An investment in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an investment in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In any such case, the market price of our Shares could decline, and you may lose all or part of your investment.

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

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) key risks relating to our business, business operations, intellectual property rights and financial prospects; (ii) other risks relating to our financial position and need for additional capital; (iii) other risks relating to our business, comprising (a) risks relating to the development of our drug candidates, (b) risks relating to extensive government regulations, (c) risks relating to manufacturing of our products, (d) risks relating to commercialization of our products, (e) risks relating to our intellectual property rights; and (f) risks relating to our reliance on third parties; (iv) risks relating to our operations; (v) risks relating to our doing business in China; and (vi) risks relating to the [**REDACTED**].

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

KEY RISKS RELATING TO OUR BUSINESS, BUSINESS OPERATIONS, INTELLECTUAL PROPERTY RIGHTS AND FINANCIAL PROSPECTS

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

The pharmaceutical industries are subject to intense competition and rapid and significant technological change. We face fierce competition from existing products and product candidates under development in the entire oncology market, in addition to approved oncology therapy options including surgery, radiotherapy and chemotherapy, and we will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are developing our drug candidates in competition with a number of pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the same

target indications as ours. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial, technical and human resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Competition may increase further as a result of advances in the commercial applicability of new or disruptive technologies.

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

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

The market opportunities for our Core Product may be small as it mainly targets late line treatment for most of its targeted indications and is limited to those patients who have failed prior treatments.

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 immuno-oncology therapies including cell therapies. Medication treatment with chemotherapy, targeted drugs and immuno-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 the fewest number of side effects. In contrast, second-line treatments are used when the first-line treatment failed to improve a cancer, or if the first-line worked initially before and then the cancer progressed. Third-line treatment may be adopted if previous treatments failed.

Our Core Product is primarily developed to target second line or later stage of treatment for cancer patients. Consequently, it is only approved for treatment of patients who are have failed prior treatments, limiting its target patients group in nature. According to J Clin Oncol. 2016 Sep 20;34(27):3300-7., J Anus Rectum Colon. 2021; 5(1): 11–24., Gastroenterology Report, Volume 9, Issue 4, August 2021, Pages 279–289., KEYNOTE-177., KEYNOTE-158., TUMOR, 2015, 35(3): 322-332, the second line progression percentage for MSI-H/dMMR solid tumors, the approved target indication of our Core Product, is only over 50% in previously treated MSI-H/dMMR advanced solid tumors. These numbers have been derived from a variety of sources, such as scientific literature or surveys of clinics, and they may prove to be incorrect. Regulatory authorities also may establish narrower definitions around when a patient is ineligible for other treatments than we have used in our projections, and that would reduce the size of the patient population eligible for our drug candidates. Furthermore, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our Core Product may be limited or may not be amenable to treatment with our Core Product.

Our market opportunities may also be limited by competitor treatments that may enter the market. See the risk factor above "Risk Factors – Key Risks Relating to Our Business, Business Operations, Intellectual Property Rights and Financial Prospects – We face substantial competition in the entire oncology market and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do."

Our business and financial prospects depend substantially on the success of our products, clinical-stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals or 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 realize profitability is dependent on our ability to successfully complete the development of our products and drug candidates, obtain necessary regulatory approvals, and manufacture and commercialize our products and drug candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing product and drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our products and drug candidates.

The majority of our drug candidates are still in pre-clinical and clinical development. We have obtained investigational new drug, or IND, approvals from the NMPA, PMDA, FDA or other regulatory authorities for the relevant indications of our drug candidates in clinical development. However, we cannot guarantee that we will be able to obtain additional regulatory approvals for our products and drug candidates in a timely manner, or at all, which could be subject to various factors, including without limitation, the ongoing conflicts between the U.S. and China. Significant delays in our ability to obtain approval for and/or to successfully commercialize our products and drug candidates would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Most of our product and drug candidates will require additional clinical development, regulatory approvals, development of manufacturing supply and capacity, substantial investment and significant marketing efforts before we generate any revenue from product sales. Further, our licensors are concurrently conducting clinical trials for some of our in-licensed drug candidates in the U.S. or other countries. We are not in control of such clinical trials or their strategies for obtaining regulatory clearance and our licensors may be driven by strategical goals or concerns that do not align with ours. If our licensors fail to obtain regulatory approval for those drug candidates in the U.S. or other countries, it would be more difficult for us to obtain regulatory approval from the regulatory authorities in other jurisdictions where we have exclusive rights to develop the drug candidates for regulatory approval. We may need to conduct additional clinical trials to obtain more clinical data than we have originally planned, which may result in increased costs or affect the timing or outcome of our planned clinical trials, adversely affecting our ability to advance the development of our products and drug candidates.

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

- successful enrollment of patients in, and completion of, clinical trials, as well as completion of pre-clinical studies;
- favorable safety and efficacy data from our pre-clinical studies, clinical trials and other studies;
- obtaining 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;
- obtaining sufficient supplies of any drug products that are used in combination with our products and drug candidates, competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials;
- capabilities and competence of our collaborators to perform their duties under their agreements with us, 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 effort;
- establishing sufficient commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;

- 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;

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

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

- obtaining and maintaining favorable reimbursement from third-party payers for drugs, if and when approved;

- competition with other drug candidates and drugs; and

- continued acceptable safety profile of our products and drug candidates following regulatory approval.

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

Investment in pharmaceutical drug companies is highly speculative. We have incurred substantial R&D expenses to date, and expect to continue to incur significant expenses related to clinical trials and pre-clinical studies. However, we cannot assure you that our drug candidates will obtain regulatory approvals and/or become commercially viable. 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.

Substantially all of our operating losses have resulted from costs and expenses incurred by our research and development programs and in relation to our operations. The amount of our future net losses will depend, in part, on our future expenditures resulted from costs and expenses incurred by our research and development programs and in relation to our operations, the cost of commercializing any approved products, 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. 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 product pipeline;
- initiate pre-clinical, clinical or other studies for new drug candidates;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- manufacture our drug candidates for clinical trials and for commercial sale;
- develop and expand our commercialization team to commercialize any drug candidates in our pipeline for which we may obtain regulatory approval;
- acquire or in-license other drug candidates, intellectual property assets and technologies;
- incur costs to develop or manufacture drug candidates under any collaboration or in-license agreements;
- maintain, protect, expand and enforce our intellectual property portfolio;
- attract and retain skilled personnel, and grant share options to our employees under our share incentive schemes; and
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

In addition, considering the numerous risks and uncertainties associated with regulatory approval, we are unable to accurately predict the timing or amount of additional expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the NMPA, FDA or other similar authorities to perform studies in addition to those that we currently anticipate. Even if our drug candidates are approved for commercial sale, we expect to continue incurring significant costs associated with the manufacturing and the commercial launch of the drug candidates.

Even if we are able to generate revenue from the sale of our approved drug candidates, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or obtain sufficient equity or debt financings, we may be unable to continue our operations according to our plans and be forced to scale back our operations. Moreover, even if we manage to achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. Our failure to become and remain profitable may also impact investors' perception of the potential value of our company and could impair our ability to raise additional capital, expand our business or continue our operations. Failure to become and remain profitable may also adversely affect the market price of our Shares. A decline in the market price of our Shares could cause potential investors to lose all or part of their investment in our business.

We are exposed to credit risk of our customers and we may experience delays or defaults in our trade and other receivables.

Our trade receivables as of December 31, 2020 and 2021 and May 31, 2022, were nil, RMB65.1 million and RMB101.9 million, respectively. Our loss allowance for impairment of trade receivables in 2020, 2021 and the five months ended May 31, 2022 were nil, RMB130,000 and RMB204,000, respectively. In the event that Simcere Group, or a significant number of our customers fail to settle the trade receivables in full for any reason, our cashflow level may be adversely affected, and we may have to make provision for impairment, write-off the receivables and/or incur legal costs to recover the outstanding sum from Simcere Group or our customers, which may in turn have a material and adverse impact on our business, financial conditions and results of operations.

We have entered into collaborations with our partners, including Alphamab Group, and may form or seek additional collaborations or strategic alliances or enter into additional licensing or sub-licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing or sub-licensing arrangements, and disputes may arise between us and our collaboration partners.

We have in the past entered into co-development and licensing arrangement and may in the future seek and form further collaborations or strategic alliances, or enter into additional co-development and licensing arrangement, including entering into co-development and 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. We entered into the Co-Development Agreements with Alphamab Group through which we maintain the rights to develop our Core Product envafolimab globally in oncology field and co-own patent rights in relation to envafolimab. In addition, certain of our collaboration agreements are sub-licensing arrangements that involve our collaborator sub-licensing us intellectual property developed by third parties. For more details of our collaboration agreements, please refer to the paragraphs headed "Business – Collaboration Agreements" in this document. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

Our strategic collaboration with partners involves numerous risks, which may include the following:

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

- collaboration partners may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaboration partners may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new design of a drug candidate for clinical testing;

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

- collaboration partners may renew the existing collaboration agreements with us on less favorable terms to us;

- collaboration partners with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

- disputes may arise between a collaboration partner and its sub-licensor or between us and a collaboration partner 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;

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

- 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 litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; and

- collaborations may be terminated and, if terminated, may result in our inability to generate revenue in the foreseeable future and a need for additional capital to pursue further development or commercialization of the applicable drug candidates.

Under the Co-Development Agreements with Alphamab Group, the worst case scenario in the event of termination is that the non-breaching party would have unilateral decision-making power over envafolimab and the licensing of the Patent Rights. For further details on the Co-Development Agreements, please refer to the paragraph headed "Business – Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab."

Under the SELLAS Agreement, in the event of termination, depending on the reason for the termination, the consequences could be that (i) all licenses and other rights granted by SELLAS Group to us shall terminate, and all of our rights under the intellectual property with respect to the SELLAS Licensed Products shall revert to SELLAS Group; (ii) we shall cease any and all development, manufacture and commercialization activities relating to the SELLAS Licensed Products; and (iii) we shall, at our own cost, wind down any of our ongoing clinical trials of the SELLAS Licensed Products or transfer such clinical trials to SELLAS Group. For further details on the SELLAS Agreement, please refer to the paragraph headed "Business – Collaboration Agreements – Collaboration with SELLAS Group for 3D189 and 3D059."

