development expenses were RMB112.9 million, RMB157.3 million and RMB63.7 million, respectively, accounting for approximately 78.2%, 88.5% and 90.3% of our operating expenses (being the research and development expenses and administrative expenses) for the same years/periods, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our 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.

Investors have a high investment risk as the addressable market of our Core Product, M701, might be limited

We are currently developing M701 primarily as a palliative care for the treatment of MA and MPE, which are severe complications that typically occur in late-stage cancer patients who have widespread metastases to the pleura or peritoneum, and not for the treatment of cancer itself. These patients represent an insignificant subset of the overall cancer population.

Moreover, late-stage cancer patients have a relatively short life expectancy and may not prefer to spend substantial financial resources to acquire expensive drugs merely for palliative care instead of fundamentally curing of their diseases.

In addition, the market potentials of M701 may face other limitations and imminent risks. For details, please refer to the paragraphs headed "Industry Overview – CD3 Targeted Bispecific Antibody Market – EpCAM × CD3 Targeted BsAb – Limitations and Imminent Risks on the Market Potential of Innovative Drugs for MA and MPE" in this document.

The limited market size of our core product, M701, may place considerable constraints on our operational outcomes and profitability potential. Should the actual market size be smaller than anticipated or the market penetration be less successful due to factors such as pricing, competition, or patient preferences, our revenues may fall short of expectations. Additionally, the limited market size restricts our capacity for scale, which might lead to relatively higher operational costs per unit sold, further squeezing profit margins. A smaller market could also limit our investment in further product development. If these factors play out, they may adversely affect our overall business performance and results of operations.

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

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 for the treatment of cancer and its complications, or other indications for which we are developing 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 instance, M701 faces intense competition from various angles. Firstly, M701 faces competition from current medical treatment methods for MA and MPE. For more details of such current medical treatment methods, please refer to the paragraphs headed "Industry Overview – CD3 Targeted Bispecific Antibody Market – EpCAM x CD3 Targeted BsAB – Treatment Paradigm for MA and MPE in China" in the document. Among these current treatment options for MA and MPE, therapeutic paracentesis is recommended by clinical guidelines for controlling MA/MPE which can alleviate symptoms

for one to two weeks. For details, please refer to the paragraphs headed "Industry Overview – CD3 Targeted Bispecific Antibody Market – EpCAM × CD3 Targeted BsAb – Treatment Paradigm for MA and MPE in China" in this document. In clinical application, we expect M701 monotherapy could be used in addition to paracentesis to control MA and MPE, with an aim to improve the effectiveness and reduce the side effects of frequent paracentesis. However, this method will also be more expensive. We may face competition from less costly current treatment options for MA and MPE.

In addition, M701 also faces competition from multiple peer products under development for the treatment of MA and MPE. According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative drugs under clinical development globally that were specifically developed for the treatment of MA or MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins.

Moreover, M701 faces competition from peer products targeting identical molecular targets as M701. According to public information, there are BsAb pipelines targeting EpCAM and CD3 and mAb, antibody fusion protein and CAR-T pipelines targeting EpCAM currently under clinical development globally. Among them, LintonPharm Co., Ltd., a Guangzhou-based clinical-stage biopharmaceutical company, is evaluating catumaxomab in clinical trials for advanced gastric cancer and for non-muscle invasive bladder cancer in China. Based on publicly available information, LintonPharm are developing catumaxomab in collaboration with LINDIS Biotech, a research partner of TRION Pharma GmbH. In the bladder cancer Phase I clinical trial sponsored by LintonPharm Co., Ltd., 6 participants received catumaxomab through intravesical instillation. After the first tumor evaluation, all participants achieved a complete response, with the duration of response lasting 9.5 months. In addition to the above pipelines, Amgen Inc. commenced a multicenter Phase I clinical trial of solitomab, a bispecific EpCAM×CD3 T-cell engager BsAb in patients with refractory solid tumors in 2008. According to public information, Amgen Inc. has removed solitomab from its pipeline update since 2015, indicating that it may have suspended the clinical development plan for the drug candidate. We have not learned from public information that solitomab has safety or effectiveness issues. Amgen's suspension of this pipeline may be due to strategic considerations.

Furthermore, we face indirect competition from other therapies for primary and metastatic cancers, including but not limited to chemotherapy, targeted therapies, and immunotherapies. These therapies, while not directly targeting MA and MPE, can help control these complications. Approximately 10% of patients with mild symptoms of MA and MPE only need these cancer therapies to control their MA and MPE. These therapies for cancer thereby indirectly limit the market size for M701. In addition, multiple companies, including large multi-national pharmaceutical companies, are also developing CD3 targeted BsAbs for hematological malignancies and solid tumors, including AbbVie Inc., Pfizer Inc., Johnson & Johnson and Roche Ltd, which, if successfully developed and subsequently approved for marketing, may compete with our CD3-targeted BsAbs. 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 and efficacy, 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. In addition, any new drug that competes with an approved drug must demonstrate compelling advantages in efficacy, immunogenicity, convenience, tolerability and/or safety in order to overcome price competition and to be commercially successful. 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.

As of the Latest Practicable Date, all of our seven drug candidates were under clinical development in China. Commencement of a clinical trial is subject to finalizing trial design based on ongoing discussions with the NMPA, the FDA or other comparable regulatory authorities. We cannot assure you as to when the clinical trials for our drug candidates in discovery and pre-clinical stages will begin, if at all.

Successful completion of our clinical trials is a prerequisite to receiving BLA or similar approvals from the NMPA, the FDA or other comparable regulatory authorities for each drug candidate and, consequently, the ultimate commercialization of our drug candidates. As of the Latest Practicable Date, except for certain delays in our clinical trials due to the impact of COVID-19, none of our clinical trials had failed, been delayed or suspended. For more details, please refer to the paragraphs headed "Summary – Impact of the COVID-19 Outbreak" in this document. However, clinical trials are expensive, difficult to design and implement, and can take years to complete with uncertainty as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing.

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 with regulatory requirements; 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. We may be unable to obtain reimbursement for use of the drug.

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, or at all. 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 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 as required by the NMPA, the FDA or similar regulatory authorities, 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 such as our CROs and SMOs;
- 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, such as COVID-19; 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.

Results of earlier studies and trials may not be predictive of future trial results.

The results of pre-clinical 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 pre-clinical 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 pre-clinical 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 by the NMPA, the FDA or other comparable regulatory authorities. 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 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 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 be shown to lack meaningful clinical response or have other unexpected characteristics, such as short-term DOR 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.

Immune-oncology therapies, including immune checkpoint inhibitors, may cause undesirable side effects.

Immune-oncology therapies such as immune checkpoint inhibitors are still considered as emerging and relatively novel therapeutics for treating cancer. Their mechanisms of action are yet to be thoroughly understood, and adverse events or side effects have been observed in clinical studies and reported by medical practitioners in connection with their usage in cancer patients. In particular, we are developing a number of BsAb drug candidates for oncology, which represent innovative, next generation medical therapies. BsAb treatments are largely still under development, with numerous pre-clinical studies and clinical trials to determine their safety and efficacy in oncology. To date, only a few BsAbs have been approved for oncology treatments in the world.

