

---

## RISK FACTORS

---

An [REDACTED] in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before deciding to [REDACTED] in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any such an event, the market price of our Shares could decline, and you may lose all or part of your [REDACTED]. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-Looking Statements” in this document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to our pre-clinical and clinical development of our drug candidates; (ii) risks relating to our reliance on third parties; (iii) risks relating to manufacturing and commercialization of our drug candidates; (iv) risks relating to extensive government regulation; (v) risks relating to our intellectual property rights; (vi) risks relating to our operations; (vii) risks relating to our financial position and need for additional capital; (viii) risks relating to doing business in China; and (ix) risks relating to the [REDACTED].

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

### **RISKS RELATING TO OUR PRE-CLINICAL AND CLINICAL DEVELOPMENT OF OUR DRUG CANDIDATES**

*We face fierce competition from existing products and product candidates under development in the entire oncology market. Our competitors may discover, develop or commercialize competing drugs earlier or more successfully than we do. If we fail to effectively compete with our competitors, our competitive position in our target markets may be undermined, our drug candidates, if and when approved, may fail to be commercially successful and our business, financial condition, results of operations and prospects could be adversely affected.*

We face fierce competition from existing products and product candidates under development in the entire oncology market, in particular in the AKT inhibitor market. Competition in therapeutic areas such as oncology to which our Core Products and most of our other pipeline assets belong is intense given the abundance of existing competing oncology therapy options, approved drugs and drug candidates that continue to increase. In particular, for selective inhibitors, especially AKT inhibitors including our Core Product LAE002, there are

---

## RISK FACTORS

---

a large number of competing drug candidates currently under different development stages. 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.

In particular, the wide application of traditional cancer therapies, such as surgeries, radiotherapies and chemotherapies, also poses significant competition for our drug candidates. Surgery is a procedure in which a surgeon removes tumors and nearby tissues from the patient's body. Radiotherapies deliver high doses of radiation to kill cancer cells and shrink tumors, while chemotherapies use single or combination anti-cancer drugs to stop or slow the growth of cancer cells. Our drug candidates and lines of treatments may not be selected unless and until one or more of these more conventional and widely adopted cancer treatments have been adopted, which could potentially negatively affect the size of our total addressable market for our drug candidates.

Our commercial opportunities may deteriorate if our competitors develop and commercialize drugs that are safer, more effective, more convenient, or less expensive than any of the drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA, the FDA, or other comparable regulatory authorities for their drugs more quickly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. This may render our drug candidates obsolete or less competitive before we can recover the expenses of developing and commercializing our drug candidates.

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

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

We face uncertainties in clinical trial development which are subject to a variety of factors, including satisfactory safety and efficacy results from clinical trials, successful enrollment of patients, and performance of CROs and other parties involved in clinical trial development and others. For example, perifosine, another AKT inhibitor, failed the Phase III clinical trial for treatment of colon cancer and relapsed and refractory multiple myeloma because of the lack of significant difference in the primary endpoints between the perifosine treatment group and the placebo group. Roche recently also terminated two Phase III studies

---

## RISK FACTORS

---

of ipatasertib, another AKT inhibitor, for breast cancer and prostate cancer because the studies failed to meet all of their primary endpoints. Despite that LAE002 is different from perifosine and ipatasertib in many aspects, such as the target patient population, mechanism of actions, PK profiles and others as applicable, our development of LAE002 may still be subject to development risks, including these faced by perifosine or ipatasertib in their development.

In addition to the completion of clinical trial development, the success of our drug candidates will depend on many other factors, including but not limited to:

- receipt of regulatory approvals;
- obtaining sufficient supplies of any qualified drug products that are used in combination with our drug candidates, competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- establishing sufficient commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- avoiding infringement, misappropriation or violation of 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 drug candidates, if and when approved;
- obtaining and maintaining favorable reimbursement from third-party payers for drugs, if and when approved;
- competition with other drug candidates and drugs; and
- continued acceptable safety profile of our drug candidates following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in obtaining approval for and/or successfully commercializing our drug candidates, which would materially and adversely affect our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

---

## RISK FACTORS

---

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

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or strengthen our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. For example, we have entered into license agreements with Novartis in relation to LAE001, LAE002, LAE005 and LAE003, and a collaboration agreement with Innovent in relation to LAE002. 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 otherwise adversely affect our business if such relationships were disrupted.

Our strategic collaboration with partners involves numerous risks. For example, Novartis may terminate the license agreements with us if we fail to demonstrate our commercially reasonable efforts in the R&D, manufacturing and commercialization of in-licensed products. 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. Even if we achieve the expected benefits, they may not be achieved within the anticipated timeframe. 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. Disputes may arise between us and our collaboration partners. Such disputes may cause delay or termination of the research, development or commercialization of our drug candidates, or may result in costly litigation or arbitration that diverts management attention and resources.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development 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.

---

## RISK FACTORS

---

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 our third-party collaborator is not successful, our revenue-generating growth potential will be adversely affected.

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

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

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

---

## RISK FACTORS

---

***We rely on certain third-party collaborators for some of our clinical development activities. In particular, sintilimab has been issued a CRL by the FDA and it may negatively affect our overseas development and commercialization of combination therapies involving sintilimab globally.***

We rely on certain third parties for some of our clinical trials. In particular, we have initiated a Phase I/II clinical trial for LAE002 in combination with anti-PD-L1 antibody sintilimab supplied by Innovent. However, in March 2022, the FDA issued a complete response letter (CRL) indicating it cannot approve the biologics license application for sintilimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of advanced NSCLC. The CRL also included a recommendation for an additional clinical study, specifically a multi-regional clinical trial comparing the first-line standard of care therapy for metastatic NSCLC to sintilimab with chemotherapy utilizing a non-inferiority design with an overall survival as the endpoint. As of the Latest Practicable Date, sintilimab was not an approved product in the U.S. If we plan to extend the combination study overseas and the FDA rejected our study plan in the U.S., our overseas development and commercialization of combination therapies involving sintilimab globally may be negatively affected.