Under the Aravive Sub-Licensing Agreement, in the event of termination, the consequences could be that (i) all licenses and other rights granted by Aravive to us would terminate, and all of our rights under the licensed intellectual property in relation to 3D229 shall revert to Aravive; and (ii) we would, at our own cost, wind down any ongoing clinical trials for 3D229 or and transfer such clinical trials to Aravive, unless the Aravive Sub-Licensing Agreement is terminated by us due to Aravive's material breach or bankruptcy, at Aravive's reasonable request. For further details on the Aravive Sub-Licensing Agreement, please refer to the paragraph headed "Business – Collaboration Agreements – Collaboration with Aravive for 3D229."

Under the ImmuneOncia Agreement, in the event of termination, the consequences could be that (i) the license granted by ImmuneOncia to us would terminate; and (ii) we would terminate our ongoing clinical trial for 3D197 or, if ImmuneOncia agrees, transfer such clinical trial to ImmuneOncia. For further details on the ImmuneOncia Agreement, please refer to the paragraph headed "Business – Collaboration Agreements – Collaboration with ImmuneOncia for 3D197."

Under the Y-Biologics Agreement, in the event of termination, the consequences could be that (i) the license granted by the Y-Biologics to us would terminate and revert to Y-Biologics; (ii) unless our activities, rights and benefits under the Y-Biologics Agreement have been adversely affected by Y-Biologics's breach, we would still pay the 50% development costs, upfront payment, milestone payments and royalty payments; and (iii) we would terminate the ongoing clinical trial of 3D057 or transfer such clinical trial to Y-Biologics or its designee. For further details on the Y-Biologics Agreement, please refer to the paragraph headed "Business – Collaboration Agreements – Collaboration with Y-Biologics for 3D057."

Furthermore, a number of our collaboration partners are listed companies in various jurisdictions and subject to the compliance with securities laws and regulations in such jurisdictions. However, there is a risk that, if our collaboration partners fail to comply and were subject to securities litigations, they would be adversely impacted and our existing relationship with them would be jeopardized. In addition, we may not achieve the revenue and cost synergies expected from the transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that these synergies will be achieved.

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 of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

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

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;

- difficulty of effective enforcement of contractual provisions in local jurisdictions;

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

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

- unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements;

- economic weakness, including inflation;

- compliance with tax, employment, immigration and labor laws for employees traveling abroad;

- the effects of applicable foreign tax structures and potentially adverse tax consequences;

- currency fluctuations, which could result in increased operating expenses and reduced revenue;

- workforce uncertainty and labor unrest;

- failure of our employees and contracted third parties to comply with United States Department of the Treasury's Office of Foreign Assets Control rules and regulations and the United States Foreign Corrupt Practices Act of 1977, as amended ("**FCPA**"); and

- business interruptions resulting from geopolitical actions, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. If our drug candidates or our collaborators' data 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 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 unsatisfactory clinical trial results. In addition, if we terminate our studies or cease further development of certain of our drug candidates due to the change of our strategy, we would also have expended a significant amount of capital and would not realize any revenue on such drug candidate. Such an uncompensated expenditure could materially adversely affect our business, financial condition, results of operations and prospects.

The International Multi-Regional Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》) (the "**Multi-Regional Clinical Trial Guidelines**"), promulgated by the CFDA in January 2015 and came into effect in March 2015, provided guidance on the implementation of international MRCT in China. According to the Multi-Regional Clinical Trial Guidelines, international MRCT applicants may simultaneously perform clinical trials in different regions using the same clinical trial protocol. Please refer to the paragraphs headed "Regulatory Overview – Regulations in relation to the Registration of New Drugs – Regulations relating to International Multi-Center Clinical Trials and Acceptance of Overseas Clinical Trial Data" in this document. As we plan to join and use data derived from the international MRCTs for approval of some of our drug candidates, if the international MRCTs conducted by our partners fail to demonstrate satisfactory safety and efficacy profiles, we may not be able to complete the development of such drug candidates. Moreover, if competing drugs conducted by others fail to demonstrate satisfactory safety and efficacy profiles during the development process, it might also adversely impact the development of our related drug candidates.

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

Our drug candidates are considered as emerging and relatively novel cancer therapeutics. The adverse events or side effects of some of our drug candidates in connection with their usage in patients are yet to be thoroughly tested and understood, and may only arise after a longer period of observation. Undesirable adverse events caused by our drug candidates, or caused by our drug candidates when used in combination with other drugs, could potentially cause significant negative consequences, including but not limited to:

- regulatory authorities could interrupt, delay or halt pending clinical trials;
- we may suspend, delay or alter development or marketing of our drug candidates;
- regulatory authorities may order us to cease further development of, or delay or even deny approval of, our drug candidates for any or all targeted indications if results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events;
- regulatory authorities may withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug, issue safety alerts or other communications containing warnings or other safety information of such approved drug, or impose other limitations on such approved drug;

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

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

- we could be subject to litigation proceedings and held liable for harm caused to patients exposed to or taking our drug candidates may suffer from adverse events related to the treatment and patients;

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

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

- the product may become less competitive;

- we could be required to recall our drug candidates 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, and could significantly harm our business, results of operations and prospects.

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, among other things, on our ability to enroll a sufficient number of patients who 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 these trials as required by the NMPA, FDA, PMDA 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:

- severity of the disease under investigation;

- total size and nature of the relevant patient population;
- design and eligibility criteria for the trial in question;
- the size of the study population required for analysis of the trial's primary endpoints;
- our resources to facilitate timely enrollment in trials;
- patient referral practices of physicians;
- the proximity of prospective patients to available trial sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our investigator's or clinical trial site's efforts to screen and recruit eligible patients;
- 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;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will not complete a clinical trial;
- the availability of approved therapies that are similar in mechanism to our drug candidates; and
- the negative impact of COVID-19 on patient enrolment and clinical progress.

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 who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to 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 prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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

Although our R&D capabilities enable us to design, evaluate and select optimal candidates and continue to enrich our pipeline, we cannot guarantee that we will be successful in identifying potential new drug candidates. 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 are technically challenging to develop and manufacture. We may also pursue collaboration with third parties in the discovery, development and in-licensing of potential drug candidates, but we cannot assure you that such collaboration will be able to deliver the intended results. We may not realize the benefits of our existing and future collaborations, strategic alliances or licensing arrangements. Please refer the paragraph headed "– Other Risks Relating to Our Business – Risks Relating to Our Intellectual Property Rights – If we fail to comply with our obligations in the agreements under which we license intellectual property rights to or from third parties or otherwise experience disruptions to our business relationships with our collaborators, we could be required to pay monetary damages or could lose license rights that are important to our business" in this section.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial and human resources. Our research programs may initially show promising results 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;

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

- 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.

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 adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

We 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 collaborators, such as CROs, 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, FDA, PMDA and other comparable regulatory authorities for all of our drug candidates 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, FDA, PMDA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. 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. 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 pre-clinical studies, and clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding 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, financial condition and prospects.

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approval. Our arrangements with such collaborators will be critical to successfully bringing our drug candidates to market and commercializing them. We rely on third-party collaborators in various respects, including but not limited to undertaking research and development programs, conducting clinical trials, managing or assisting with the regulatory filings and approval process, and assisting with our commercialization efforts. We do not control our collaborators; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If 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 collaborators and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product, which could materially and adversely affect our business, financial condition, cash flows and results of operations.

Furthermore, 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 or related actions are taken.

We have no track record and limited experience in commercialization of drugs. Although we have entered into marketing agreements with third party CSOs, if we are unable to build 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 when approved. As a result, 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 launching and marketing drug candidates.

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 for any or all of our future approved drugs, we will likely continue to rely on collaborative arrangements regarding the sales and marketing of our drug candidates. We entered into a tripartite collaboration agreement with Alphamab Group and Simcere Group, together with a separate marketing and promotion agreement with Simcere Group, pursuant to which Simcere Group is responsible for the exclusive commercial promotion of the future approved product in China. Please refer to the paragraphs headed "Business – Collaboration Agreements – Collaboration with Alphamab Group and Simcere Group for Envafolimab" in this document for more details. However, there can be no assurance that we are or will be able to establish or maintain such collaborative arrangements with third party CSOs such as Simcere Group, 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, which may not be successful. 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 when approved.

In particular, given the limited experience generally in marketing recently approved innovative drugs in China, there can be no assurance that we will be able to further develop and successfully maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaboration partners to successfully commercialize any product. As a result, we may not be able to generate product sales revenue.

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

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect our product, drug candidates and technologies that we consider commercially important by filing patent applications in China, the U.S. and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. In particular, we have sought patents in China, the U.S., Japan and various other jurisdictions for our Core Products. For further information on our patent portfolio, please refer to the paragraphs headed "Business – Intellectual Property" in this document. Certain of our collaboration partners or their sub-licensors are responsible for or have the first right to prosecute, maintain and/or enforce the certain patents relevant to our product, drug candidates and technologies. For example, we and Alphamab Group are jointly responsible for the prosecution and maintenance of the patents we co-own. Further, with respect to any patents and/or patent applications in-licensed from Alphamab Group to us, Alphamab Group as the patentee is legally responsible for the prosecution, maintenance and enforcement of such licensed patents and/or patent applications according to patent laws and regulations. For details, please refer to the paragraphs headed "Business – Collaboration Agreements" in this document. If we or any of our collaboration partners or sub-licensors fail to obtain or maintain patent protection, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our product and drug candidates in the worst-case scenario. Even if we or any of our collaboration partners or sub-licensors are successful in defending against any claims challenging the inventorship of our owned or in-licensed patents, patent applications or other intellectual property, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Any failure by us or our collaboration partners or sub-licensors to obtain or maintain patent protection with respect to our product, drug candidates and technologies could materially adversely affect 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 other third parties from developing and commercializing competitive drugs in all such fields and jurisdictions.

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

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. Our pending and future patent applications may not be granted with approvals, while not being granted with such approvals may effectively prevent third parties from commercializing competitive technologies and biosimilar drug candidates. For more details, please refer to the paragraphs headed "Business – Intellectual Property" in this document. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we generally 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, collaboration partners, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we or our licensors were the first to file for patent protection of such inventions. Furthermore, China and, recently, the U.S. have adopted the "first-to-file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, even after reasonable investigation we may be unable to determine with certainty whether any of our drug candidates, processes, technologies, inventions, improvement and other related matters have infringed upon the intellectual property rights of others, because such third party may have filed a patent application without our knowledge while we are still developing that product, and the term of patent protection starts from the date the patent was filed, instead of the date it was issued. Therefore, the validity of issued patents, patentability of pending patent applications and applicability of any

of them to our programs may be lower in priority than third-party patents issued on a later date if the application for such patents was filed prior to ours and the technologies underlying such patents are the same or substantially similar to ours. If such a third party can establish that we or our licensors were not the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable, and third parties may be granted a patent relating to a technology which we invented.