The results of clinical trials for immune-oncology therapies, including immune checkpoint inhibitors and specifically, BsAb candidates, could reveal a high and unacceptable severity and prevalence of undesirable side effects, including TEAEs that may be treatment-related. Managing adverse events and toxicity for patients undergoing BsAbs treatments may be more complex. Any such side effects could adversely impact our ability to obtain regulatory approvals. For example, the NMPA, the FDA or other comparable regulatory authorities could order us to suspend or terminate the studies of or to cease further development of, or deny approval of, our drug candidates. These TEAEs may be more common in certain patient populations and may be exacerbated when immune checkpoint inhibitors are combined with other therapies. In addition, any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete trials or may result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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 pre-clinical 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 also engage in the procurement of regulatory approvals necessary for the development and commercialization of our products under development, for which we manage and submit data to governmental entities. 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. The insurance coverage for clinical trials may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on our collaboration partners and other third parties to monitor and manage data for some of our ongoing pre-clinical studies and clinical trials and control only certain aspects of their activities. If any of our CROs, our collaboration partners or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those pre-clinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For a detailed discussion, please refer to the paragraphs headed "– 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 pre-clinical 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.

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

As we have limited financial and managerial resources, we focus our product pipeline on research programs 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 programs 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 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 commercial potential for our Core Product, M701, may be limited as there are other low-cost treatment options available in the market for its targeted indications.

We are developing our Core Product, M701, for the treatment of MA and MPE. Currently, patients with MA and/or MPE have limited treatment options and poor prognosis. Although there are no established, evidence-based, universally accepted guidelines in treating MA and MPE globally, there are certain treatment options available in the market to manage MA and MPE which are usually low cost in nature, including but not limited to intra-peritoneal administered chemotherapy, diuretic treatment such as spironolactone, manual aspiration of MA and MPE. In addition, reimbursement by government authorities may be limited or not available for BsAbs solely for the treatment of MA and MPE, such as M701. If government reimbursement is not available or is available only to limited levels, patients may not be willing to pay out-of-pocket in the absence of the reimbursement by government authorities and our Core Product may fail to achieve sufficient market acceptance as expected, even if our Core Product is approved for commercial sales. As a result, we may not be able to generate significant revenue from the commercialization of M701 and our business, financial position, results of operations and prospects may be adversely affected.

Our market opportunities may also be limited by competitors' treatments for MA and MPE that may enter the market. For details, please refer to the paragraphs headed "– Risks Relating to the Research and Development of Our Drug Candidates – We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do."

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 [**REDACTED**] of our H Shares.

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

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We 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 bank loans.

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 the five months ended May 31, 2023, we had loss and total comprehensive expenses of RMB148.5 million, RMB188.9 million and RMB75.4 million, respectively. Our ability to generate significant revenue from our drug candidates 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 pre-clinical studies of our drug candidates;
- initiate pre-clinical, clinical or other studies for new drug candidates;
- construct new manufacturing facilities;

- manufacture clinical trial materials through CMOs and CDMOs in and outside China;
- 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 had 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. Net cash used in operating activities was RMB98.7 million, RMB176.7 million and RMB63.1 million for the years ended December 31, 2021 and 2022 and the five months ended May 31, 2023 respectively. 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 payments under our agreements with third parties, 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 will need to obtain additional financing to fund our operations, 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. For the years ended December 31, 2021 and 2022 and the five months ended May 31, 2023, we had net cash outflows from operating activities of RMB98.7 million, RMB176.7 million and RMB63.1 million, respectively. 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 approved 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 FVTPL.

During the Track Record Period, we had certain financial assets at FVTPL, including structure deposits and wealth management products managed by financial institutions in China. We recorded financial assets at FVTPL of RMB19.5 million, RMB47.0 million and RMB25.0 million as of December 31, 2021 and 2022, and May 31, 2023, respectively. For more details, please refer to the paragraphs headed "Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Position – Financial Assets at FVTPL" in this document. 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 FVTPL are stated at fair value, and net changes in their fair value are recorded as other gains 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 FVTPL in the future. If we incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

We have indebtedness and may incur additional indebtedness in the future, which may materially and adversely affect our financial condition and results of operations.

We maintained certain borrowings to finance our operations during the Track Record Period. We had bank borrowings of RMB28.0 million, RMB76.5 million and RMB40.0 million as of December 31, 2021 and 2022, and May 31, 2023 respectively. As of July 31, 2023, we had bank borrowings of RMB39.5 million. For more details, please refer to the paragraphs headed "Financial Information – Indebtedness – Bank Borrowings" in this document. We may incur additional indebtedness in the future and may not be able to generate sufficient cash to satisfy our existing and future debt obligations.

Our indebtedness could have a material adverse effect on us by, among others, increasing our vulnerability to adverse developments in general economic or industry conditions, such as significant increases in interest rates, and limiting our flexibility in making changes in our business and operations. Our borrowings may subject us to certain restrictive covenants which may restrict or otherwise adversely affect our operations. These covenants may restrict our ability to, among others, incur additional debt, provide loans or guarantees, provide security and quasi-security, incur liens, dispose of material assets through sale, lease or other methods, pay dividends or distributions on certain of our subsidiaries' capital stock, repay or transfer certain indebtedness, reduce registered capital, make investments and acquisitions, establish joint ventures, conduct mergers, consolidation and other change-of-control transactions, and file for bankruptcy or dissolution. In addition, some of the loans may have restrictive covenants linked to our financial performance, such as maintaining a prescribed maximum debt-to-asset ratio or minimum profitability levels during the term of the loans.

Moreover, certain of our borrowings were secured by our property, right-of-use assets and investment properties. For details, please refer to Note 24 in Appendix I to this document and the paragraphs headed "Financial Information – Indebtedness – Bank Borrowings" in this document. In the event that we default on payment obligations of the secured indebtedness or are unable to comply with the restrictions and covenants imposed by the loan agreements in our future debt obligations, banks could terminate their commitments to us, accelerate the payments and declare all amounts borrowed due and payable, enforce the security or terminate the loan agreements. If any of the foregoing events occurs, there can be no assurance that our assets and cash flow will be sufficient to repay all of our debts as they become due, or that we will be able to obtain alternative financing on commercially reasonable terms. Furthermore, if the banks enforce any security over our assets, our business, financial condition, results of operations and prospects would be materially and adversely affected.

We may be exposed to risks associated with our prepayments, deposits and other receivables.