Furthermore, during the R&D and commercialization stages for the combination treatment of LAE002 with sintilimab, we cannot guarantee that Innovent or other potential third party partners will provide stable supply of the relevant compounds, or terminate the agreements altogether. In such cases, we may need to reevaluate our approaches with respect to these combination trials, and potentially find other compounds with combination potentials with our drug candidates. We cannot guarantee that we will be able to find such alternative combination trial opportunities, or that we will not incur significant costs and efforts in so doing. If the NMPA, the FDA or another comparable regulatory agency revokes or denies its approval of sintilimab, in either the clinical design, clinical administration, therapy approval or commercialization, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results and may be subject to adjustments.***

Research programs to discover new drug candidates and new formulations or pursue the development of our drug candidates for additional indications require substantial technical, financial and human resources. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in



---

## RISK FACTORS

---

protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. Moreover, a number of factors could affect the relevant clinical results and could render cross-trial comparison results less meaningful, including the different patient enrollment standards adopted in different trials (e.g., tumor size and status, prior treatment history, age group), dose regimen, and the other aspects of clinical trial design. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the pharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Our future clinical trial results may thus not be favorable, which may materially and adversely affect our business, results of operations and prospects.

***If clinical trials of our drug candidates fail to meet the trial targets 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 meet the trial targets, including to demonstrate the safety and efficacy of our drug candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to obtain regulatory approval or commercialize our drug candidates, including but not limited to:

- regulators, institutional review boards or ethics committees not authorizing us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- manufacturing issues relating to our third-party CDMOs or after we establish our own facilities, including problems with manufacturing, supply quality, compliance with good manufacturing practice, or GMP, or obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial;
- clinical trials of our drug candidates producing negative or inconclusive results, and additional clinical trials or abandoning drug development programs being required;
- the number of patients required for clinical trials of our drug candidates being larger than we anticipate, enrollment being insufficient or slower than we anticipate, or patients dropping out at a higher rate than we anticipate;
- our third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

---

## RISK FACTORS

---

- our having to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks; and
- the cost of clinical trials of our drug candidates being greater than we anticipate; and the supply or quality of our drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates being insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be delayed in obtaining regulatory approval for our drug candidates; (ii) not obtain regulatory approval at all; (iii) obtain approval for indications that are not as broad as intended; (iv) have the drug removed from the market after obtaining regulatory approval; (v) be subject to additional post-marketing testing requirements; (vi) be subject to restrictions on how the drug is distributed or used; or (vii) be unable to obtain reimbursement for the use of the drug. For example, we received IND approval for registrational Phase II MRCT study of LAE002 plus paclitaxel versus paclitaxel in patients with PROC from the FDA in the United States. The global Phase II MRCT would be the registrational trial and appropriate to support product registration. According to the written confirmation issued by the FDA in February 2019 and by the NMPA in February 2020, the FDA and the NMPA agreed that this global Phase II MRCT would be the registrational trial and appropriate to support drug registration if the clinical results demonstrate good efficacy and safety profile. However, if our Phase II clinical results are not favorable for registrational purpose, we need to conduct Phase III clinical trials, which may negatively affect our clinical development and commercialization plan.

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

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

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;



---

## RISK FACTORS

---

- 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;
- 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.

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

---

## RISK FACTORS

---

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

The timely completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. For example, patient eligibility criteria defined in the protocols could be strict and it might increase the chances that we are not able to recruit and retain suitable patients for our clinical trials. Our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

***Our pre-clinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these drug candidates on a timely basis or at all, which would have an adverse effect on our business.***

Some of our drug candidates are still in the pre-clinical development stage, and the risk of failure of pre-clinical programs is high. Before we can commence clinical trials for a drug candidate, we must complete extensive pre-clinical testing and studies to obtain regulatory clearance to initiate human clinical trials, including based on IND applications and clinical trial applications (CTAs) in China and the U.S., as applicable. We cannot be certain of the timely completion or outcome of our pre-clinical testing and studies and cannot predict (i) if the NMPA, the FDA or other regulatory authorities will accept our proposed clinical programs or (ii) if the outcome of our pre-clinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for our pre-clinical programs on the timelines that we expect, if at all, and we cannot be sure that submission of IND applications, CTAs or similar applications will result in the NMPA, the FDA or other regulatory authorities allowing clinical trials to begin.

In addition, research programs to discover new drug candidates and new formulations or pursue the development of our drug candidates for additional indications require substantial technical, financial and human resources. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. In some instances, there can

---

## RISK FACTORS

---

be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the pharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Our future clinical trial results may thus not be favorable, which may materially and adversely affect our business, results of operations and prospects.

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

We must keep pace with new technologies and methodologies to maintain our competitive position. In 2021 and 2022, our research and development expenses were RMB173.3 million and RMB313.4 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 materially and adversely affect our business and prospects.

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

We face an inherent risk of product liability as a result of the clinical trials and any future commercialization of our drug candidates inside and outside China. Liability claims may result in: decreased demand for our drug candidates, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations by regulators, costs to defend the related litigation, a diversion of management’s time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals, or labeling, marketing or promotional restrictions, loss of revenue, exhaustion of any available insurance and our capital resources, the inability to commercialize any approved drug candidate, and a decline in the market price of our Shares.