We are primarily focused on protecting our intellectual property rights in our target markets, which are China, the U.S., Japan and other jurisdictions. Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights with respect to our drug candidates in all other jurisdictions throughout the world would be prohibitively expensive for us. Besides, the actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular jurisdiction and the validity and enforceability of the patent. Our intellectual property rights in certain jurisdictions may have a less or different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of our target markets. Consequently, in some cases, we may not be able to obtain issued patents or other intellectual property rights covering our drug candidates in jurisdictions outside our target markets and, as a result, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions in and into our target markets or other jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent and other intellectual property protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patent or other intellectual property protection, but where enforcement rights are not as strong as those in markets such as the U.S. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions such as China. The legal system in these jurisdictions, particularly those in certain developing countries, does not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights in these jurisdictions. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and other intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a commercial advantage from the intellectual property that we develop or license. In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the NIPA, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Our drug candidates require substantial investments for the completion of clinical development, regulatory review, drug manufacturing, marketing and launch before they can generate product sales revenue. Our operations have consumed substantial amounts of cash since our inception. We will need to expend substantial resources on the research and development and commercialization of our product pipelines. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely identify and enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the progress, timing, scope and costs related to discovery and early development of additional drug candidates;
- the preparation required for anticipated commercialization of our drug candidates, and if regulatory approvals are obtained, to fund the product launch;
- the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates;
- selling and marketing costs associated with any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the amount and timing of any profit sharing, milestone and royalty payments we receive from our current or future collaboration partners;
- cash requirements of any future development of other pipeline drug candidates; and
- our headcount growth and associated costs.

We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates, and launching and commercializing any approved drug candidates for which we receive regulatory approvals. However, if the commercialization of our drug candidates is delayed or terminated, or if the expenses associated with drug development and commercialization increase substantially, we may need to obtain additional financing to fund our operations. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Our ability to raise funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate pre-clinical studies, clinical trials or other research and development activities or commercialization for one or more of our drug candidates, and in turn will adversely affect our business prospects.

We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control, including the COVID-19 outbreak, which may have a material adverse effect on our business, financial condition and results of operations.

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

The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in China or elsewhere in the world could materially disrupt our business and operations. For example, the recent outbreak of COVID-19 has affected many people globally, caused temporary suspension of productions and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy. The exacerbation, continuance or reoccurrence of COVID-19 has already caused and may continue to cause an adverse and prolonged impact on the economy, geopolitical and social conditions in China and other affected countries. Since late July 2021, the COVID-19 has recurred in the form of the Delta variant in China and overseas, and since November 2021, another variant designated as Omicron (together with the Delta variant, the "**COVID-19 Variants**") has also been discovered in many cases over the globe (the "**Recurrences**"). Recently, the Chinese government has implemented emergency measures in certain cities or regions, including Shanghai, in response to the Recurrence, including travel restrictions, mandatory cessations of business operations, mandatory quarantines, and limitations on social and public gathering and

lockdowns. The exacerbation, continuance or reoccurrence of COVID-19 has already caused, and may continue to cause, an adverse and prolonged impact on the economy and social conditions in China and other affected countries. The existing clinical trials and the commencement of new clinical trials could also be substantially delayed or prevented by any delay or failure in patient recruitment or enrollment in our or our collaborators' trials as a result of the outbreak of COVID-19 and the Recurrences. These factors could cause delay of clinical trials, regulatory submissions, and required approvals of our drug candidates, and could cause us to incur additional costs. If our employees or employees of our business partners are suspected of being infected with an epidemic disease, our operations may be disrupted because we or our business partners must quarantine some or all of the affected employees or disinfect the operating facilities. If we are not able to effectively develop and commercialize our drug candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, and/or failure to recruit and conduct patient follow-up, we may not be able to generate revenue from sales of our drug candidates as planned.

OTHER RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We had net liabilities and net cash outflows in operating activities during the Track Record Period.

We had net liabilities of RMB1,269.8 million, RMB2,272.6 million and RMB2,509.8 million as of December 31, 2020 and 2021 and May 31, 2022, respectively. We had net current assets of RMB146.7 million as of December 31, 2020 and net current liabilities of RMB2,328.8 million and RMB2,600.6 million as of December 31, 2021 and May 31, 2022, respectively. We had net cash flows used in operating activities of RMB278.3 million, RMB377.1 million and RMB112.9 million for the years ended December 31, 2020, 2021 and the five months ended May 31, 2022, respectively. While we believe we have sufficient capital to fund our current operations, we expect that we may have net liabilities and experience net cash outflows from operating activities for the foreseeable future. A net current liabilities or net liabilities position can expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources such as equity or equity-linked instruments and external debt, which may not be available on terms favorable or commercially reasonable to us or at all. If we are unable to maintain adequate working capital or obtain sufficient equity or debt financings to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale down our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We have a limited operating history and have only recently begun commercializing our drug candidates, which may make it difficult to evaluate our current business and predict our future performance.

We are a development-stage biotechnology company with a relatively short operating history as a standalone company. Please refer to the section headed "History, Development and Corporate Structure" in this document. Our operations have focused on the pre-clinical studies and clinical trials of oncology-focused drug candidates. We also have limited experience in commercial-scale manufacturing and sales of drugs. For these reasons, particularly in light of the rapidly evolving pharmaceutical industry, it may be difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

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

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through equity or convertible equity-linked securities, the value of 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 Shares. Incurring additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and 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, the issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline.

In the event we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party our rights to technologies or drug candidates on unfavorable terms, which we would have otherwise sought to develop or commercialize ourselves or reserve for future potential arrangements when we are more likely to achieve more favorable terms.

Fair value changes in our financial instruments issued to investors and related valuation uncertainty may materially affect our financial condition and results of operations.

The financial instruments with preferred rights, which mainly includes our preferred shares during the Track Record Period, were not traded in an active market and the fair value is determined by using valuation techniques. The discounted cash flow method and back-solve method were used to determine the underlying share value and the equity allocation model was adopted to determine the fair value of the financial instruments with preferred rights as of each date of issuance and as of December 31, 2020 and 2021 and May 31, 2022. Key valuation assumptions used to determine the fair value of the preferred shares include risk-free interest

rate, volatility and discount for lack of marketability. Any change in the assumptions may lead to different valuation results and, in turn, changes in the fair value of these financial instruments with preferred rights. To the extent we need to revalue the financial instruments with preferred rights prior to the closing of the [**REDACTED**], any change in fair value of the financial instruments with preferred rights and related valuation uncertainty, for example, resulted from the use of unobservable inputs, could materially affect our financial position and performance. As of December 31, 2020 and 2021 and May 31, 2022, we recorded financial instruments with preferred rights as our non-current liabilities of RMB1,430.4 million, RMB38.8 million and RMB42.5 million, respectively. We also recorded fair value losses on preferred shares of RMB319.2 million, RMB954.7 million and RMB143.6 million as of December 31, 2020 and 2021 and May 31, 2022, respectively. We expect that we will recognize significant additional losses on the fair value changes of the financial instruments with preferred rights from December 31, 2020 to the [**REDACTED**] because of the significant increase in the fair value of such financial instruments during such period. After the automatic conversion of all preferred shares into Shares upon the closing of the [**REDACTED**], we do not expect to recognize any further gains or losses on fair value changes from the financial instruments with preferred rights in the future.

Fair value change for financial assets at fair value through profit or loss may materially affect our financial performance.

We had financial assets at FVTPL of nil, RMB50.2 million and RMB50.0 million, as of December 31, 2020 and 2021 and May 31, 2022, respectively, which were wealth management products we purchased from banks in China. Pursuant to the Guidance on Regulating Financial Institution's Asset Management Business (《關於規範金融機構資產管理業務的指導意見》) promulgated by the People's Bank of China, the China Banking and Insurance Regulatory Commission, the China Security Regulatory Commission and the State Administration of Foreign Exchange on April 27, 2019, financial institutions selling wealth management products shall not guarantee the returns of principal and interest of such products. As a result, the returns of our investments on the wealth management products were not guaranteed, and therefore were measured at fair value through profit or loss. We are exposed to credit risks in relation to these financial assets, which may adversely affect their fair value.

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

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

We adopted share incentive scheme for the benefit of our employees as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our Company. For details, please refer to the paragraphs headed "History, Development and Corporate Structure – Share Incentive Scheme" in this document. During 2020, 2021 and for the five months ended May 31, 2022, we incurred share-based payments of nil, RMB105.1 million and RMB55.4 million, respectively. To further incentivize our employees to contribute to us, we may grant additional share-based payments in the future. Issuance of additional Shares with respect to such share-based payments may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payments may also increase our operating expenses and therefore have a material and adverse 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, among other things, the policies of the PRC Government and changes in China's international, political and economic conditions, as well as supply and demand in the local market. It is difficult to predict how market forces or government policies may impact the exchange rate between RMB and the Hong Kong dollar, the U.S. dollar or other currencies in the future. In addition, the PBOC regularly intervenes in the foreign exchange market to limit fluctuations in RMB exchange rates and achieve policies goals.

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

Substantially all of our costs are denominated in RMB and U.S. dollars, most of our assets are cash and bank balances primarily denominated in RMB and U.S. dollars, and our [**REDACTED**] from the [**REDACTED**] will be denominated in Hong Kong dollars. In 2020, 2021 and for the five months ended May 31, 2021, we had foreign exchange losses of RM5.9 million, RMB3.7 million and RMB1.4 million, respectively, while for the five months ended May 31, 2022, we had foreign exchange gains of RMB17.8 million resulted from the appreciation of the U.S. dollar against RMB. Any significant change in the exchange rates of the Hong Kong dollar against RMB or U.S. dollars against RMB may materially and adversely affect the value of and any dividends payable on, our Shares in Hong Kong dollars.

OTHER RISKS RELATING TO OUR BUSINESS

Risks Relating to the Development of Our Drug Candidates

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical trials are expensive, difficult to design and implement, and can take years to complete with inherent uncertainty as to outcome. Failure can occur at any time during the clinical trial process.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive 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;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the 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 number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- our drug candidates may lack meaningful clinical responses or the participants may be exposed to unacceptable health and safety risks;
- regulators may require that we or our investigators suspend or terminate clinical research for various reasons such as non-compliance with regulatory requirements;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;
- 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; and
- 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.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, 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;
- obtain approval for proposed indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

Delays in clinical trials 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 delays in clinical trials could also shorten any periods during which we have the 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.

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 successful initial or interim results of a clinical trial do not necessarily predict successful final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. 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. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives.