Our prepayments, deposits and other receivables consist primarily of (i) prepayments for research and development services which were mainly related to upfront fees paid for research and development services for the clinical and non-clinical studies of our drug candidates; (ii) prepayments for [**REDACTED**] expenses and [**REDACTED**] costs; (iii) deferred [**REDACTED**] costs; and (iv) advance to staff. As of December 31, 2021 and 2022, and May 31, 2023, our prepayments, deposits and other receivables amounted to RMB14.1 million, RMB27.8 million and RMB25.5 million, respectively. We cannot assure you that we will be able to request the refund of prepayments or deposits if relevant parties delay or default in performing their obligations, or collect other receivables on time pursuant to the agreed payment schedule. The time frame and method for the refund may not be specified, and there may not be a mechanism in place to ensure that the refund will be made on a timely basis. Moreover, we may not be able to receive relevant parties' payments in full, or at all. As a result, we may need to make provisions for prepayments, deposits and other receivables. The occurrence of such event may materially and adversely affect our financial condition and results of operations.

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

We established two employee incentive platforms, Wuhan Caizhi and Caizhi No. 2, in recognition of the contributions of certain eligible employees and directors. For further details, please refer to the paragraphs headed "History, Development and Corporate Structure – Employee Incentive Platforms" in this document. For the years ended December 31, 2021 and 2022 and the five months ended May 31, 2023, we incurred share-based payment expenses of RMB39.6 million, RMB1.6 million and nil, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a negative effect on our financial performance.

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

The change in the value of RMB against the Hong Kong dollar and other currencies may fluctuate and is affected by various factors. Most all of our costs are denominated in RMB, most of our assets are cash and cash equivalents primarily denominated in RMB, and our [**REDACTED**] from the [**REDACTED**] will be denominated in Hong Kong dollars. Any significant change in the exchange rates of the Hong Kong dollar against RMB may adversely affect the value of and any dividends payable on, our H Shares in Hong Kong dollars. For example, a further appreciation of Renminbi against the Hong Kong dollar would make any new Renminbi denominated investments or expenditures more costly to us, to the extent that we need to convert Hong Kong dollars into Renminbi for such purposes. Conversely, if we decide to convert our Renminbi into Hong Kong dollars for the purpose of making payments for dividends on our H Shares or for other business purposes, appreciation of the Hong Kong dollar against Renminbi would have a negative effect on the Hong Kong dollar amount available to us.

RISKS RELATING TO COMMERCIALIZATION OF OUR DRUG CANDIDATES

We have limited experience in the commercialization of drugs. 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.

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, including the price reduction during the negotiation for inclusion in the national reimbursement drug lists in the PRC;
- 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.

We may be unable to produce a successful COVID-19 vaccine and generate demand for our vaccine before the COVID-19 outbreak is effectively contained or the risk of coronavirus infection is significantly diminished. Even if we are successful in producing a vaccine against COVID-19, we may need to devote significant resources to its scale-up and development.

Concurrently, a large number of vaccine manufacturers, academic institutions and other organizations are in the process of developing COVID-19 vaccine candidates. Our competitors pursuing COVID-19 vaccine candidates may have greater financial, development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their COVID-19 vaccine candidates.

Our efforts to develop Y2019 for regulatory approval and commercialization or generate demand for Y2019 may fail if our competitors develop and commercialize one or more COVID-19 vaccines that are safer, more effective, produce longer immunity against COVID-19, require fewer administrations, have fewer or less severe side effects, have broader market acceptance, or are more convenient or are less expensive than any vaccine candidate that we may develop. Since late 2020, multiple SARS-CoV-2 variants including variants of concern have emerged. As such, since the COVID-19 pandemic continues to evolve in China and globally, the long-term effectiveness of, and the protection provided by, any marketed or development-stage COVID-19 vaccines against various SARS-CoV-2 strains continue to be evaluated in longitudinal studies.

Clinical trials for COVID-19 vaccines involve a lengthy and expensive process with an uncertain outcome. Given the severity and urgency of the COVID-19 pandemic, we have committed significant capital and resources to fund the development of Y2019. However, there are uncertainties surrounding the longevity and extent of the COVID-19 pandemic as a global health concern. The COVID-19 pandemic may have been controlled before we successfully commercialize a successful COVID-19 vaccine and obtain adequate market demand for our vaccine candidate and realize any return on our investment in the research and development of our vaccine candidate. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

Furthermore, during a global health crisis, such as the COVID-19 pandemic, where the spread of a disease needs to be controlled, closed or heavily regulated national borders will create challenges and potential delays in our development and production activities and may necessitate that we pursue strategies to develop and produce our vaccine candidate at potentially much greater expense and with longer timeframes for public distribution.

Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or not immediately available in the relevant countries for our drug candidates, and we may be subject to unfavorable pricing regulations, which may affect our profitability.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approvals of the sale price of a drug before marketing. In many countries, the pricing review period commences after marketing or licensing approvals are granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approvals are granted. As a result, we might obtain regulatory approvals for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approvals. For example, according to a statement, Opinions of the State Council on Reforming the Review and Approval System for Pharmaceutical Products and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》), issued by the PRC State Council in August 2015, the enterprises applying for new drug approval will be required to undertake that the selling price of a new drug in the PRC market shall not be higher than the comparable market prices of the product in its country of origin or PRC's neighboring markets, as applicable.

The successful commercialization of our drugs also depends on the extent to which reimbursement for these drugs and related treatments will be available from relevant health administrative authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and healthcare organizations, decide which medications they will pay for and stipulate reimbursement levels. With the trend of cost containment in the global healthcare industry, government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. There are an increasing number of third-party payers requiring companies to provide them with predetermined discounts from list prices and challenging the prices charged for medical products. There can be no assurance as to whether or to what extent reimbursement will be available for any drug we commercialize. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approvals. Obtaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a doctor. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we have developed.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the indications and purposes for which the drug candidates are approved by the NMPA, the FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may be subject to change. 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 drugs with lower cost that have been covered in reimbursement policies, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by governmental healthcare programs or private payers and by any future lift or relaxation of laws and regulations that presently restrict imports of drugs from countries where they may be sold at lower prices than in the jurisdictions in which we operate or have a presence. 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, financial condition, results of operations and prospects.

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 candidate 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 the NMPA, the FDA or another comparable 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.

The illegal and/or parallel imports and 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 China and other countries where we plan to commercialize our drug candidates. Unapproved foreign imports of prescription drugs are illegal under current laws of China. However, illegal imports 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. In addition, competent government authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products from outside China or other countries where we operate. Any future legislation or regulations that increase consumer access to lower priced medicines from outside China or other countries where we operate could have a material adverse effect on our business.

Certain 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. These products are generally referred to as counterfeit pharmaceutical products. The regulatory control and law enforcement system in relation to the counterfeit pharmaceutical products, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products in a timely manner, or at all. 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.

Lack of third-party combination drugs may materially and adversely affect demand for our drugs.

Our drug candidates may be administered in combination with drugs of other pharmaceutical companies as one regimen. We may also use third-party drugs in our development and clinical trials as controls for our studies. For example, we are currently conducting a Phase II clinical trial to evaluate the efficacy of our Core Product, M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) in MA patients in China. We also commenced a Phase Ib/II clinical trial of Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for advanced/metastatic pancreatic cancer patients in China in February 2023 and a Phase Ib/II clinical trial of Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China in March 2023. As a result, both the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. We generally have no influence over the availability and pricing of such drugs. If other pharmaceutical companies discontinue these combination drugs, or if these drugs become prohibitively expensive, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs in a timely manner and on commercially reasonable terms, or at all. As a result, demand for our drugs may be lowered, which would in turn materially and adversely affect our business, financial condition, results of operations and prospects.