---

## RISK FACTORS

---

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

The development and commercialization of new drugs is highly competitive. We face potential competition from many different sources working to develop therapies targeting the same indications against which we are developing our drug candidates. These include major pharmaceutical companies, academic institutions, government agencies and research institutions. Some of these competitors have better resources and expertise than us. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are 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, the FDA, 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 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.

---

## RISK FACTORS

---

*We may not be able to identify, discover or in-license new drug candidates, and may allocate our limited resources to pursue a particular candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success, that could materially and adversely affect our future growth and prospects.*

Historically, we have in-licensed a number of drug candidates to develop and commercialize. These assets are important to our portfolio. We will continue to seek collaboration opportunities, including in-licensing, if certain drug candidate fits our development plan. However, we cannot guarantee that we will be able to successfully identify, discover and in-license new drug candidates with high potential for a number of reasons, including but are not limited to:

- the research methodology used may not be successful in discovering new drug candidates or formulations or developing additional potential indications;
- there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

### RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

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

We have relied upon and plan to continue to rely upon third-party CROs and SMOs to generate, monitor or manage data for our ongoing pre-clinical and clinical programs. We rely on these parties for execution of 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 reliance on the CROs and SMOs does not relieve us of our regulatory responsibilities. We, our CROs and SMOs for our clinical programs and

---

## RISK FACTORS

---

our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the NMPA and other comparable regulatory authorities in China and the U.S. for all of our drugs in clinical development. If we or any of our CROs and SMOs or clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our registrational clinical trials must be conducted with product produced under GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs and SMOs terminate, we may not be able to enter into arrangements with alternative CROs and SMOs on commercially reasonable terms, or at all. In addition, our CROs and SMOs are not our employees. Except for remedies available to us under our agreements with such CROs and SMOs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If CROs and SMOs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

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

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including obtaining regulatory approval. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts. We do not control our collaborators. Therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If third parties fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We cannot guarantee the satisfactory performance of any of our collaborators and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed drug which could materially and adversely affect our business, financial condition, cash flows and results of operations.



---

## RISK FACTORS

---

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

We currently use third parties for our manufacturing process and for the clinical supply of our drug candidates. We expect to continue to rely on third-parties to supply raw materials for us to manufacture or manufacture the approved drugs in the future. Reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA, the FDA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and cGMP-compliance inspections by the NMPA, the FDA or other comparable regulatory authorities;
- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by the regulatory authorities to ensure strict compliance with cGMP and other government regulations. We do not have control over third-party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- manufacturers may infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- active pharmaceutical ingredients ("APIs") used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and

---

## RISK FACTORS

---

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

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

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

***Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, vendors, CROs, SMOs and CDMOs may engage in misconduct or other improper activities, and we may be unable to detect, deter and prevent all instances of misconduct.***

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

- regulations of the NMPA, the FDA or other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information;

---

## RISK FACTORS

---

- manufacturing standards; or
- laws that require the true, complete and accurate reporting of financial information or data.

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

### **RISKS RELATING TO MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES**

*We have no experience in manufacturing pharmaceutical products, 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 no experience in manufacturing of our future approved products for commercial use. Moreover, the manufacturing of pharmaceutical products is highly complex. Problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of APIs;
- delays in the construction of new facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;

---

## RISK FACTORS

---

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

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

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

---

## RISK FACTORS

---

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.

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

We do not have manufacturing experience previously, but we plan to build manufacturing facilities in eastern China. 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 other sources.

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

- achieving adequate or clinical-grade materials that meet NMPA, the FDA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;

---

## RISK FACTORS

---

- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the NMPA, the FDA or other comparable regulatory agencies.

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

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

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

***We rely on certain reagents, specialized equipment, and other specialty materials to manufacture our drug candidates. Such supplies may not be available to us on acceptable terms or at all, and an increase in the market price of such supplies may adversely affect our results of operations.***

The manufacturing process of our drug candidates requires many reagents, specialized equipment and other specialty materials manufactured by other third parties. During the Track Record Period, we had not encountered material supply difficulties with respect to reagents, equipment or other materials necessary for our manufacturing of drug candidates. However, as we continue to develop and scale our manufacturing process and capacity, there is no assurance



---

## RISK FACTORS

---

that we will be able to, at all times, procure such reagents, equipment and materials in adequate amount or on commercially reasonable terms, in a timely manner or at all. There is also no assurance that we will be able to identify alternative sources of supply or suitable substitutes for the reagents, equipment or other materials. If we encounter difficulties in procuring necessary reagents, equipment or other materials for manufacturing our drug candidates, we may be forced to delay or suspend our manufacturing activities, which may have a material adverse effect on our clinical development, regulatory approval, future commercialization efforts, results of operations and our prospects.

In addition, for some of these reagents and equipment, we may in the future rely on single source vendors or a limited number of vendors. We might in the future encounter temporary difficulties in sourcing key raw materials as a result of health epidemics or outbreaks of contagious diseases as well as natural disasters, which could have a material impact on our business operations. For the risks associated with health epidemics or outbreaks of contagious diseases as well as natural disasters, see “– Risks Relating to Our Operations – Our business operations may in the future be affected by health epidemics or outbreaks of contagious diseases as well as natural disasters.” We may not be able to continue to source product from any of these suppliers, which could be due to factors beyond our control, such as regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues. Failure to obtain sufficient supply of these reagents, equipment, and materials could adversely affect our ability to satisfy demand for our drug candidates, which could adversely and materially affect our development process, future commercialization efforts and operating results.

Furthermore, as our manufacturing processes require substantial amounts of supplies, and fluctuations in price of such supplies may directly and adversely impact on our gross margins. During the Track Record Period, we had not experienced significant fluctuations in prices of supplies, and they are generally available and in sufficient quantity to meet our demands. However, we cannot assure you that this will continue to be the case in the future. The prices of supplies we use in manufacturing our drug candidates may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, natural disasters such as fires, outbreak of epidemics or diseases, and the PRC and global economic conditions. A significant increase in the costs of supplies may directly and negatively affect our profit margins and, ultimately, our business, financial conditions, results of operation and prospects.