In some instances, there can be significant variability in safety 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 type of the patient populations, including ethnical and genetic differences, patient adherence to the dosing regimen and other trial protocol elements, the rate of dropout among clinical trial participants, and other compounding factors, such as other medications or pre-existing medical conditions. In the case of any trials we conduct, results may differ from earlier trials due to, among other things, the larger number of clinical trial sites, additional countries and languages involved in such trials, the different conductors of our conducting the trials, different clinical trial standards required in different jurisdictions, different patient population, and different standard of care and pretreatment of patients before enrolling in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, which could delay completion of clinical trials, delay approval of our drug candidates and/or jeopardize our ability to commence commercialization of our drug candidates.

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 in-licensed 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. 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 development and commercialization rights to such drug candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Risks Relating to Extensive Government Regulations

All material aspects of the research, development, manufacturing and commercialization of our drug candidates are heavily regulated.

All jurisdictions in which we intend to develop and commercialize our drug candidates regulate these activities in great depth and detail. We intend to focus our activities in China while pursuing international opportunities, such as in the U.S. and Japan. These jurisdictions all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of the development, approval, manufacturing, marketing, sales and distribution of 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. 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, however, it is unknown at this time whether and what specific policies and actions will be adopted by the U.S. government. Our business and operations in the U.S. primarily involve conducting clinical trials subject to the approval of the FDA. We therefore expect that the Executive Order will have no immediate impact on our research and development activities in the United States. Nevertheless, 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 investment of substantial time and financial resources. Any recently enacted and future legislation may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical industry, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures, which would lower the entry barrier for potential competitors, or an increase in regulatory requirements, which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations, and prospects.

Failure to comply with the applicable requirements at any time during the product development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include but are not limited to a regulator's refusal to approve pending applications, withdrawal of an approval, revocation of a license, a holding off of clinical trials, voluntary or mandatory recalls of products, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties. Any occurrence of the foregoing could therefore materially adversely affect our business, financial condition, results of operations and prospects.

The regulatory approval processes of the NMPA, FDA, PMDA and other comparable regulatory authorities 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 countries, our business may be substantially harmed.

The time required to obtain approval by the NMPA, FDA, PMDA, and other comparable regulatory authorities is inherently unpredictable but typically takes 10-15 years following the commencement of pre-clinical studies and clinical trials and depends on numerous factors in recent years, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. We cannot guarantee that we will be able to obtain regulatory approvals for our existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future.

Our drug candidates could fail to receive regulatory approval of the NMPA, FDA, PMDA or a comparable regulatory authority for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities in the design or implementation of our clinical trials;
- failure to demonstrate that our drug candidate is safe, pure and potent for its proposed indications;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure of our clinical trial process to pass relevant good clinical practice, or GCP, inspections;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- insufficient data collected from the clinical trials of our drug candidates or disagreement with our interpretation of data from pre-clinical studies or clinical trials that result in failure to support the submission and filing of a new drug application, or NDA, or other submissions or to obtain regulatory approval;
- failure of our drug candidates to pass current Good Manufacturing Practice, or GMP, inspections during the regulatory review process or across the production cycle of our drug;
- failure of our clinical sites to pass audits carried out by the NMPA, FDA, PMDA or comparable regulatory authorities, resulting in a potential invalidation of our research data;

- findings by the NMPA, FDA, PMDA or comparable regulatory authorities of deficiencies related to our manufacturing processes or the facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;

- changes in approval policies or regulations that render our pre-clinical and clinical data insufficient for approval;

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

- data integrity issues related to our clinical trials;

- disagreement with our interpretation of data from pre-clinical studies or clinical trials; and

- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

The NMPA, FDA, PMDA or comparable regulatory authorities may require more information, including additional analyses, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. Even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, FDA, PMDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. For example, the Guiding Principles for Clinical Research and Development of Anti-Tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》) (No. 46[2021], the "**Guiding Principles**") issued by NMPA's Center for Drug Evaluation came into force in November 2021. The Guiding Principles call for a patient-oriented approach to the R&D of oncology drugs and require drug innovators to use the standard-of-care treatment as control in late-stage clinical trials, rather than comparing to treatments that have already been replaced in clinical practice. Consequently, it may increase the cost of conducting oncology drug trials and raise the bar for regulatory approval. 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.

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.

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

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

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

We believe that our drug candidates' Category 1 designation in China should confer certain regulatory advantages on us. These advantages may not result in commercial benefits to us as we have expected, and these advantages may change in the future in a manner adverse to us.

In China, prior to seeking approval from the NMPA, a pharmaceutical company needs to determine the drug's registration category, which will determine the requirements for its clinical trial and marketing application. Among our pipeline of 12 drug candidates, eight are in clinical development in China, all of which are designated as Category 1 drug candidates.

The NMPA has adopted several mechanisms for expedited review and approval for drug candidates that apply to Category 1 drug candidates. While we believe that the Category 1 designation of our internally developed clinical stage drug candidates should provide us with a significant regulatory, and therefore commercial, advantage over non-Chinese companies seeking to market products in China, we cannot be sure that this will be the case. The pharmaceutical regulatory environment is evolving quickly, and changes in laws, regulations, enforcement and internal policies could result in the "favored" status of Category 1 products changed, or being eliminated altogether or our products classification in Category 1 changed. We cannot be certain that the advantages we believe will be conferred by our Category 1 classifications will be realized or result in any material development or commercial advantage.

We may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials.

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

Such data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects' private or medical records without their consent, they will be held liable for damages caused thereby. We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring our employees to maintain the confidentiality of our subjects' medical records. However, these measures may not always be effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials frequently also involve professionals from third party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. Please refer to the paragraphs headed "– Risks Relating to Our Operations – Our internal information technology and other infrastructure, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches" in this section. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure to protect the confidentiality of subjects' medical records and personal data, or any restriction on or liability as a result of, our use of medical data, could have a material adverse effect on our business, financial condition and results of operations.

The Data Security Law of the PRC (《中華人民共和國數據安全法》), which took effect on September 1, 2021, provides that the relevant authorities will promulgate measures for cross-border transfers of important data. If any company violates the Data Security Law of the PRC to provide important data outside China, it may be subject to penalties, fines, suspension of business operation and/or revocation of business license. However, as of the Latest Practicable Date, the Chinese government has not promulgated the important data catalogs.

In addition, there are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as "**protected health information**") and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly

disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act ("**HITECH**"), and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services ("**HHS**"), and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

Additionally, the Gramm-Leach-Bliley Act of 1999 (along with its implementing regulations) (the "**GLBA**") restricts certain collection, processing, storage, use and disclosure by covered companies of certain personal information, requires notice to individuals of privacy practices and provides individuals with certain rights to prevent the use and disclosure of certain non-public or otherwise legally protected information. The GLBA also imposes requirements regarding the safeguarding and proper destruction of personal information through the issuance of data security standards or guidelines. In addition, many U.S. states have laws that protect the privacy and security of sensitive and personal information. Certain U.S. state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Consumer Privacy Act of 2018 (the "**CCPA**"), which went into effect on January 1, 2020, imposes stringent data privacy and security requirements and obligations with respect to the personal information of California residents and households. Among other things, it requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information that may increase the likelihood of, and risks associated with, data breach litigation. The CCPA was amended in September 2018 and November 2019, and it is possible that further amendments will be enacted. It remains unclear how various provisions of the CCPA will be interpreted and enforced, and multiple states have enacted or are expected to enact similar laws. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we may be subject.

In Europe, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, in the European Economic Area (the "**EEA**") and the United Kingdom, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the "**GDPR**"). The GDPR came into effect in May 2018, superseding the European Union Data Protection Directive, and imposing more stringent data privacy and security requirements on companies in relation to the processing of personal data of EU data subjects. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal data. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates,

the transfer of personal data out of the EEA or the United Kingdom, security breach notifications and the security and confidentiality of personal data. The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater. Such fines are in addition to any civil litigation claims by customers and data subjects. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which contribute to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices is often updated or otherwise revised. Further, while the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit, Brexit has created uncertainty with regard to the future of regulation of data protection in the United Kingdom. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services.

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

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

If the NMPA, FDA, PMDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration,

random quality control testing, adherence to any chemistry, manufacturing, and controls, or CMC, specifications, continued compliance with current GMPs, and GCPs and potential post-approval studies for the purposes of license renewal.

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

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 significantly harm our business, financial condition and prospects.

The NMPA, FDA, PMDA and other regulatory authorities strictly regulate the marketing, labelling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, FDA, PMDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

If we are able to commercialize our drug candidates, we may face uncertainties from national, provincial or other third party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from jurisdiction to jurisdiction. We intend to seek approval to market our drug candidates in China, the U.S., and in other jurisdictions. In both China and the U.S., the pricing of pharmaceutical products is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

In China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), or the National Reimbursement Drug List (the "**NRDL**"), or provincial or local medical insurance catalogues for the National Medical Insurance Program, regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our future approved drugs will be included in the NRDL or relevant provincial or local medical insurance catalogs. Products included in the NRDL or relevant provincial or local medical insurance catalogs are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL or relevant provincial or local medical insurance catalogs due to the affordability of the government's Basis Medical Insurance. In particular, the PRC government has implemented significant reforms of the pharmaceutical industry in recent years and may enforce additional measures in the future which may adversely affect our pricing strategy drugs. Even if our drug candidates have already obtained regulatory approval, any adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates.

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

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

associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates that we successfully develop.

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

We may be directly or indirectly subject to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could, in the event of noncompliance, 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 recommending and prescribing any products for which we obtain regulatory approval. If we obtain the NMPA, FDA, PMDA or other comparable regulatory authorities' approval for any of our drug candidates and begin commercializing those drugs in China, the U.S. or other applicable jurisdictions, our operations may be subject to various fraud and abuse laws of such jurisdictions, including, without limitation, the PRC Anti-Unfair Competition Law (《反不正當競爭法》), the PRC Criminal Law (《刑法》), the Federal Anti-Kickback Statute and the Federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs.

In addition, we 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. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirement, we could be subject to penalties.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the Federal False Claims Act as well as under the false claims laws of several states.

Neither the PRC government nor the PRC courts have provided 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. Furthermore, if any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business.

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

Any tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. The U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs affecting certain products manufactured in China. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry. While we have not started commercialization of drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our future approved drugs, the competitive position of our future approved drugs, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our future approved drugs in certain countries. If any new tariffs, legislation and/or regulations are implemented, or in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations. It also remains unclear what actions, if any, the U.S. government will take with respect to other

existing international trade agreements. If the U.S. were to withdraw from or materially modify certain international trade agreements to which it is a party, especially with respect to intellectual properties transfer, our business, financial condition and results of operations could be negatively impacted.