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

The field of cancer treatment has advanced rapidly in recent decades, progressing from surgery and radiotherapy, to chemotherapy and, more recently, to targeted drugs and immune-oncology therapies including cell therapies. Medication treatment with chemotherapy, targeted drugs and immune-oncology therapies can be characterized as first-line, second-line or third-line based on the timing of the treatment. First-line treatment or therapy simply refers to the initial, or first treatment recommended for the cancer, which, for most people, is expected to provide the best results with fewest side effects. In contrast, second-line treatments are used when the first-line treatment failed, or if the first-line worked initially and then the cancer progressed. Third-line treatment may be adopted if previous treatments failed.

For certain indications with well-established standard of care therapies, we may initially seek approval of our drug candidates as a later stage therapy for patients who have failed other approved treatments. For drugs that prove to be sufficiently beneficial, we may subsequently seek approval as an early-line therapy for these indications, but there is no guarantee that our drug candidates would be approved for early-line therapy. Our projections of the number of patients in a position to receive a later stage therapy and those who can potentially benefit from treatment with our drug candidates as a second- or first-line of therapy, are based on our estimates and may be inaccurate.

Further, new studies may change the estimated incidences or prevalence of these cancers. The potentially addressable patient population for our drug candidates may turn out to be limited and lower than expected, or may not be amenable to treatment with our drug candidates. Our business may suffer if the market opportunities for our drug candidates are smaller than we anticipate, or the regulatory approvals we obtain for our drugs are based on a narrower definition of the patient population. Even if we obtain significant market shares for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including the use as an early-line therapy.

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.

We may face difficulties in leveraging the clinical results of our drug candidates for late-stage clinical development in other jurisdictions.

There have been recent examples of the FDA declining to approve drugs mainly based on the clinical data generated in other jurisdictions, including sintilimab, a lung cancer drug candidate and surufatinib, a pancreatic and extra-pancreatic neuroendocrine tumor drug candidate. Sintilimab has not undergone any clinical trial in the U.S., while surufatinib has only been tested in a small-scale bridging trial in the U.S. Neither drug has been evaluated in pivotal clinical trials involving diverse populations in the U.S., nor have their pivotal clinical trial protocols been reviewed or approved by the FDA. After completing the Phase II clinical trial of M701 and the Phase Ib/II clinical trials of Y101D in China, we plan to leverage the clinical results generated in China to support the late-stage clinical development in the U.S. We plan to collaborate with overseas partners to confirm the design of late-stage clinical trials with FDA and conduct such clinical trials in the U.S., which will enable us to obtain efficacy data encompassing multiple ethnicities and form the basis for us to obtain regulatory approvals to commercialize M701 in the U.S. and some other overseas markets. However, we cannot guarantee that the FDA will accept our clinical results generated in China to support pivotal clinical trials in the U.S., and we may face difficulties and incur additional costs thereof.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and certain other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict post-approval activities and affect our ability to sell profitably any drug candidates for which we obtain marketing approval.

The United States Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA, the following may be of importance to our drug candidates:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act's pharmaceutical pricing program;
- new requirements to report to Centers for Medicare & Medicaid Services financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report to the FDA drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, on our drug candidates may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

RISKS RELATING TO MANUFACTURING OF OUR DRUG CANDIDATES

We have limited experience in manufacturing therapeutic biologic products, 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 pre-clinical studies and clinical trials. For details, please refer to the paragraphs headed "Business – Our R&D Platform – Chemistry, Manufacturing, and Controls (CMC)" in this document. We have limited experience in large-scale manufacturing of our drug candidates.

We rely on CMOs/CDMOs as well as our inhouse manufacturing capability to support the supply of drug candidates to meet our clinical and pre-clinical demands. We expect to engage third-party CMOs/CDMOs to manufacture certain of our products after they are commercialized, such as M701 and Y101D. We also plan to establish new production lines to meet the manufacturing demands for pivotal clinical trials and commercial production of Y150 and Y332. As of the Latest Practicable Date, our manufacturing center consisted of 28 members with extensive experience in CMC and manufacturing of BsAbs led by Dr. Yang Bin who has over ten years of experience in CMC processes management and drug development. However, we have seven drug candidates under clinical development and the process development and scale up of sophisticated biologics such as BsAbs are resource-intensive and time-consuming. We cannot guarantee that we will not encounter a shortage of manufacturing professionals or that our CMC technology will be able to support the production of complex BsAbs. If our in-house capacity fails to meet our clinical manufacturing needs or we are unable to engage suitable CMOs/CDMOs in a timely manner, our clinical trials may be significantly delayed, and the commercialization progress of our drug candidates could be severely impacted.

If we are unable to identify an appropriate production site or a suitable partner to develop the manufacturing infrastructure, or fail to do so in a timely manner, it may lead to significant delays in the manufacturing of our drug candidates after we have obtained regulatory and marketing approvals. Investments in constructing or leasing new biologics manufacturing facilities which are in compliance with GMP regulations may result in significant cost for us and in turn would have a material adverse effect on our commercialization plans. We may also fail to attract and retain personnel with the requisite skills and experience for drug manufacturing.

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

We may also encounter problems with achieving adequate or clinical-grade products that meet the standards or specifications of the NMPA, the FDA, or other comparable regulatory agencies, 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.

The manufacturing of therapeutic biologics products is highly complex and if we encounter problems in manufacturing our products, our business could be materially and adversely affected.

The manufacturing of therapeutic biologics products is highly complex and we have limited experience in commercial manufacturing. Problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of products produced
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. We face additional manufacturing risks in relation to the CMOs that we may engage from time to time. For details, please refer to the paragraphs headed "– Risks Relating to Our Reliance on Third Parties – We currently rely on third parties to manufacture a portion of our drug candidates for clinical development, and we may rely on third parties to manufacture our drug candidates for commercial sales in the future. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices" in this section.

Any disruption of our current facilities or in the development of new facilities, could reduce or restrict our production capacity or our ability to develop or sell products, which could have a material adverse effect on our business, financial condition and results of operations.

We currently manufacture certain of our existing drug candidates for research and development purposes in Wuhan, China. We also engage third-party CMOs/CDMOs for the manufacturing of a portion of our drug candidates for preclinical studies and clinical trials. Our manufacturing capacity of our drug candidates may be limited, which would delay or limit our development and commercialization activities and our opportunities for growth.

Our manufacturing facilities are required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA, the FDA, or other comparable regulatory authorities 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. We cannot guarantee that we will be able to adequately follow and document our adherence to such GMP regulations or other regulatory requirements. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to follow and document our adherence to such GMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or 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.