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

We are initially seeking approval of the use of some of our drug candidates in certain indications, such as mCRPC, PROC, TNBC, and other solid tumors as a therapy for patients who have progressed after other approved treatments. For example, we are currently and primarily developing LAE002 as a second or later lines of treatment of its target indications. However, there is no guarantee that our product candidates, even if initially approved as a

---

## RISK FACTORS

---

second or later lines of treatment, would be approved as a first line therapy. To develop our drug candidates as a first line treatment, we may have to conduct additional clinical trials at a much larger scale, which may not be successful. As a result, even though the number of patients of the indications we are developing may be large, the actual addressable patients for our drug candidates may be limited to those that have failed prior treatments which may be small. Additionally, regulatory authorities may establish narrower definitions around when a patient is eligible for treatment using our products than we have used in our projections and the number of addressable patients may turn out to be lower than expected.

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

Our future approved drug candidates may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current treatments for cancers and liver cirrhosis 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 indications. In addition, physicians, patients and third-party payors may prefer other novel products to ours. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals and patients considering our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;

---

## RISK FACTORS

---

- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and
- the effectiveness of our sales and marketing efforts.

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

***We have no experience in launching and marketing drug candidates. If we are unable to maintain sufficient marketing and sales capabilities, or to effectively build and manage our sales network, we may not be able to generate product sales revenue as planned.***

We have no track record in commercialization, and if we are unable to build sufficient sales and marketing capabilities, we may be unsuccessful to raise awareness and sell our drug candidates successfully. We have not yet demonstrated an ability to launch and commercialize any of our drug candidates. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risks, take longer, and cost more than it would if we were a company with experience launching and marketing drug candidates.

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

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

***Other downward pressure in the pricing of our products when commercialized may have a material adverse effect on our business and results of operations.***

In addition to governmental price control measures, we may experience downward pressure in pricing of our drug candidates from other sources, some of which may be beyond our control. For example, competing products, once approved for marketing, may allow our future customers to gain more bargaining power to lower the retail prices of our drug candidates in light of the availability of alternative products. Similarly, as more competing products that target the same indications as our drug candidates may become available for

---

## RISK FACTORS

---

hospitals and patients to choose, therefore would decrease our bargaining power to set price for our drug candidates. Furthermore, with the development of technologies and increasing competition in the industry, we may need to lower the price for our drug candidates in light of the potential launch and commercialization of competing products that tackle similar indications with improved efficacy and safety profile. If we experience such downward pressure in the pricing of our drug candidates, our revenues from sales of drug candidates will decrease, which may have a material adverse effect on our business and results of operations.

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

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

### **RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATION**

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

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

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Any recently enacted and future legislation may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical industry such as a relaxation in regulatory requirements or the introduction of

---

## RISK FACTORS

---

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

The time required to obtain approval by the NMPA, the FDA and other comparable regulatory authorities is unpredictable but typically takes 10 to 15 years following the commencement of pre-clinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities. As of the Latest Practicable Date, we have not obtained qualifications for expedited registration pathways, breakthrough therapies or similar accelerated review channels in any jurisdictions for our drug candidates.

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

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

---

## RISK FACTORS

---

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

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

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



---

## RISK FACTORS

---

company officials and public censure, claims for damages by patients and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

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 during data storage and data transfer. If such institutions or personnel divulge the subjects’ private or medical records without their consent, they will be held liable for damage caused thereby. We have a number of ongoing clinical studies in China and the U.S. Any storage, transfer and/or use of clinical trial data concerning a certain amount of personal data or other critical data categories is subject to the applicable local data and privacy protection laws, including those in China and the U.S. We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring our employees to maintain the confidentiality of our subjects’ medical records. However, these measures may not be always effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials frequently also involve professionals from third party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. Furthermore, any change in such laws and regulations could affect our ability to store, transfer and/or use medical data and subject us to liability for the process of such data for previously permitted purposes. Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. Any failure to protect the confidentiality of patients’ medical records and personal data during data processing processes including data storage, transfer and/or use or any restriction on or liability as a result of our aforementioned data processing activities including data storage, transfer and/or use, could have a material adverse effect on our business, financial condition and results of operations.

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

On December 28, 2021, the Cyberspace Administration of China (“CAC”), jointly with the other 12 governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “MCR”), which took effect on February 15, 2022. For details relating to the MCR, please refer to “Regulatory overview – Data Security, Cyber Security and Data Privacy Protection”. Pursuant to Article 2 of the MCR, besides the procurement of network products and services by critical information infrastructure operators, any data

---

## RISK FACTORS

---

processing activity by network platform operators that affects or may affect national security shall be subject to the cybersecurity review. In accordance with Article 7 of the MCR, network platform operators mastering personal information of more than one million users must apply to the Cybersecurity Review Office for cybersecurity review when listing abroad (國外上市).

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

On May 17, 2022, our PRC Legal Adviser and Sponsors’ PRC legal adviser conducted an anonymous oral consultation with the China Cybersecurity Review Technology and Certification Center (the “**Center**”), which is authorized by the Cybersecurity Review Office of the CAC to accept public consultation and cybersecurity review submissions and is the competent authority to provide views and interpretation relating to the MCR. According to the Center, (i) the [REDACTED] in Hong Kong does not fall within the scope of “listing abroad”; (ii) critical information infrastructure operators are identified by the governmental authorities of corresponding industry; (iii) if the platforms of the companies are not involved in the collection and processing activities of personal information, such companies would not be viewed as network platform operators; and (iv) at present, the CAC does not require the companies to make their own assessment of whether they affect or may affect national security, therefore it’s not necessary for the companies to take the initiative to declare a cybersecurity review according to the MCR. If the companies affect or may affect national security, the relevant governmental authorities will initiate cybersecurity review at their own discretion, the relevant companies shall cooperate with such cybersecurity review.