Risks Relating to Manufacturing of Our Products

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

We have limited experience in large-scale manufacturing of our products for commercial use. Moreover, the manufacturing of pharmaceutical drug products is highly complex. Problems may arise during manufacturing for a variety of reasons, including but not limited to:

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

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 we engage from time to time. Please refer to the paragraphs headed "– Other Risks Relating to Our Business – Risks Relating to Our Reliance on Third Parties – We may rely on third parties to

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

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

We may also encounter problems with achieving adequate or clinical-grade products that meet the NMPA, FDA, PMDA or other comparable regulatory authority standards or specifications, and maintaining consistent and acceptable production costs. We may also experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the equipment in them. In such events, 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. It could delay our clinical trials and/or the availability of our future approved products for commercial sale. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities.

In addition, the quality of our products, including drug candidates manufactured by us for research and development purposes and, in the future, drugs manufactured by us for commercial use, depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. We are, however, working on improving our documentation procedures for quality control and quality assurance activities. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, or not in compliance with the relevant requirements of the GMP 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.

Any delays in completing and receiving regulatory approvals for our manufacturing facilities, or 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 and adverse effect on our business, financial condition and results of operations.

We currently cooperate with third-party collaboration partners to manufacture our existing drug candidates for research and development purposes, and we have been building our in-house production facilities in Xuzhou, Jiangsu province, with cGMP-compliant manufacturing system and facilities to meet stringent global standards. In anticipation of large needs of our drugs upon commercialization, we purchased the use right to land in Xuzhou with an aggregate area of 65,637.97 square meters. We have obtained the construction permit and started construction of new manufacturing facilities in Xuzhou. We expect to complete building the facilities and commence operation by 2024. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction, regulatory evaluation and/or approval of our new facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates and our drugs, if approved, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from various sources.

Our future manufacturing facilities will be required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA, FDA, PMDA 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 cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to any inspection observations if we are to build manufacturing facilities in the future. 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 cGMP regulations or other regulatory requirements may lead to significant delays in the construction of our manufacturing facilities and 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. We cannot assure you that we will not experience any disruptions to the construction of our manufacturing facility, and there could be delays in completing and receiving regulatory approvals for our new manufacturing facility.

In addition, to obtain FDA approval for our products in the U.S., we would need to undergo strict pre-approval inspections of our manufacturing facilities. Historically, manufacturing facilities in China have had difficulty in meeting FDA standards. When inspecting our manufacturing facilities, the FDA may cite cGMP 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 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 could suffer.

Manufacturers of drug products oftentimes encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel and compliance with strictly-enforced regulations. If our manufacturing facilities encounter unanticipated delays and expenses as a result of any of these difficulties, or if construction, regulatory evaluation and/or approval of our new facilities is delayed, we may not be able to

manufacture sufficient quantities of our drug candidates, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could also require us to raise additional funds from other sources.

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

In anticipation of commercialization of our drug candidates, we aim to significantly expand our manufacturing capacity, mainly through the construction of new manufacturing facilities. However, the timing and success of these plans are subject to significant uncertainty.

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

Risks Relating to Commercialization of Our Products

The actual market size of our product and drug candidates might be smaller than expected and our drug and 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 their commercial success.

Some of our product and drug candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods, which carries inherent development risks and could result in delays in clinical development, regulatory approval or commercialization. Our drug and drug candidates (once approved), may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community, who may prefer other drugs to ours. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our drug candidates that are in clinical trials for the same or similar cancer indications. In addition, physicians, patients and third-party payers may prefer other novel products to ours. If our drug or future approved drugs do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drug and drug candidates, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our product and drug candidates are approved;
- physicians, hospitals, medical treatment centers and patients considering our drug to be safe and effective;
- product labeling or package insert requirements of the NMPA, FDA, PMDA or other comparable regulatory authorities, including limitations or warnings contained in the labeling;
- whether our drug and drug candidates have achieved first-in-class or best-in-class status and the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- the timing of market introduction of our drug and drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;

- availability of adequate coverage and reimbursement under the NRDL and provincial reimbursement drug lists in China, or from third-party payers and government authorities in other applicable jurisdictions;

- 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 with alternative treatments and competitive therapies; and

- the effectiveness of our sales and marketing efforts.

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

Risks Relating to Our Intellectual Property Rights

The scope of our patent protection may be uncertain. Our current or any future patents may not be successful and any patent rights we or our licensing partners have may be challenged and invalidated even after issuance, which would materially adversely affect our ability to successfully commercialize any product or technology.

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

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

Despite the measures we or our licensing partners have taken to obtain patent protection with respect to our major drug candidates and technologies, any of such issued patents could be challenged or invalidated. For example, if we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the U.S., for example, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in China, the U.S. or in other jurisdictions, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, interference proceedings, derivation, invalidation, revocation and equivalent proceedings in non-U.S.

jurisdictions, such as opposition proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer adequately cover and protect our drug candidates.

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

Even if we are able to obtain patent protection for our drug candidates, the life 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 or patent rights of similar products, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.

Although various adjustments and extensions may be available, the life of a patent, and the protection it affords, is limited. For example, in the U.S., the expiration of a patent is generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority. In the U.S., a patent's term may be extended or adjusted to account for administrative delays during prosecution by the USPTO, in excess of a patent applicant's own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights. As a result, we may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in "Business – Intellectual Property" of this document. Upon the expiration of our patent rights or patent rights of similar products, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, which could result in downward pricing pressures, 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 owned and licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. 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 products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

The implementation of patent linkage, patent term extension and data and market exclusivity for pharmaceutical products in China and the United States, as applicable, remain uncertain and could increase the risk of early generic competition for our products in China.

In the U.S., the Federal Food Drug and Cosmetic Act (the "**FDCA**"), as amended by the law generally referred to as "Hatch-Waxman," provides the opportunity for limited patent term extension. Hatch-Waxman permits a patent-term restoration that provides a patent term extension of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval; only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. Depending upon the timing, duration and specifics of any FDA marketing approval process for any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under Hatch-Waxman. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we license in from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extensions or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Moreover, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the U.S. Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

In China, the fourth Amendments to the PRC Patent Law (《中華人民共和國專利法》), which was adopted on October 17, 2020 and was put into effect on June 1, 2021, provides a drug-patent linkage system, as well as Patent Term Extension for drug patents.

According to the drug-patent linkage system, "During the review and approval of marketing authorization of a drug, when the applicant of drug marketing authorization and the patentee or interested party have dispute regarding patent rights of the drug under application, relevant parties may file a lawsuit with the people's court and pursue judgement for whether the relevant technical solution of the drug under application falls within the scope of protection of the relevant patent rights. The drug regulatory authority of the State Council may make a decision on whether to suspend the drug marketing authorization according to effective judgment of the people's court within specified period. The applicant of drug marketing authorization and the patentee or interested party may also apply for an administrative ruling to the patent administration department of the State Council regarding patent right dispute related to the drug under application of marketing authorization."

As to the Patent Term Extension for drug patents, the fourth Amendments provides that, "In order to compensate for the time occupied by review and approval for marketing the new drugs, the patent administration department of the State Council may extend the period of the patent right for an invention patent of new drug that obtains the marketing authorization in China upon the patentee's request. The compensation period shall not exceed 5 years, and the total effective term of the patent right of the innovative drug after being put into the market shall not exceed 14 years.", which is in line with corresponding provisions in the Economic and Trade Agreement Between the Government of the People's Republic of China and the Government of the United States of America (中華人民共和國政府和美利堅合眾國政府經濟貿易協議) with the U.S. government entered into in January 2020.

Certain detailed implementation rules and interpretation rules for drug-patent linkage are published for solicitation of public comments, including Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial) (《藥品專利糾紛早期解決機制實施辦法(試行)》) published by the NMPA and the China National Intellectual Property Administration the "CNIPA") on July 4, 2021, and Provisions on Several Issues Concerning

the Application of Law in the Trial of Patent Civil Cases Involving Drug Marketing Review and Approval of Patent (Draft for Solicitation of Comments) (《關於審理涉藥品上市審評審批專利民事案件適用法律若干問題的規定(徵求意見稿)》) published by Supreme People's Court on October 29, 2020. However, the implementing rules for the drug-patent linkage system have not yet been adopted and therefore the implementation, interpretation and enforcement of laws and regulations regarding the drug-patent linkage system remain uncertain in China.

In view of the uncertainty in the implementation rules in patent term extension and patent linkage, and also in view of the lack of effective law or regulation providing regulatory data protection, a lower-cost generic drug can emerge onto the market much more quickly. These factors result in weaker protection for us against generic competition in China than could be available to us in the United States. For instance, it remains unclear whether the patents we have in China would be eligible to be extended for patent term lost during clinical trials and the regulatory review process, and currently no regulatory data protection is available to us to extend exclusivity of our drug products. If we are unable to obtain patent term extension, or the term of any such extension is less than that we request, our competitors or other third parties may obtain approval of competing products following our patent expiration. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Competitors or other third parties may infringe our or our licensors' patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement, misappropriation or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Therefore, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

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

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

Moreover, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our drug candidates.

Additionally, while we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaboration partners or other third parties have an interest in our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, collaboration partners, consultants or others who are involved in developing our drug candidates or technology. Litigation may be necessary to defend against these and other claims challenging inventorship of our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Application fees, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and patent applications are due to be paid to the NIPA, the USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The NIPA, the USPTO and other patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We rely on our in-house and outside counsel and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include 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 or other third parties might be able to enter the market, which would have a materially adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

We may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our drug candidates or future drugs, as a result of litigation or other proceedings relating to patent or other intellectual property rights.