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 we are unable to meet the increasing demand for our existing drug candidates and future drug products by ensuring that we have adequate manufacturing capacity, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business 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 aim 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, land use rights or regulatory issues, which could result in loss of business opportunities;

- construction cost overruns, which may require diverting resources and management's attention from other projects; and

- difficulty in finding sufficient numbers of trained and qualified staff.

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

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 technologies that we consider commercially important by filing patent applications in different jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. A portion of our patent portfolio currently comprises pending patent applications that have not yet been issued as granted patents. For further information on our patent portfolio, please refer to the paragraphs headed "Business – Intellectual Property" in this document. Whether we can obtain the approval for each pending application is subject to the examination opinions from the applicable patent examination authorities during the ordinary pendency and examination of such patent applications. If we or our collaboration partners are unable to obtain and maintain patent and other intellectual property protection with

respect to our drug candidates and technologies, our competitors could develop and commercialize drugs and technologies similar or identical to ours, and our ability to successfully commercialize our drugs and technologies may be harmed, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 third parties from developing and commercializing competitive drugs in all such fields and jurisdictions. If we 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. In addition, the requirements for patentability differ in certain jurisdictions. 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 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.

Patent applications may not be granted, and the granted patents may be invalidated for a number of reasons, including known or unknown prior art, deficiencies in the patent application, the lack of novelty of the underlying invention or technology or failure to comply with the confidentiality examination requirement. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Any of these reasons may delay or interfere with our commercialization plans in China and globally. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaboration partners, outside scientific collaboration partners, 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 different jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, China and the United States have adopted the "first-to-file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. An adverse determination in any proceeding challenging our patent rights could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. In addition, the patent position of biopharmaceutical and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our drug candidates in all countries across the world could be prohibitively expensive. Competitors may use our technologies in jurisdictions in which we have not obtained patent protection to develop their own drug candidates and may export otherwise infringing drug candidates to territories, where we have patent protection, given that the levels of law enforcement vary across jurisdictions. These drug candidates may compete with our drug candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant difficulties in registering, protecting and defending such rights in some jurisdictions. Furthermore, the legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, there can be no assurance that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may expect to market our drug candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have a material adverse effect on our ability to successfully commercialize our drug candidates in all of our expected significant markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Even if we are able to 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. For example, the expiration of a patent is generally 20 years for invention in the PRC and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the United States. 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, please refer to the paragraphs headed "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.

Our owned patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings. If we or our collaboration partners are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture and commercialization of one or more of the drug candidates we may develop, which could materially and adversely impact our business.

We or our collaboration partners may be subject to claims that former employees, collaboration partners or other third parties have an interest in our owned patents or other intellectual property. If we or our collaboration partners are unsuccessful in any interference proceedings or other priority, inventorship or validity disputes to which we or they are subject, we may lose valuable intellectual property rights, such as loss of one or more patents or exclusive ownership, or our patent claims' being narrowed, invalidated, or held unenforceable. As a result, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes, in order to continue the development, manufacture and commercialization of one or more of our drug candidates. However, such licenses may not be available on commercially reasonable terms or at all or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to modify or cease the development, manufacture, and commercialization of one or more of our drug candidates. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

We may also engage third-party contractors, including CROs, to assist us with the research and development of our drug candidates. There can be no assurance that such contractors will not transfer the drug candidates to other third parties without our permission. Such unauthorized transfer may also result in the loss or restriction of our intellectual property rights and therefore limit our ability to develop, manufacture and commercialize the drug candidates.

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, the United States Patent and Trademark Office (the "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 and other 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, 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 interpretation in different jurisdictions 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, the AIA, 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.

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 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.

Granted patents covering one or more of our major drug candidates or technologies could be found invalid or unenforceable if challenged in court.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, the CNIPA or the applicable foreign counterpart, or made a misleading statement, during prosecution. Even if we conduct 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.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a drug candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/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. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activities and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future drug candidates. Any loss of patent protection could have a material adverse impact on one or more of our drug candidates and our business.

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.

We currently own issued trademark registrations and have trademark applications pending, any of which 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 before the CNIPA, the USPTO or comparable agencies in many foreign 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.

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

The degree of protection afforded by our intellectual property rights is essentially uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The limitations of currently available intellectual property protection regimes include that:

- 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.

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. We may be subject to claims that we, our employees, consultants and advisors, 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.

We may be unsuccessful in executing the agreements assigning intellectual property to us with our employees, consultants and contractors who in fact develop 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.

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 pre-clinical 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, including SMOs, to monitor and manage data for our ongoing pre-clinical and clinical programs. We work with these parties to execute our pre-clinical 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 product produced under GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs 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 cost and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business.

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.

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, please refer to the paragraphs headed "Business – Raw Materials and Suppliers" in this document.

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 studies, 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. 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 collaborated with third parties in the development of drug candidates, and may seek 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 collaboration arrangements with third parties in relation to the development of our drug candidates. For details, please refer to the paragraphs headed "Business – Collaboration Agreements" 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 currently rely on third parties to manufacture a portion of our drug candidates for clinical development, and we may rely on third parties to manufacture our drug candidates for commercial sales in the future. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices.

During the Track Record Period, we outsourced certain manufacturing activities of our drug candidates to selected CMOs/CDMOs. Such outsourcing occurs when our own manufacturing capacity is insufficient and when we seek to reduce regulatory compliance costs. Going forward, we plan to continue to work with industry-leading and reputable CMOs/CDMOs. Reliance on third-party CMOs/CDMOs would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or in a timely manner, or at all, because the number of potential manufacturers is limited and the NMPA, the FDA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and GMP-compliance inspections by the NMPA, the FDA or other comparable regulatory authorities;

- our CMOs/CDMOs might be unable to timely produce the drug candidates or not in the quantity and quality required to meet our needs for clinical trials and commercial sales, if any;

- manufacturers are subject to ongoing periodic inspections by the NMPA or the FDA, or other comparable regulatory authorities, as applicable, to ensure strict compliance with GMP and other government regulations and we do not have control over CMOs/CDMOs' compliance with these regulations and requirements;

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;

- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- manufacturers may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;

- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and

- our CMOs/CDMOs and critical raw materials suppliers may be subject to inclement weather, as well as natural or man-made disasters.

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

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

RISKS RELATING TO EXTENSIVE 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 uncertainties and changes in the laws and regulations 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.

The regulatory approval processes of the relevant regulatory authorities in different jurisdictions 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 relevant regulatory authorities in different jurisdictions is unpredictable but typically takes 10 to 15 years following the commencement of pre-clinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities. 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 a relevant regulatory authority in a certain jurisdiction 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 different 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 failure to meet the requirements of 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 pre-clinical 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 relevant 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 pre-clinical 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.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, and could materially and adversely affect our business, financial condition, results of operations and prospects.

The regulatory pathway for COVID-19 vaccines is highly dynamic and continues to evolve and may result in unexpected or unforeseen challenges.

The speed at which all parties are acting to develop and test many vaccines against the SARS-CoV-2 virus is unusual, and evolving or changing plans or priorities within the NMPA, the FDA, the WHO and other regulatory authorities, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for Y2019.