As of the Latest Practicable Date, (i) we have not been notified of the results of any determination that we have been identified as a critical information infrastructure operator or that any of our systems have been identified as critical information infrastructure by the relevant governmental authorities; (ii) the MCR does not clearly define “network platform operator”, and we believe that we should not be classified as network platform operator taking into consideration of the fact that we do not engage in business of providing network platform services; (iii) the MCR provides no further explanation or interpretation for “affect or may affect national security”, which remains to be clarified and elaborated by the CAC. As of the Latest Practicable Date, we have not received any notification of cybersecurity review from relevant governmental authorities due to our impact or potential impact on national security; and (iv) we have taken reasonable and adequate technical and management measures to ensure data security, we are of the view that the likelihood that our business operation or [REDACTED] might give rise to national security risks is relatively low.

---

## RISK FACTORS

---

Therefore, as advised by our PRC Legal Adviser, our Directors believe that as long as there is no material change to our current business and if no further rules are introduced and no significant changes to the enforcement of the MCR by governmental authorities, cybersecurity review under the article 2 and article 7 of the MCR shall not be applicable to us. Based on the above, with the support of our PRC Legal Adviser, we do not foresee any material obstacles to comply with the MCR in all material aspects and we believe the MCR would not have a material adverse impact on our business operations or our [REDACTED]. Given the aforementioned assessment regarding the limited application and implication of the MCR to our business operation or our [REDACTED], and also supported by the industry precedent, our PRC Legal Adviser and our Directors are of the opinion that an anonymous consultation with CAC is sufficient.

*We may be subject to evolving economic sanctions of the U.S., the European countries, the United Kingdom and other relevant sanctions authorities.*

The U.S. and other jurisdictions or organizations, including the European countries, the United Kingdom, have, through executive order, passing of legislation or other governmental means, implemented measures that impose economic sanctions against such countries or against targeted industry sectors, groups of companies or persons, and/or organizations within such countries. We cannot provide assurances that our future business will be free of risk under sanctions implemented in these jurisdictions or that we will conform our business to the expectations and requirements of all government authorities, including those that do not have jurisdiction over our business but nevertheless assert the right to impose sanctions on an extraterritorial basis. Our business and reputation could be adversely affected if any government authority were to determine that any of our activities constitutes a violation of the sanctions they impose or provides a basis for a sanctions designation of our Company. In addition, because many sanctions program are evolving, new requirements or restrictions could come into effect which might increase scrutiny on our business or result in one or more of our business activities being deemed to have violated sanctions, or being sanctionable.

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

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

---

## RISK FACTORS

---

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, the FDA 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, the FDA 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 GCP, for any clinical trials that we conduct subsequent to the approval.

The NMPA, the FDA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, the FDA 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.

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

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

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

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

---

## RISK FACTORS

---

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

Pursuant to the relevant laws, regulations and relevant regulatory practice by governmental authorities, we and/or other parties related to our operations, such as landlords or managers of premises on or local science parks in which we operate, are required to make various filings with, or obtain and maintain 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 make filings or obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including fines or orders issued by the relevant regulatory authorities causing operations to cease, and may include corrective measures requiring capital expenditure or remedial actions, which in the future could materially and adversely affect our business, financial condition and results of operations. There is also no assurance that the relevant authorities would not take any enforcement action against us. In the event that such enforcement action is taken, our business operations could be materially and adversely disrupted.

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

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

Our strategy to develop combination therapies depends on the safety and efficacy of each component drug within each combination therapy. If the NMPA, the FDA or another comparable regulatory agency revokes or denies its approval of a component therapeutic, in either the clinical design, clinical administration, therapy approval or commercialization stage, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts. In addition, we may fail our commercialization effort because products that facilitate the use of our drug candidates incur safety, efficacy or availability issues. The lack of regulations presents uncertainties to our commercialization efforts and may have an adverse effect on our business and results of operations.

---

## RISK FACTORS

---

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

China imposes controls on the import and export of technology and software products. Under the Regulations on Administration of Imports and Exports of Technologies (《技術進出口管理條例》) promulgated by the State Council, which were amended in November 2020, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approvals by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts (《技術進出口合同登記管理辦法》), issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology.

We are also subject to export control and import laws and regulations in the U.S., including the U.S. Export Administration Regulations, U.S. Customs regulations, economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. The U.S. Department of Commerce Bureau of Industry and Security (BIS) regulates the export of certain biological and chemical agents, and an export license may be required for the exchange of certain equipment and information we need to operate our business. Approval of such export license applications is based on the technology involved, the destination, and current U.S. foreign policy. We have not received any notification from any U.S. governmental authority requesting any approval for our exports.