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our drug candidates. We may also be unaware of third-party patents or patent applications, and given the dynamic area in which we operate, additional patents are likely to be issued that relate to aspects of our business. There are a substantial amount of litigations and other claims and proceedings involving patent and other intellectual property rights in the pharmaceutical industry generally. As the pharmaceutical industry expands and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patents or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would substantially divert diversion of employee resources from our business. In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the market price of our Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, the fourth Amendments to the PRC Patent Law was put into effect on June 1, 2021, provides a patent term extension and patent term adjustment. Patent term extension of up to five years is available to invention patents claiming new drugs, to compensate for the time occupied by review and approval for marketing the new drugs. Patent term adjustment is available to all invention patents, to compensate unreasonable delays caused by CNIPA during the patent examination procedures. The Proposed Amendments to Implementing Rules of the Patent Law of the People's Republic of China (Draft) (《專利法實施細則修改建議(徵求意見稿)》) was published by the CNIPA on November 27, 2020, and proposed detailed implementation rules for patent term extension and adjustment, including for example, the eligible type of patents, requirements for the application for patent term extension and adjustment, how to calculate the extension, and limitations during the extended patent term. However, the implementing rules for the drug patent extension system have not yet been finalized or adopted, and therefore the implementation, interpretation and enforcement of laws and regulations regarding the patent extension system remain uncertain. As a result, patents owned by third parties eligible for submitting applications for a patent term extension may be extended, which may in turn affect our ability to commercialize our drug candidates without facing infringement risks. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our drug candidates non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

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

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

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, and we may be subject to claims asserting ownership of what we regard as our own intellectual property.

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

Furthermore, many of our employees, consultants, and 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, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such intellectual property rights would harm our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates and technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management.

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

Moreover, our trade secrets and other proprietary or confidential information may become known or be independently developed by a third party, or misused by any collaborator or other third party to whom we disclose such information. Although we seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems,

confidential or proprietary information and other intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

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

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

We have in the past and may in the future enter into collaboration agreements with third parties providing us or such third parties with rights to various intellectual property, including rights in patents, patent applications and copyrights. These collaboration agreements may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us or the third party. If we fail to comply with our obligations under our current or future collaboration agreements, our counterparties may have the right to terminate these agreements and, upon the effective date of such termination, may have the right to terminate our exclusive rights or all of our rights and acquire rights to certain of our intellectual property. If any of our collaborators terminate any license we rely upon, we might not be able to develop, manufacture or market any drug candidate related to the intellectual property licensed under these agreements and we may face other additional penalties. For example, according to our Co-Development Agreements with Alphamab Group, if one party (the breaching party) causes losses to the other party (the non-breaching party) due to its breach of the agreement and fails to indemnify promptly, the non-breaching party shall have a unilateral right to transfer the patents related to envafolimab, and the proceeds from transfer or license shall be first used to compensate the losses of the non-breaching party. If we breach the Co-Development Agreements and fail to indemnity promptly, Alphamab Group may be entitled to exercise the unilateral right to transfer the Co-Owned Patents, which may cause us to lose control over the Co-Owned Patents in the worst case scenario. Such an occurrence could diminish the value of these products and our business. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less

favorable terms, or cause us to lose our rights under such agreements to important intellectual property or technology or our rights to develop and commercialize our drug candidates. In addition, such an event may cause us to experience significant delays in the development and commercialization of our drug candidates or incur liability for damages. If any such license is terminated, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our drug candidates.

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

Disputes may arise regarding intellectual property subject to a license agreement, including:

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

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

If our trademarks and trade names are not adequately protected, then we may not be able to build brand 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 USPTO and in proceedings before 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 cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature in the future, upon regulatory approval, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may be unsuccessful 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any drug candidates or any potential drug candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;

- we, our licensors or 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 may license in or own in the future;

- we, our licensors or current or future collaboration partners might not have been the first to file patent applications covering certain of our or their inventions;

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

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

- issued patents that we hold rights to may not provide us with a competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

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

- we may not be able to successfully maintain our intellectual property rights in compliance with various procedural, document submission, fee payment and other requirements in each jurisdiction;

- we may not successfully continue to apply for, obtain or maintain related intellectual properties to further develop our product pipeline;

- we may not develop additional proprietary technologies that are patentable;

- the patents of others may harm our business;

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

- the success of licensed-in products depends upon our and our current or future collaboration partners' ability to obtain and maintain intellectual property protection for our products and technologies, and it is difficult and costly to protect our proprietary rights and technology, and we and our current or future collaboration partners may not be able to ensure such protections.

Should any of these events occur, they could materially adversely affect our competitive position, business, financial condition, results of operations and prospects.

Risks Relating to Our Reliance on Third Parties

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

We currently rely on and may continue to rely on third parties such as CMOs for our manufacturing process and for the clinical supply and commercial sales of our drug candidates in the future. Reliance on third-party CMOs would expose us to the following risks:

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

- our third-party CMOs might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;

- third-party CMOs are subject to ongoing periodic unannounced inspection and other government regulations by the NMPA, FDA, PMDA or other comparable regulatory authorities to ensure strict compliance with cGMP. We do not have control over third-party CMOs' 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 CMOs in the manufacturing process for our drug candidates;

- third-party CMOs 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;

- third-party CMOs 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;

- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and

- we may lose or fail to maintain our relationship with our third-party CMOs and may incur additional costs in identifying and engaging qualified replacement in a timely manner.

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

Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or because 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 drugs for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs, and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

We depend on a stable and adequate supply of quality materials, including reagents and consumables and R&D 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, such as reagents and consumables, as well as equipment and other materials needed for research and development as well as manufacturing purposes. 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. Please refer to the paragraphs headed "Business – Raw Materials and Suppliers" in this document.

Currently, the materials and equipment are supplied by a limited number of major source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationship with alternative sources based on supply continuity risk assessment. However, since we have a limited number of major source suppliers during the Track Record Period, there is a risk that, if supplies were interrupted, our business and results of operations would be materially harmed. 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 regulatory approval, but there is no assurance that current suppliers have the capacity to meet our demand. Any significant 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 or alter the commercials terms in an unfavorable way to us at any time.

We are also exposed to the possibility 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 approved drugs and services 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, although we have implemented quality inspection on the materials before using them in the manufacturing process, we cannot assure you that we will be able to identify all of the quality issues.

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. Failure to do so by them 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-party suppliers 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 and adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO OUR OPERATIONS

We operate in a competitive industry and may fail to compete effectively.

The pharmaceutical industry in which we operate is highly competitive and rapidly changing. Large multinational pharmaceutical companies, established biopharmaceutical 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 or other indications for which we are developing our drug candidates.

Many of our competitors have substantially more developed commercial infrastructure, greater financial, technical and human resources as well as more drug candidates in late-stage clinical development than we do. Even if successfully developed and subsequently approved by the NMPA, FDA, PMDA or other comparable regulatory authorities, our drug candidates will still face competition based on 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 product that competes with an approved product must demonstrate compelling advantages in efficacy, 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 non-competitive. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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

Pursuant to 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 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.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, suppliers and other contractors and consultants, could be subject to natural or man-made disasters or business interruptions. In addition, we rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or funding withdrawals. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and could increase our costs and expenses. Moreover, we rely on third-party manufacturers to produce and process supplies of our future approved drugs and drug candidates. Our collaborations with CMOs, our operation of our new manufacturing facility (upon construction completed) and our ability to obtain supplies for manufacturing our drug candidates or future approved drugs could be disrupted if the operations of these collaborators, suppliers or our new manufacturing facility are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our corporate, development, research or manufacturing facility due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. Our insurance might not cover all losses under such circumstances and our business and financial condition may be seriously harmed by such delays and interruption.

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 success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as other key clinical and scientific personnel, and other employees and consultants. The loss of services of any of these individuals or one or more of our senior management could delay or prevent the successful development of our drug candidates.

Although we have not historically experienced unique difficulties in attracting and retaining qualified employees, we could experience such problems in the future. Competition for qualified employees in the pharmaceutical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain experienced senior management or key clinical and scientific personnel in the future. The departure of one or more of our senior management or key clinical and scientific 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 and adverse effect on our business and results of operations. In addition, we will need to hire additional employees as we build and expand our commercialization team. We may not be able to attract and retain qualified employees on acceptable terms.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading.

We are subject to the anti-bribery laws of various jurisdictions, particularly in China and the U.S. As our business expands, the applicability of the anti-bribery laws to our operations will increase. We may be exposed to fraud, bribery or other misconduct committed by our employees, principal investigators, consultants and commercial partners that could subject us to financial losses and sanctions imposed by government authorities, which may adversely affect our reputation. Our procedures and controls to monitor compliance with anti-bribery law may fail to protect us from reckless or criminal acts committed by our employees or other commercial partners. We could be liable for actions taken by them that violate anti-bribery, anti-corruption and other related laws and regulations in China, the U.S. or other jurisdictions. The government authorities may limit the sales of the products involved in any illegal or improper conduct engaged in by our employees or commercial partners. We may be subject to claims, fines or suspension of our operations. Our reputation, our sales activities or the price of our Shares could be adversely affected if we are associated with any negative publicity as a result of illegal or improper actions, or allegations of illegal or improper actions, taken by our employees or commercial partners.

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 and adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, including past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

We are subject to the risks of doing business globally.

Because we operate in China and other jurisdictions, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

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

- unexpected changes in laws and regulatory requirements in local jurisdictions;

- 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;
- the burden of complying with a variety of foreign laws including difficulties in effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- the effects of applicable local tax regimes and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

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

Product and professional liability claims or lawsuits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

We face an inherent risk of product and professional liability as a result of the clinical testing and any future commercialization of our drug candidates in China, the U.S., and any of our targeted markets. 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 or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our drug candidates; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related

litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labelling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; significant increase in insurance premium; the inability to commercialize any approved drug candidate; and a decline in the market price of our Shares.

To cover such liability claims arising from clinical studies, we purchase clinical trial insurance in the conduct of our clinical trials. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability 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.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

We are subject to laws and regulations governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials. Our operation involves the use of hazardous materials, including chemicals, and may produce hazardous waste products. We cannot eliminate the risks of contamination or personal injury from these materials.

We do not maintain insurance for environmental liability claims that may be asserted against us in connection with our storage or disposal of hazardous materials. In the event of contamination or personal injury resulting from our use of hazardous materials or our or third parties' disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We may incur substantial costs in order to comply with current or future laws and regulations on use of hazardous materials. These current or future laws and regulations may have significant adverse impact on our research our research, development or production activities. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Despite the implementation of security measures, our information technology systems and those of our current or future CROs, consultants and other service providers are vulnerable to damage from cyber-attacks, computer viruses, malicious codes, unauthorized access, employee theft or misuse, natural disasters, fire, power loss, terrorism, war, and telecommunication and electrical failures, among other things. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach may result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed. In addition, a security breach may result in the loss of, damage to, or public disclosure of personally identifiable information, and such an event could have serious negative consequences, including disputes, regulatory action, investigation, litigation, fines, penalties and damages, and time-consuming and expensive litigation, any of which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, system malfunction or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including but not limited to personal information of our employees and patients, and companies, vendors and the other

users of our vendors' confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data or systems. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, results of operations, financial condition or prospects. If we experienced any such material system failure or security breach and interruptions in our operations, it could result in a material disruption of our development programs and our business operations, a breach of sensitive personal information or a loss or corruption of critical data assets including trade secrets or other proprietary information. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. 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 adversely influenced. 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. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we engage in more electronic transactions with payers and patients and collect and store an increasing volume of data, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

We may not have adequate insurance coverage to compensate for any losses associated with a system failure, any breach of our computer systems or other cybersecurity attack or any violation of any privacy laws or other obligations. Any breach or failure of our or our vendors' computer systems, information technology and other infrastructure could materially adversely affect our business, financial condition, results of operations and prospects.