Results from clinical testing may also raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. For example, The NMPA and the WHO prioritize the regulatory administration on COVID-19 vaccines, while emphasizing on various regulatory requirements on pre-clinical studies and clinical trials. We cannot be certain that, as the regulatory pathway continues to evolve, we will be able to complete future clinical trials for Y2019 in accordance with the applicable guidance and regulations then in effect.

A failure to complete a clinical trial in accordance with guidance and regulations then in effect could impair our ability to obtain approval for Y2019, which may adversely affect our operating results, reputation and ability to raise capital and enter into or maintain collaborations to advance our other product candidates.

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

We routinely receive, collect, generate, store, process, transmit and maintain medical data, treatment records and other personal details of 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 various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of

these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officers and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

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. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. Whilst we have adopted security policies and measures to protect our proprietary data and patients' privacy, privacy leakage incidents might not be avoided due to hacking activities, human error, employee misconduct or negligence or system breakdown.

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.

China has adopted management and administration measures of the import and export of technology and software products. Under the Regulations on Administration of Imports and Exports of Technologies (《技術進出口管理條例》) promulgated by the State Council, 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 (《技術進出口合同登記管理辦法》), 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 required to be registered with applicable PRC governmental authorities. We are also subject to regulatory supervision over genetics and data-related operations. To carry out clinical trials, as a foreign-invested enterprise, we are required to obtain approval from the Office of Human Genetic Resources Management under the Ministry of Science and Technology (科學技術部人類遺傳資源管理辦公室) who will conduct genetics and data safety review. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all. In addition, we may also be subject to similar requirements of overseas regulatory authorities.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret or individual privacy may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any relevant laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad. If we are unable to obtain necessary approvals or fail to obtain such approvals in a timely manner, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. 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 CMC, variations, continued compliance with GMPs, cGMPs, GCPs, good storage practices (GSPs) and good vigilance practices (GVPs) 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 by the NMPA, the FDA or a comparable regulatory authority for marketing, 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 NMPA, the FDA or comparable 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 NMPA, the FDA or comparable 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.

The NMPA, the FDA and comparable 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 NMPA, the FDA and other comparable 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 some jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. 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 than others and may apply to healthcare services reimbursed by any source, which may include not only governmental payers, but also private insurers, and if we fail to comply with any such requirement, we could be subject to penalties.

There is no definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. 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 current or future 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, contractual damages, 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 in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Moreover, although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act (the "FCPA"). The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. There is no assurance that policies or procedures to ensure the compliance with anti-bribery laws 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.

RISKS RELATING TO OUR OPERATIONS

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

Our commercial success depends significantly on the continued service of our senior management. For more details of our senior management, please refer to the section headed "Directors, Supervisors 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.

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

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

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 health epidemics and other outbreaks of contagious diseases, including the COVID-19 outbreak.

Since the end of December 2019, the outbreak of a novel strain of coronavirus named COVID-19 has materially and adversely affected the global economy. Many countries and regions had been affected by the COVID-19 outbreak and, in response, had imposed certain pandemic control measures to contain the spread of the virus. Due to the COVID-19 outbreak, we may experience one or more of the following disruptions to drug development efforts and business operations:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in logistics that may affect the transport of clinical trial materials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, patient treatment and efficacy evaluation;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- temporary closure of certain office facilities and adopting remote working where possible;
- restriction of employee travels, which may adversely affect the sales and marketing efforts;
- disruption to the manufacturing activities;
- disruption to the supplies of our drug candidates in clinical trials; and
- delays in or temporary suspension of the construction of our manufacturing facilities.

These disruptions could cause delay of clinical trials, regulatory submissions, and required approvals of our drug candidates, and could cause us to incur additional costs. If we are not able to effectively develop and commercialize our drug candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, and/or failure to recruit and conduct patient follow-up, we may not be able to generate revenue from sales of our drug candidates as planned. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section. For details, please refer to the paragraphs headed "Financial Information – Impact of the COVID-19 Outbreak" in this document.

Since the beginning of 2022, there have been a number of regional resurgences of COVID-19 cases in the world due to the spread of the Omicron variant. The COVID-19 related pandemic control measures adopted by the Chinese government were lifted in various regions in China in December 2022. However, the exacerbation, continuance or resurgence of COVID-19 has already caused, and may continue to cause, an adverse and prolonged impact on the economy and social conditions in the affected countries. We cannot predict when the COVID-19 outbreak and resurgences will become completely under control and we cannot guarantee that the COVID-19 outbreak and resurgences will not worsen. The extent to which the COVID-19 outbreak and resurgences may impact our business in the future will depend on future developments, which are highly uncertain and unpredictable, such as the duration of the outbreak, the effectiveness of vaccines and vaccination rates, and other measures to contain the outbreak and its impact in countries and regions where we operate. Having considered that the past occurrences of epidemics, depending on their scale, have caused different degrees of damage to the global economy, the COVID-19 outbreak and any other global public health crisis may result in material disruptions to our operations, which in turn 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 overseas, 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, including, for example, the outbreak of COVID-19.

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 the 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, please refer to the paragraphs headed "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.

We benefit from certain preferential tax treatments and government grants, and the expiration of or changes to these incentives or policies or our failure to satisfy any condition for these incentives would have an adverse effect on our results of operations.

During the Track Record Period, we enjoyed preferential tax treatment. For example, pursuant to the Notice of Raising the Proportion of Weighted Pre-tax Deduction of Research and Development Expenses (關於提高研究開發費用稅前加計扣除比例的通知) issued by the Ministry of Finance, the State Administration of Taxation and the Ministry of Science and Technology on September 20, 2018, we enjoyed super deduction of 175% on qualifying research and development expenses during the Track Record Period. We cannot assure you that these preferential tax treatments will continue to be available to us in the future, or that these preferential tax treatments will not be changed, as a result of changes in government policy, administrative decisions or otherwise, in which case our financial condition and results of operations may be adversely affected. Moreover, we recorded government grants of RMB12.1 million, RMB2.3 million and RMB6.4 million for the years ended December 31, 2021 and 2022, and the five months ended May 31, 2023 respectively. These government grants were generally in support of our research and development activities, including subsidies to encourage R&D activities, reimbursement for R&D expenses and subsidies for talent recruitment.

The government authorities determine the timing, amount and criteria of such financial incentives based on applicable laws and regulations and may review and assess such criteria conditions from time to time. One of the government subsidies we received during the Track Record Period is subject to a condition that we should complete the R&D projects for Y2019. Our compliance with such condition is under the assessment of the relevant government authority. Although we do not expect any material impediment to get approved in such assessment, we generally do not have the ability to influence government authorities in making these decisions. Government authorities may decide to reduce or eliminate incentives. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including achievement of technological innovation, recruitment and retention of talent, compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, otherwise we may be deprived of all or part of the incentives. For instance, we received a government subsidy for construction of R&D facilities, with a condition that the construction should be completed and approved by the relevant PRC

government authority before December 31, 2016. As of the Latest Practicable Date, we had not fulfilled such condition. As a result, this subsidy is repayable to the relevant PRC government authority on demand. For more details, please refer to the paragraphs headed "Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Positions – Trade and Other Payables" in this document.