As of the Latest Practicable Date, our agreements in effect with CROs in the PRC were signed by our PRC subsidiaries, while our agreements with CROs outside the PRC (including in the U.S) were not signed by our PRC subsidiaries. Therefore, our PRC Legal Adviser is of the view that the relevant agreements with CROs in the PRC in effect as of the Latest Practicable Date did not constitute import or export of technology and were not subject to the Regulations on Administration of Imports and Exports of Technologies, and were not required to be registered with competent authorities. To our best knowledge, we have obtained the relevant approvals required from the U.S. governmental authorities regarding our operations in the U.S., and we are not aware of any violation of U.S. import law with respect to our in-licensing.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret or individual privacy may be transferred abroad or to foreign parties. Further, any researcher



---

## RISK FACTORS

---

conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any relevant laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

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

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

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

---

## RISK FACTORS

---

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

International market conditions and the international regulatory environment have historically been affected by competition among countries and geopolitical frictions. Changes to trade policies, treaties and tariffs, or the perception that these changes could occur, could adversely affect the financial and economic conditions in the jurisdictions in which we operate, as well as our overseas expansion, our financial condition and results of operations. The U.S. administration has advocated greater restrictions on international trade generally and significant increases on tariffs on certain goods imported into the U.S., particularly from China, and has taken steps toward restricting trade in certain goods. For example, in 2018, the United States announced three finalized tariffs that applied exclusively to products imported from China, totaling approximately US\$250 billion, and in May 2019, the U.S. increased the rate of certain tariffs previously levied on Chinese products from 10% to 25%. In addition, in August 2019, Former President Donald J. TRUMP threatened to impose additional tariffs on remaining Chinese products, totaling approximately US\$300 billion. Although on January 15, 2020, the U.S. and China signed an agreement on the phase one trade deal, under which both parties made certain concessions and agreed not to proceed with additional tariffs against one another, the 25% tariffs on US\$250 billion of Chinese imports are still in place. These concerns and threats to impose new tariffs or sanction on China, have resulted in increased tensions in China's international relations. Moreover, the bilateral relationship is an ongoing matter, evolving sometimes from day to day, and we cannot predict how the relationship will further evolve or what impact any subsequent developments in the relationship may have on our business. In light of the current situations and the nature of the biopharmaceutical industry, we are of the view that the U.S.-China tension has not had any material impact on our business or operations, our clinical trial designs and execution, patient enrollment, data transfer, related regulatory approval processes, and ability to find alternative suppliers to source, develop and manufacture our pipeline products, and prospects. We cannot guarantee, however, that the U.S.-China tension will not escalate to the extent that will have a material impact on the aforementioned aspects of our businesses, which may have a material adverse effect on our results of operations.

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

---

## RISK FACTORS

---

Furthermore, we formed licensing agreements with Novartis based in the Switzerland. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. As a result, China’s political relationships with those foreign countries and regions may affect the prospects of maintaining existing or establishing new collaboration partnerships and licensing agreements, and the communication and transfer of know-how. Any tensions and political concerns between China and the relevant foreign countries or regions, including the U.S. and Switzerland, may adversely affect our business, financial condition, results of operations, cash flows and prospects. If Novartis terminates these license agreements due to the international trade policies, our business, financial condition and results of operations will be materially and adversely impacted.

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

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

We are subject to numerous environmental, health and safety laws and regulations, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in the process of our business operations. In addition, our construction projects can only be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety have examined and approved the relevant facilities in certain jurisdictions. We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our construction projects may affect our abilities to develop, manufacture and commercialize our pipeline products as we plan. As requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may not be able to comply with, or accurately predict any potential substantial cost of complying with, these laws and regulations. If we fail to comply with environmental protection, 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.

---

## RISK FACTORS

---

In addition, we cannot fully eliminate the risk of accidental contamination, chemical hazards or personal injury at our facilities during the process of research, testing, development and manufacturing of pharmaceuticals. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could materially and adversely affect our business. Other adverse effects could result from such liability, including reputational damage. We may also be forced to close or suspend operations at certain of our affected facilities temporarily, or permanently. As a result, any accidental contamination 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.

### RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in China and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. For further information on our patent portfolio, see “Business – Intellectual Property.” If we or our licensors are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

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 and patent applications 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. Furthermore, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates.

---

## RISK FACTORS

---

As of the Latest Practicable Date, we haven’t obtained patent protections for certain of our early-stage drug candidates. As of the Latest Practicable Date, our non-patented drug candidates included LAE102, LAE104, LAE105, LAE106, LAE109, LAE111, LAE112, LAE113, LAE117, LAE118, LAE119, and LAE120. For further details of our non-patented drug candidates, please see “Business – Intellectual Property” in this document. Although we plan to initiate patent applications in due course, currently there is no patent protection available for such drug candidates until the relevant patent applications are successful.

The requirements for patentability differ in certain jurisdictions, particularly developing countries. For example, methods of treatment of diseases are not patentable subject matters in China. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, according to the PRC Patent Law, for public health purposes, the State Intellectual Property Office of the PRC may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded. The U.S. does not have any provisions for a compulsory license. 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 patent or patent application 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. To our best knowledge, as of the Latest Practicable Date, drug products belonging to the same class of our product candidates had not been subjects of compulsory licensing in China and the U.S.

It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators and contract manufacturers, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, China and, in 2013 the U.S., have adopted the “first-to-file” system under which the first inventor to file a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

---

## RISK FACTORS

---

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 file in advance to China National Intellectual Property Administration (CNIPA), for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. In addition, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Consequently, we do not know whether any of our platform advances and 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.