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

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

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

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

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (《關於外國投資者併購境內企業的規定》) (the "**M&A Rules**"), and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on national economic

security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, according to the Anti-Monopoly Law of PRC (《反壟斷法》) and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (《關於經營者集中申報標準的規定》) (the "**Prior Notification Rules**") issued by the State Council, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (《實施外國投資者併購境內企業安全審查制度的規定》) (the "**Security Review Rules**"), issued by the MOFCOM, specify that mergers and acquisitions by foreign investors that raise "national defense and security" concerns, and mergers and acquisitions through which foreign investors may acquire the *de facto* control over domestic enterprises that raise "national security" concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval and filing processes, including obtaining approval or filings from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises "national defense and security" or "national security" concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to security review, in which case our future acquisitions in China, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

Further, we may also discover deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in businesses we acquire which we did not uncover prior to such acquisition. As a consequence, we may become subject to penalties, lawsuits or other liabilities. Further, any difficulties in the integration of acquired businesses, product or technologies or unexpected penalties, lawsuits or liabilities in connection with such businesses, product or technologies could have a material adverse effect on our business, financial condition and results of operation. 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.

If we or our CROs/CDMOs/CMOs fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially adversely affect the success of our business.

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

In addition, we cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facility 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. Other adverse effects could result from such liability, including reputational damage. We may also be forced to close or suspend operations at certain of our affected facility temporarily, or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material and adverse impact on our business, financial condition, results of operations and prospects.

We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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

We have historically benefited from government grants, subsidies and other preferential policies as incentives for our research and development activities. We recorded government grants of RMB0.6 million, RMB8.4 million and RMB0.7 million, for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. Apart from the government grants, our subsidiary in China, 3DMed Beijing, was recognized as a High and New Technology Enterprise in 2019 and therefore is entitled to a preferential income tax rate of 15% for a three-year period. These government grants were generally in support of our research and development activities of our drugs on oncology. Please refer to the paragraphs headed "Financial Information – Description of Certain Key Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Other Income and Gains" in this document and note 5 to the Accountants' Report set out in Appendix I to this document for further details. Our government grants may vary from period to period going forward and our results of operations may be affected as a result. Our eligibility for government grants and the preferential income tax treatment is dependent on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, the availability of funding at different granting authorities and the research and development progress made by other peer companies. The incentives are subject to the discretion of the central government or relevant local government authorities, which could determine at any time to eliminate, suspend or reduce these financial incentives, generally with prospective effect. In addition, the policies according to which we historically received government grants may be halted by the relevant government entities at their sole discretion. Since our receipt of the government grants and eligibility for the preferential income tax treatment are subject to periodic time lags and inconsistent government practice, as long as we continue to receive these government grants and enjoy the preferential income tax treatment, our net income in a particular period may be higher or lower relative to other periods depending on the potential changes in these government grants or preferential income tax policies in addition to any business or operational factors that we may otherwise experience. There is no assurance that we will continue to receive such government grants, receive similar level of government grants, or at all, or be eligible to enjoy the preferential income tax treatment in the future. The discontinuation of government grants, subsidies and our eligibility for the preferential income tax treatment currently available to us could have a material adverse effect on our business, financial condition and results of operations.

We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which we may not be able to do successfully.

The global pharmaceutical drug 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, 2020 and 2021 and the five months ended May 31, 2022, our research and development costs were RMB264.0 million, RMB371.2 million and RMB138.3 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We intend to continue to enhance our technical capabilities in drug 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 enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could harm our business and prospects.

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

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

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- continuing to innovate and develop advanced technology in the highly competitive pharmaceutical market;
- managing our relationships with third parties, including suppliers and 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.

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

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

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

Since our operations are labor-intensive and our operations, to a certain extent, require the use of technical skills and know-how of our employees, our success depends in part on our ability to attract, retain and motivate a sufficient number of qualified employees. We have implemented a number of initiatives in an effort to attract, retain and motivate our qualified and competent staff. There is no assurance that these measures will be effective or that supply of skilled labor in local markets will be sufficient to fulfil our needs. Competition for competent and skilled labor is intensive in the industry. Our failure to hire and retain enough skilled employees could delay the anticipated pre-clinical studies or clinical trials timeframe or receipt of regulatory approvals to commercialize our drug candidates, or result in our expenses exceeding our initial budget. Any of the foregoing changes could have a material adverse effect on our business, profitability and prospects.

Further, substantially our entire workforce is employed in China. The average labor cost in China has been steadily increasing over the past years as a result of government-mandated wage increases and other changes in the PRC labor laws. Further changes in the labor laws, rules and regulations may be promulgated by the Chinese government in the future and our operations may be materially adversely affected if such laws, rules or regulations impose additional burden on the employers. The labor cost will continue to increase in the future which is in line with the economic growth in China. Competition for employees would require us to pay higher wages, which would result in higher labor costs.

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

We maintain insurance policies that are required under the PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in China, we have elected not to maintain certain types of insurance, such as insurance for environmental liability. Our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facility 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.

Any failure to comply with the PRC regulations regarding mandatory social insurance and housing fund contributions may subject us to fines and other legal or administrative sanctions.

According to the Social Insurance Law (《中華人民共和國社會保險法》) which was last amended on December 29, 2018 and other applicable PRC regulations, any employer operating in China must open social insurance registration accounts and contribute social insurance premium for its employees. Any failure to open social insurance 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 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 within a specified period of time, and the competent authority may further impose fines or penalties. According to the Regulation on the Administration of Housing Accumulation Funds (《住房公積金管理條例》), as amended in 2002 and 2019, the relevant housing fund authority may order an enterprise to pay outstanding contributions within a prescribed time limit.

During the Track Record Period, we have engaged a third party human resources company to pay, on behalf of the Company, the relevant contribution for certain offsite employees. As a result, we may be required by competent authorities to rectify the non-compliance and could be subject to a fine or penalty. As of the Latest Practicable Date, no competent government authorities had imposed administrative action, fine or penalty to us with respect to this non-compliance incident. We cannot assure you that we will not be subject to any penalty, or order to rectify non-compliance in the future. We may incur additional expenses to comply with such laws and regulations.

We have been building our in-house production facilities in Xuzhou and any disruptions to the future operation of our in-house production facilities could materially adversely affect our business, financial condition and results of operations.

As of the Latest Practicable Date, we owned land use rights to one parcel of land in Xuzhou Economic and Development Area with an area of 65,637.97 square meters and we have been building our in-house production facilities on this parcel of land. We have obtained the construction permit and started construction of new manufacturing facilities in Xuzhou. Please refer to the paragraphs headed "Business – Production and Quality Control – In-house Production Facilities and Future Expansions" in this document for more details. The future operation of our in-house production facilities might be substantially interrupted due to a number of factors, many of which are outside of our control, including but not limited to fires, floods, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars, loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities, and regulatory changes.

If the future operation of any of our in-house production facilities is substantially disrupted, we might not be able to replace the equipment at such facilities, or use a different facility to continue production in a timely and cost-effective manner. As a result, we might fail to fulfill contract obligations or meet market demand for our products, and our business, revenue and profitability could be materially adversely affected.

We are subject to risks associated with leasing space.

We lease our some of our offices in China. The lessors of the leased properties may not have valid title or have the legal rights to such leased properties or may not have complied with all the necessary procedures. In addition, as our leases expire, we may fail to negotiate renewals, either on commercially acceptable terms or at all, which could require us to close such offices. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially adversely affect our business, results of operations and financial condition.

Under the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. However, as of the Latest Practicable Date, because the lessors failed or are reluctant to provide necessary documents for us to register the leases, a few of the lease agreements for the premises under which we operated our branch offices had not obtained such registrations. We may be required by relevant government authorities to file these lease agreements for registration within a time limit, and may be subject to a fine for non-registration exceeding such time limit, which may range from RMB1,000 to RMB10,000 for each lease agreement.

Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation and may, as a result, negatively affect our business, financial condition and results of operations.

We, our Shareholders, Directors, officers, employees and business partners may be subject to negative media coverage and publicity from time to time. Any negative publicity concerning us, our affiliates or any entity that entitled the "3DMed" name, our Shareholders, Directors, officers, employees and business partners, management, even if untrue, could adversely affect our reputation and business prospects. 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 and business partners were incompliant with any laws or regulations or became involved in lawsuits, disputes, or other legal proceedings or became subject to administrative measures, penalties or investigations by regulatory authorities, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity. In addition, referrals and word of mouth have significantly contributed to our ability to establishing new partnerships. As a result, any negative publicity about us could adversely affect our ability to maintain our existing collaboration arrangements or attract new collaboration partners, and we may not be able to diffuse such negative publicity to the satisfaction of our investors and customers.

RISKS RELATING TO OUR DOING BUSINESS IN CHINA

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

We conduct almost all of our operations in China, which we believe confers clinical, commercial and regulatory advantages. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. Please refer to the section headed "Regulatory Overview" in this document for a discussion of regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China, which would materially adversely affect our business, financial condition, results of operations and prospects. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are consistent with the Chinese government's policies, but we cannot ensure that our strategy and approach will continue to be consistent.

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

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China's economy differs from the economies of developed countries in many respects, including with respect to the extent of government involvement, level of development, growth rate, control of foreign exchange, allocation of resources, an evolving regulatory system, and the level of transparency in the regulatory process. While China's economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. There is no assurance that future growth will be sustained at similar rates or at all.

The Chinese government implements various measures intended to encourage economic growth and guide the allocation of resources. These measures may include differential policies towards specific groups of pharmaceutical companies, such as promotion of traditional medicines or state-owned companies, or investments in pharmaceutical companies competing with us, which may have an adverse effect on us. Our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are applicable to us. Further, any adverse change in the economic conditions or government policies in China could have a material adverse effect on overall economic growth and the level of healthcare investments and expenditures in China, which in turn could lead to a reduction in demand for our products and consequently have a material adverse effect on our business.