Except as disclosed above, during the Track Record and up to the Latest Practicable Date, we had complied with all the conditions required to receive government grants. However, we cannot assure you that we will continue to receive government grants, or preferential tax treatments at the same level or at all, in which case our business, financial condition and result of operations may be adversely affected.

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 accident, 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 subject to natural disasters, acts of war or terrorism or other factors beyond our control.

Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or may be susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of 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. 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.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In addition, although currently our primary operating business is in China, we are subject to the FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. There is no assurance that our internal policies or procedures related to compliance with anti-bribery laws 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.

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 United States 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.

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 PRC government may impose fines or other penalties on us if we fail to comply with the terms of the land grant contracts.

Under PRC laws, if we fail to develop a property project according to the terms of the land grant contract, including those relating to the designated use of the land and the time for commencement and completion of the property development, government authorities may issue a warning, impose a penalty and/or order us to forfeit the land. Specifically, under current PRC laws, if we fail to pay any outstanding land grant premium by the stipulated deadlines, we may be subject to late payment penalties or the repossession of the land by the PRC government. If we fail to commence development after one year of the commencement date stipulated in the land grant contract, the relevant PRC land bureau may issue a warning to us and impose an idle land penalty equivalent to or less than 20% of the land premium. If we fail to commence development within two years from the commencement date stipulated in the land grant contract, the relevant PRC land bureau may confiscate our land use rights without compensation, except where the delay in the development is attributable to a force majeure event or the action of the relevant government department or delay in the requisite preliminary work preceding commencement of such development. Moreover, had the development of the property commenced in accordance with the timeframe stipulated in the land grant contract, however, if such development was suspended for more than one year without government approval and falls under either of the following two situations: (i) the developed land area is less than one-third of the total land area, or (ii) the total invested capital is less than one-fourth of the total planned investment in the project, then the land may be treated as idle land and will be subject to the risk of forfeiture.

We experienced certain delays in completing the construction project on a land parcel we acquired in Wuhan, Hubei in 2012 pursuant to a land grant contract with Wuhan Municipal Bureau of Natural Resources and Planning, East Lake High-tech Development Zone Branch. For more details, please refer to the paragraphs headed "Business – Land and Properties – Land, Construction-in-Progress and Owned Properties" in this document. Except for such delays, we did not have any other previous incident failing to comply the terms of the land grant contract as of the Latest Practicable Date. We cannot assure you that our property development projects will not be subject to idle land penalties or be taken back by the government as a result of such delays, nor can we assure that we will not be imposed liquidated damages by competent PRC authorities. The occurrence of such events may have a material adverse effect on our business, results of operations and financial condition.

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

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), the Regulations on Management of Housing Provident Fund (《住房公積金管理條例》) and other applicable PRC regulations, any employer operating in China must contribute social insurance premium and housing provident funds for its employees. Any failure to open social insurance or housing provident fund registration account may trigger an order of correction where correction is not made within a specified period of time, the competent authority may further impose fines. Any failure to make timely and adequate contribution of social insurance premium or housing provident funds for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium or housing provident funds within a specified period of time, and the competent authority may further impose fines or penalties. During the Track Record Period, we were not in strict compliance with the requisite contribution requirements in relation to some of our PRC employees. For more details, please refer to the paragraphs headed "Business – Employees – Employee Benefits" in this document. 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 are subject to risks associated with leasing space.

We lease some of our offices, laboratories and facilities 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. If lessors are not entitled to lease properties to us, relevant leases might be invalidated. We may have to renegotiate with new lessors and the terms of the new leases may be less favorable to us. 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. As of the Latest Practicable Date, six of our leases had not been filed with the governmental authorities. For more details, please refer to the paragraphs headed "Business – Land and Properties – Leases" in this document. The failure to file and obtain property leasing filing certificates for such six leases, as required under PRC laws, may subject us to a fine ranging from RMB1,000 to RMB10,000 for each agreement not filed. If such fines are imposed, the maximum penalty we may be required to pay would be approximately RMB70,000.

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 and outsourced vendors. 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 at our Company or vendors that provide information systems, networks or other services to us 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. In addition, the COVID-19 pandemic has intensified our dependence on information technology systems as many of our critical business activities are currently being conducted remotely.

If any such material system failure, accident, or security breach 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, our third-party vendors, and clinical sites, including personal information of our employees and, potentially, our clinical study patients, and company and vendor confidential data. In addition, third parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to 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 or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

In addition, we could be subject to regulatory actions 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. The development and maintenance of the systems, controls, and processes to prevent such events from occurring and/or identify and mitigate threats 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 outsource more of our information systems to vendors, 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.

RISKS RELATING TO DOING BUSINESS IN CHINA

Changes in, as well as the interpretation and implementation of the relevant laws, 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 and legal developments in the PRC. 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 in the regulatory regime of marketed drugs could have impacts on our commercialization of drug candidates. 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. 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.

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

While we have not started commercialization of any of our drug candidates, any 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 effect on our business, financial condition and results of operations.

Gains on the sales of H Shares and dividends on the H Shares may be subject to PRC income taxes.

Holders of H Shares, being non-PRC resident individuals or non-PRC resident enterprises, whose names appear on the register of members of H Shares of our Company, are subject to PRC income tax in accordance with the applicable tax laws and regulations, on dividends received from us and gains realized through the sale or transfer by other means of H shares by such shareholders.

According to the Individual Income Tax Law of the PRC and the Implementation Regulations for the Individual Income Tax Law of the PRC, both came into effect on January 1, 2019, the tax applicable to non-PRC resident individuals is proportionate at a rate of 20% for any dividends obtained from within China or gains on transfer of shares and shall be withheld and paid by the withholding agent. Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (the "Arrangements") executed on August 21, 2006, the PRC Government may levy taxes on the dividends paid by PRC companies to Hong Kong residents in accordance with the PRC laws, but the levied tax (in the case the beneficial owner of the dividends are not companies directly holding at least 25% of the equity interest in the company paying the dividends) shall not exceed 10% of the total dividends.

According to the Enterprise Income Tax Law of the PRC, which was newly revised and implemented on December 29, 2018, and the Implementation Regulations for the Enterprise Income Tax Law of the PRC, which was newly revised and implemented on April 23, 2019, if a non-resident enterprise has no presence or establishment within China, or if it has established a presence or establishment but the income obtained has no actual connection with such presence or establishment, it shall pay an enterprise income tax on its income derived from within China with a reduced rate of 10%. Pursuant to the Arrangements, dividends paid by PRC resident enterprises to Hong Kong residents can be taxed either in Hong Kong or in accordance with the PRC laws. However, if the beneficial owner of the dividends is a Hong Kong resident, the tax charged shall not exceed: (i) 5% of the total amount of dividends if the Hong Kong resident is a company that directly owns at least 25% of the capital of the PRC resident enterprise paying dividends; (ii) otherwise, 10% of the total amount of dividends.