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

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



---

## RISK FACTORS

---

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

We or our licensing partners may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property. If we or our licensing partners are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which our or the in-licensed intellectual properties are subject to, we may lose valuable intellectual property rights through the loss of one or more patents or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensing partners are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership. If we or our licensing partners are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our drug candidates. The loss of exclusivity or the narrowing of our or our licensing partners' patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

***Our current or any future patent applications 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 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 result in the issuance of patents at all, and even if were granted patents, they may not be issued in a form, or with a scope of claims, that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, its scope can be reinterpreted after issuance and changes in either the patent laws or interpretation of the patent laws in China, the U.S. and other jurisdictions may diminish the value of our patent rights or narrow the scope of our patent

---

## RISK FACTORS

---

protection. Any patents that we own or in-license may be challenged, narrowed, circumvented or invalidated by third parties. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will successfully result in the issuance of any 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 or our licensing partners may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings challenging our patent rights or the patent rights of others. If we or our licensing partners are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which our or the in-licensed intellectual properties are subject, we may lose valuable intellectual property rights through the loss of one or more patents or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensing partners are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership. If we or our licensing partners are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our drug candidates. The loss of exclusivity or the narrowing of our or our licensing partners' patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

Despite measures we or our licensing partners take 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 litigations 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 patent invalidity claims before administrative

---

## RISK FACTORS

---

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. Even if a third party 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 such third party and others.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, USPTO and other governmental patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. 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

---

## RISK FACTORS

---

or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

*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.*

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 Standing Committee of the National People’s Congress (SCNPC) promulgated the Amendment to the PRC Patent Law (effective from June 1, 2021), which introduces patent extensions to eligible innovative drug patents and patent term adjustment. Patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products without facing infringement risks. It may also enable the patent owner to submit applications for a patent term extension or enable CNIPA to adjust the patent term. The length of any such extension or adjustment is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our products non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Recently enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to the 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

---

## RISK FACTORS

---

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 all of which could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial conditions, results of operations and prospects.

***FIRRMA may restrict our ability to acquire technologies and assets in the U.S. that are material to our commercial success.***

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



---

## RISK FACTORS

---

***We may face intense competition from manufacturers of generic or biosimilar drugs after the expiration of patent protection periods.***

Although various extensions may be available, the life of a patent and the protection it affords is limited. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. For example, patents related to composition of matter of LAE002 or LAE003 may expire in 2028, and we plan to apply patent term extension for LAE002 or LAE003 in China, the U.S. and other jurisdictions. Upon the expiration of relevant patents, we may face fierce competition from generic or biosimilar products, including from the ATK inhibitors in generic or biosimilar form of LAE002 and LAE003. Although we plan to apply for an extension of the patent term of LAE002 or LAE003 after the patent expires and we have developed a commercialization strategy for LAE002 and LAE003 to compete with their potential competitors, there can be no assurance that our application and commercialization strategy will be successful. If we fail to extend the patent term of LAE002 and LAE003 or our commercialization strategy prove to be unsuccessful, our results of operations may be adversely affected.

***If we are unable to protect the confidentiality of our trade secrets and other confidential information, including unpatented know-how upon which we rely on, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisers have wrongfully used or disclosed alleged trade secrets of their former employers, and we may be subject to claims asserting ownership of what we regard as our own intellectual property.***

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



---

## RISK FACTORS

---

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. In addition, some courts in China, the U.S. and other jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, consultants, and advisers, including our senior management, may currently be, or were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisers, including each member of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisers 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 individuals 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 materially and adversely affect 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

---

## RISK FACTORS

---

monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

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

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

The registered or unregistered trademarks or trade names that we own or license may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. If third parties succeed in registering or developing common law rights in trademarks similar or identical to our trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our products. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. As our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

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

Our commercial success depends upon our ability to develop, manufacture, market and sell our drug candidates without infringing, misappropriating or otherwise violating the intellectual property rights of others. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. We cannot guarantee that our

---

## RISK FACTORS

---

drug candidates or any uses of our drug candidates do not and will not in the future infringe third-party patents or other intellectual property rights. It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

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

Parties making infringement, misappropriation, or other intellectual property claims against us may obtain injunctive or other equitable relief, which could block our ability to further develop and commercialize one or more of our drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. In addition, even if we believe any third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of validity, enforceability, priority, or non-infringement. A court of competent jurisdiction could hold that such third party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any of our products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such third-party U.S. patents in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

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

---

## RISK FACTORS

---

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated adverse impacts on our business.

*Intellectual property rights do not necessarily address all potential threats.*

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents and trademarks of our trade name. As of the Latest Practicable Date, we owned 174 patents and patent applications (including in-licensed patents and patent applications with global rights), and we were also the registered owner of three domain names. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

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

---

## RISK FACTORS

---

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

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

### RISKS RELATING TO OUR OPERATIONS

*Our business operations may in the future be affected by health epidemics or outbreaks of contagious diseases as well as natural disasters.*

Any occurrence of force majeure events, natural disasters or outbreaks of epidemics and contagious diseases, including the COVID-19, avian influenza, severe acute respiratory syndrome, swine influenza caused by the H1N1 virus, or H1N1 influenza or the Ebola virus, may materially and adversely affect our business, financial condition and results of operations. For example, the COVID-19 pandemic and its recurrence have in the past caused temporary disruption to our certain aspects of our operations, including clinical development, which had a negative impact on our operations during the Track Record Period. Any future occurrence of severe natural disasters or outbreaks of epidemics and contagious diseases in China or globally, or the measures taken by the Chinese government or other countries in response to such contagious diseases, may materially and adversely affect their economy and our business.

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

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

---

## RISK FACTORS

---

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

We depend on principal members of our management and scientific teams. Our employment agreements with our executive officers do not prevent our executives from terminating their employment with us at any time. We do not maintain key-person insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

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

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

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



---

## RISK FACTORS

---

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

We had 92 employees as of the Latest Practicable Date. As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

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

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

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

***Increased labor costs could result in exceeding expenses, slow our growth and adversely affect our profitability.***

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 fulfill 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.

---

## RISK FACTORS

---

Further, most of our workforce is employed in China where the average labor cost has been steadily increasing over the past years as a result of inflation, government-mandated wage increases and other changes in labor laws and local economics. In particular, further changes in the labor laws, rules and regulations may be promulgated by the PRC government in the future and our operations may be materially and 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 may be involved in lawsuits, claims, administrative proceedings or other legal proceedings against us, which could adversely affect our business, financial conditions, results of operations and reputation.*

We may be involved in lawsuits, claims, administrative proceedings or other legal proceedings arising in the ordinary course of business or pursuant to governmental or regulatory enforcement activity from time to time. Litigation and governmental proceedings can be expensive, lengthy and disruptive to normal business operations, and can require extensive management attention and resources, regardless of their merit. Furthermore, any litigations, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake, and the parties involved.