The Chinese economy has been transitioning from a planned economy to a more market-oriented economy. Although the Chinese government has implemented reform measures allowing for an increasingly market-based economy, reduced state ownership of productive assets and established sound corporate governance practices in business enterprises, a substantial portion of the productive assets in China is owned by the Chinese government. The continued control of these assets and other aspects of the national economy by the Chinese government could materially and adversely affect our business. The Chinese government also exercises significant control over Chinese economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies.

Changes and developments in China's economic, political and social conditions could adversely affect our financial condition and results of operations. For example, the pharmaceutical market may grow at a slower pace than expected, which could adversely affect our business, financial condition or results of operations.

In addition, in the past the Chinese government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

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

Substantially all of our operations are conducted in China, and are governed by PRC laws, rules and regulations. The Chinese legal system is a civil law system based on written codes and statutes. Unlike the common law system, prior court decisions may be cited as persuasive authority with limited precedential value, but do not have legally binding force.

In 1979, the Chinese government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by Chinese regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the non-binding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the Chinese legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Additionally, the NMPA's recent reform of the drug-approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our drug candidates in a timely manner.

Moreover, Chinese administrative and court authorities also have significant discretion in interpreting and enforcing statutory and contractual terms. Depending on the government agency or how an application or a case is presented to such agency or other factors, we may receive less favorable application of law.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than we would in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

Finally, we cannot predict the effect of future legal developments in China, including promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, the preemption of local rules and regulations by national law, the overturn or modification of the lower-level authority's decisions at the higher level, or the changes in judiciary and administrative practices. As a result, there is substantial uncertainty as to the legal protection available to us or to our investors.

We may be restricted from transferring our scientific data abroad or from overseas to China.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the "**Scientific Data Measures**"), which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, where scientific data involving state secrets needs to be provided to foreign parties during the relevant foreign contacts and cooperation, corporate entities shall provide the type, scope and usage of the scientific data, and submit the information to the competent authorities for approval according to the specified procedures for confidentiality management. Upon approval by the competent authorities, corporate entities shall undergo the required procedures, and enter into the confidentiality agreements with the users of the scientific data. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given that the term "state secret" is not clearly defined, if and to the extent our R&D of medical drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals or comply with the regulatory requirements in a timely manner, or at all, our R&D of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

In addition, some foreign jurisdictions have stringent laws and regulations on collection, use, security, disclosure and transfer of personal information and privacy data. Non-compliance could result in proceedings against us by data protection authorities, which might subject us to fines, penalties, judgments and negative publicity, and may otherwise materially and adversely affect our business, financial condition and results of operations. Please refer to the paragraphs headed "– Other Risk Relating to Our Business – Risks Relating to Extensive Government Regulations – We may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials" in this section for more details.

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

We may pursue partnerships with entities in foreign countries and regions, in particular in the U.S. and Japan, and establishing new collaboration partnerships is key to our future growth. We may also sell a portion of our products to certain foreign countries in the future. Our business is therefore subject to constantly changing international economic, regulatory,

social and political conditions, and local conditions in foreign countries and regions. As a result, China's political relationships with those foreign countries and regions may affect our development of drug candidates and our commercialization of our drug candidates, upon approval, in foreign countries.

It is notably that the U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs which have led to other countries, including China and members of EU, imposing tariffs against the U.S. in response. Please refer to the paragraphs headed "– Other Risks Relating to Our Business – Risks Relating to Extensive Government Regulations – Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results" in this section. These trade disputes may escalate going forward and may result in certain types of goods, such as advanced R&D equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export.

Tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. China's political relationships with those foreign countries and regions may also affect the prospects of our relationship with third parties. There can be no assurance that our existing or potential service providers, collaboration partners, or customers will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions, and such alteration may cause a decline in the demand for our products and adversely affect our business, financial condition, results of operations, cash flows and prospects.

Furthermore, in the event that China and/or the countries from which we import raw materials impose import tariffs, trade restrictions or other trade barriers affecting the importation of raw materials, we may not be able to obtain a steady supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected.

We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company. Gains on the sales of Shares and dividends on the Shares may be subject to PRC income taxes.

The indirect transfer of equity interests in PRC resident enterprises by a non-PRC resident enterprise is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. On February 3, 2015, the SAT issued the Public Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (the "**Circular 7**") (《國家税務總局關於非居民企業間接轉讓財產企業所得税若干問題的公告》), which supersedes certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax on Non-Resident Enterprises (the "**Circular 698**") (《(國家税務總局關於加強非居民企業股權轉讓所得企業所得税管理的通知》), which was previously issued by

the SAT on December 10, 2009, as well as certain other rules providing clarification on Circular 698. Circular 7 provides comprehensive guidelines relating to, and also heightened the PRC tax authorities' scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise ("**PRC Taxable Assets**").

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

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

Circular 7 contains certain exemptions, including (i) the Public Market Safe Harbor described below; and (ii) where there is an indirect transfer of PRC Taxable Assets, but if the non-resident enterprise had directly held and disposed of such PRC Taxable Assets, the income from the transfer would have been exempted from enterprise income tax in the PRC under an applicable tax treaty or arrangement. Provisions of Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to "non-resident enterprise acquiring and disposing of the equity interests of the same offshore listed company in a public market" (the "**Public Market Safe Harbor**"), which is determined by whether the parties, number and price of the shares acquired and disposed are not previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to one implementing rule for Circular 698. In general, transfers of the Shares by Shareholders on the Stock Exchange or other public market would not be subject to the PRC tax liabilities and reporting obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. However, it remains unclear whether any exemptions under Circular 7 will be applicable to the transfer of our Shares that do not qualify for the Public Market Safe Harbor or to any future

acquisition by us outside of the PRC involving PRC Taxable Assets, or whether the PRC tax authorities will reclassify such transactions by applying Circular 7. Therefore, the PRC tax authorities may deem any transfer of our Shares that do not qualify for the Public Market Safe Harbor by our Shareholders that are non-resident enterprises, or any future acquisition by us outside of the PRC involving PRC Taxable Assets, to be subject to the foregoing regulations, which may subject our Shareholders or us to additional PRC tax reporting obligations or tax liabilities.

Governmental control of currency conversion, and restrictions on the remittance of Renminbi into and out of China, may adversely affect the value of your investment.

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

The RMB is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and foreign currency debt. Approval from appropriate government authorities is required where the RMB 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. 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. However, the relevant Chinese government authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions.

The Chinese Government may also at its discretion restrict access in the future to foreign currencies for current account transactions. Since 2015, in response to China's declining foreign currency reserves, the Chinese Government has placed increasingly stringent restrictions on the convertibility of the RMB into foreign currencies. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay 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 the RMB into or out of China.

You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing original actions in China against us or our management named in the documents based on Hong Kong or other foreign laws.

Majority of our operational subsidiaries are incorporated under the laws of China, and substantially all of our assets are located in China. A majority of our Directors, Supervisors and senior management personnel also reside in China, and substantially all of their assets are located in China. As a result, it may not be possible for investors to effect service of process upon us or our Directors, Supervisors and senior management personnel in China.

On July 14, 2006, the Supreme People's Court of 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 (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the "**Arrangement**"). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case 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 PRC court is expressly designated as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. Although the Arrangement became effective on August 1, 2008, the outcome and effectiveness of any action brought under the Arrangement remain uncertain.

On January 18, 2019, the Supreme People's Court of 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 (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the "**New Arrangement**"), which seeks to establish a mechanism with further clarification on and certainty for recognition and enforcement of judgments in a wider range of civil and commercial matters between Hong Kong Special Administrative Region and PRC. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People's Court of PRC and the completion of the relevant legislative procedures in Hong Kong Special Administrative Region. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in PRC if the parties in the dispute do not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors to effect service of process against our assets or management in China in order to seek recognition and enforcement of foreign judgments in China.

Furthermore, China has not entered into treaties or arrangements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the U.S., the United Kingdom, or most other western countries, and Hong Kong has no arrangement for the reciprocal enforcement of judgments with the U.S. As a result, recognition and enforcement in PRC or Hong Kong of judgment of a court in the U.S. or any other jurisdictions mentioned above in relation to any matter that is not subject to a binding arbitration provision may be difficult or impossible.

RISKS RELATING TO THE [REDACTED]

No public market currently exists for our Shares; an active trading market for our Shares may not develop and the market price and trading volume of our Shares may decline or became volatile, which could lead to substantial losses to investors.

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

In addition, the [**REDACTED**] and [**REDACTED**] of the Shares may be subject to significant volatility in responses to various factors, including:

- variations in our operating results;
- changes in financial estimates by securities analysts;
- announcements made by us or our competitors;
- regulatory developments in China affecting us, our customers or our competitors;
- investors' perception of us and of the investment environment in Asia, including Hong Kong and China;
- developments in China's healthcare market;
- changes in pricing made by us or our competitors;
- acquisitions by us or our competitors;
- the depth and liquidity of the market for our Shares;

- additions to or departures of, our executive officers and other members of our senior management;
- release or expiry of lock-up or other transfer restrictions on our Shares;
- sales or anticipated sales of additional 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 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 Shares, and the price of our Shares when [REDACTED] begins could be lower than the [REDACTED].

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

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

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

You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future.

The [**REDACTED**] of the [**REDACTED**] is higher than the net tangible asset value per Share immediately prior to the [**REDACTED**]. Therefore, purchasers of the [**REDACTED**] in the [**REDACTED**] will experience an immediate dilution in pro forma net tangible asset value. In order to expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the [**REDACTED**] may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time. Furthermore, we may issue Shares pursuant to the Share Schemes, 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 price appreciation of our 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 research and development, regulatory filings and commercialization of our drug candidates. As a result, we might not pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our Shares as a source for any future dividend income.

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

We are a Cayman Islands company and the laws to protect the interests of minority shareholders may be different from those provided for in Hong Kong.

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

Certain information in this Document relating to the PRC economy and the pharmaceutical industry may not be fully reliable.

Certain information and statistics set out in this Document were extracted from the report prepared by Frost & Sullivan, which was commissioned by us, and from various official government publications and other publicly available publications. We engaged Frost & Sullivan to prepare an independent industry research report in connection with the [**REDACTED**]. However, the information from official government sources has not been independently verified by us, the Joint Sponsors, the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], any of their respective directors, employees, agents or advisers or any other person or party involved in the [**REDACTED**], and no representation is given as to its accuracy, fairness and completeness.

You should read the entire [REDACTED] 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 do not have sufficient control over the press and media coverage, and analysts might issue negative views or recommendations on us, which could have an adverse effect on the market price of Shares. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.

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