The interpretation and enforcement of applicable tax laws and regulations in the PRC by the PRC tax authorities, including whether and how income tax will be levied on non-PRC resident shareholders, will be determined according to the laws and regulations then in effect. Non-PRC resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers by other means of the H Shares.

Governmental administration of currency conversion, and restrictions on the remittance of Renminbi into and out of China, may adversely affect the value of your [REDACTED].

The convertibility of Renminbi is currently subject to certain regulations. A substantial majority of our future revenue is expected to be denominated in Renminbi. Shortages in availability of foreign currency may then restrict our ability to remit sufficient foreign currency to pay dividends, if any, to holders of our H Shares, or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under China's current foreign exchange administration system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. There may be certain regulations in the future which restrict our access to foreign currencies for current account transactions. If the foreign exchange administration system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders. Further, there is no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.

You may experience difficulties in effecting service of legal process to us or our management named in the documents.

We are incorporated under the laws of China, and substantially all of our assets are located in China. In addition, a majority of our Directors, Supervisors and senior management personnel reside within the PRC, and substantially all of their assets are located within the PRC. Therefore, it may be difficult for investors to effect service of process upon us or our Directors, Supervisors 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.

RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our H Shares, and an active [REDACTED] for our H Shares may not develop and their liquidity and [REDACTED] may be volatile, especially taking into account that all of our existing Shareholders are subject to statutory lock-up arrangements for 12 months after the [REDACTED].

No public market currently exists for our H Shares. The initial [**REDACTED**] for our H Shares to the public will be the result of negotiations between our Company, the [**REDACTED**] and the [**REDACTED**] on behalf of the [**REDACTED**]) and the [**REDACTED**] may differ significantly from the [**REDACTED**] of the H Shares following the [**REDACTED**]. We have applied for [**REDACTED**] of and permission to [**REDACTED**] in our [**REDACTED**] on the Stock Exchange.

In particular, certain part of the H Shares in [**REDACTED**] as of the date of this document will be subject to a lock-up period from the [**REDACTED**] Date and only [**REDACTED**]% of our [**REDACTED**] Shares, or [**REDACTED**]% of our H Shares in [**REDACTED**], upon [**REDACTED**] (assuming an [**REDACTED**] of HK$[**REDACTED**] per H Share, being the low-end of the proposed range of the [**REDACTED**] and without taking into account [**REDACTED**]) will not be subject to any lock-up arrangements, which may significantly affect the liquidity and [**REDACTED**] of our H Shares in the short term following the [**REDACTED**].

As such, a [**REDACTED**] on the Stock Exchange does not guarantee that an active and liquid [**REDACTED**] for the H Shares will develop, especially during the period when certain portion of our H Shares may be subjected to the lock-up, or if it does develop, that it will be sustained following the [**REDACTED**], or that the [**REDACTED**] of the H Shares will not decline following the [**REDACTED**].

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

The [**REDACTED**] and [**REDACTED**] of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the [**REDACTED**] and [**REDACTED**] of our H Shares. In addition to market and industry factors, the [**REDACTED**] and [**REDACTED**] of our H Shares may be highly volatile for specific business reasons, including but not limited to:

- the results of clinical trials of our drug candidates;
- the results of our applications for regulatory approvals of our drug candidates;
- regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters;
- fluctuations in our revenue, earnings, cash flows, investments and expenditures;
- relationships with our collaboration partners and suppliers;
- movements or activities of key personnel;
- announcements made by us or our competitors;
- acquisitions by us or our competitors;
- other actions taken by competitors;
- release or expiry of lock-up or other transfer restrictions on our H shares; and
- the general economy and other factors.

Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in price not directly related to our performance.

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

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

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

Prior to the [**REDACTED**], there has not been a public market for our H Shares. Future sales or perceived sales by our existing Shareholders of our H Shares after the [**REDACTED**] could result in a significant decrease in the prevailing [**REDACTED**] of our H Shares. Only a limited number of the H 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 H Shares in the public market or the perception that these sales may occur could significantly decrease the prevailing [**REDACTED**] of our H Shares and our ability to raise equity capital in the future.

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

We may finance our future cash needs through equity offerings, licensing arrangements or other collaborations, government funding arrangements, debt financings, or any combination thereof. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our H Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the [**REDACTED**] of our H Shares to decline.

Potential investors will experience immediate and substantial dilution as a result of the [REDACTED] and will experience further dilution if we [REDACTED] additional Shares or other equity securities in the future.

Potential investors will pay a [**REDACTED**] per H Share in the [**REDACTED**] that substantially exceeds the per H Share value of our tangible assets after subtracting our total liabilities as of May 31, 2023. Therefore, [**REDACTED**] of our H Shares in the [**REDACTED**] will experience a substantial immediate dilution in [**REDACTED**] net tangible assets, and our existing Shareholders will receive an increase in the [**REDACTED**] adjusted net tangible assets per Share on their Shares. As a result, if we were to distribute our net tangible assets to the Shareholders immediately following the [**REDACTED**], potential investors would receive less than the amount they paid for their H Shares. For more details, please refer to "Appendix II – Unaudited [**REDACTED**] Financial Information" to this document.

In order to expand our business, we may consider [**REDACTED**] and issuing additional Shares in the future. Purchasers of our H Shares may experience dilution in the net tangible asset value per share of their H Shares if we [**REDACTED**] additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time. Furthermore, we may grant additional share-based compensation to eligible personnel and [**REDACTED**] additional Shares pursuant to share incentive schemes in the future, which would further dilute Shareholders' interests in our Company.

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

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

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

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

Certain facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources and for reference only, including information provided or published by government agencies, and we can not guarantee either the quality nor reliability of such source materials. We believe that the information originated from appropriate sources and was extracted and reproduced after taking reasonable care. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, neither we, the Sole Sponsor, the [**REDACTED**], the [**REDACTED**] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the pharmaceutical industry in and outside China may be inaccurate, and you should not place undue reliance on 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 statements and information that are forward-looking and uses forward-looking terminology such as "believe," "expect," "estimate," "predict," "aim," "intend," "will," "may," "plan," "consider," "anticipate," "seek," "should," "could," "would," "continue," and other similar expressions. You are cautioned that reliance on any forward-looking statement involves risks and uncertainties and that any or all of those assumptions could prove to be inaccurate and, as a result, the forward-looking statements based on those assumptions could also be incorrect. In light of these and other risks and uncertainties, the inclusion of forward-looking statements in this document should not be regarded as representations or warranties by us that our plans and objectives will be achieved, and these forward-looking statements should be considered in light of various important factors, including those set forth in this section. Subject to the requirements of the Listing Rules, we do not intend publicly to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events, or otherwise. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to this cautionary statement.

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. You should rely solely upon the information contained in this document, the [**REDACTED**] and any formal announcements made by us in making your investment decision regarding our H Shares. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.