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

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

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

- increased operating expenses and cash requirements;

---

## RISK FACTORS

---

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

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

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors, or the M&A Rules, and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. Moreover, according to the Anti-Monopoly Law of the PRC and the Provisions on Thresholds for Prior

---

## RISK FACTORS

---

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

***Our internal information technology and other infrastructure, or those used by our CROs, SMOs, CDMOs 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, SMOs, CDMOs, consultants and other service providers are vulnerable to damage from cyberattacks, 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 were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed.

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. Disruptions in our on-site systems and by our outsourced vendors could have a material adverse impact on us and our business, including loss of data and damage to equipment, among other things.

---

## RISK FACTORS

---

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 company, vendor and the other users of our vendors' confidential data.

If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be 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. 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 do not own the real property for our current major operation sites and may be subject to risks relating to leased properties.***

We do not own any real property for our operations. As of the Latest Practicable Date, we leased four properties in China with an aggregate GFA of approximately 5,493.3 sq.m. Upon expiration of the leases, we will need to negotiate for renewal of the leases and may have to pay increased rent. We cannot assure you that we will be able to renew our leases on terms which are favorable or otherwise acceptable to us, or at all. If we fail to renew any of our leases or if any of our leases are terminated or if we cannot continue to use any of our leased property, we may need to seek an alternative location and incur expenses related to such relocation, and our operation and businesses may also be disrupted or even suspended if we are not able to complete the relocation, including the reconstruction of relevant facilities in the new location, in a timely manner.

***We may be subject to fines due to the lack of registration of our leases.***

Pursuant to 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 (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, the lease agreements shall be filed for registration and property leasing filing certificates shall be obtained. As of the Latest Practicable Date, three of our lease agreements for properties in China have not been registered with relevant authorities in China. The registration of these relevant lease agreements requires additional steps to be taken by the lessors which are beyond our control. We cannot assure you that the lessors will be cooperative and that we can complete the registration of these lease agreements. We also maintain a pool of site candidates, and believe we would be able to relocate to a different site relatively easily should we be required to do so. As advised by our PRC Legal Adviser, if we cannot complete the registration of lease agreement, we may be subject to a fine ranging from RMB1,000 to RMB10,000 for each of the lease agreements. Such non-compliance does not affect the validity of the property lease agreement, and we believe such non-compliance is unlikely to have a material adverse effect on our business operations and financial performance.

---

## RISK FACTORS

---

*We are subject to the risks of doing business, including risks relating to political and economic instability and changes in diplomatic and trade relationships, which may materially and adversely affect our business and results of operations.*

Because we operate in China, the U.S. and other jurisdictions, our business is subject to risks associated with doing business. 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 sale, 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.

Furthermore, 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 and adversely affect our business and results of operations.



---

## RISK FACTORS

---

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

Substantially all of our costs are denominated in RMB and the U.S. dollars, most of our assets are cash and cash equivalents primarily denominated in RMB and the U.S. dollars, and our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. Therefore, our results of operations may be affected by foreign exchange fluctuations. In 2021 and 2022, we incurred net foreign exchange loss of RMB1.0 million and RMB3.5 million, respectively. We recorded currency translation differences of RMB18.9 million recognized as other comprehensive income in 2021 and RMB120.6 million recognized as other comprehensive loss in 2022. The change in the value of RMB against U.S. dollars and other currencies may fluctuate and is affected by many factors, including, among other things, changes in China’s political and economic conditions and China’s foreign exchange policies. 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.

***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 the PRC, we have elected not to maintain certain types of insurance. Our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

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

We, our Shareholders, Directors, officers, employees, collaboration partners, suppliers, or other third parties we cooperate with or rely on may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees, collaboration partners, suppliers or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Any negative publicity regarding our industry could also affect our reputation and commercialization. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity that may or may not directly related to us, and may not be able to defuse them to the satisfaction of our current or future [REDACTED], customers, patients and business partners.

---

## RISK FACTORS

---

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

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

We are a development-stage pharmaceutical company. Our operations to date have focused on conducting pre-clinical studies and clinical trials of our drug candidates, establishing our intellectual property portfolio, organizing and staffing, business planning, and raising capital. As of the Latest Practicable Date, we had no product approved for commercial sale. Our limited operating history, particularly in light of the rapidly evolving pharmaceutical industry, may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other business uncertainties. If we do not address these business uncertainties and difficulties successfully, our business will suffer. These risks may cause potential [REDACTED] to lose substantially all or part of their [REDACTED].

*We have not generated any revenue, and our ability to generate revenue from future sales of our drug candidates and become profitable depends significantly on our success in a number of factors, including the success of our drug candidates.*

As of the Latest Practicable Date, none of our drug candidates had been approved for commercial sale by any relevant regulatory authorities, and therefore we had not generated any revenue. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including:

- completing non-clinical and clinical research and development of our drug candidates;
- obtaining regulatory approvals and marketing authorizations for drug candidates for which we have completed clinical trials for;
- developing a sustainable and scalable manufacturing process for our drug candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- controlling the cost of production of our drug candidates;
- launching and commercializing drug candidates for which we obtain regulatory approvals and marketing authorizations;
- obtaining market acceptance of our drug candidates as viable treatment options to be paid as an out-of-pocket expense, and availability of adequate coverage, reimbursement, pricing by third-party payors and integrated delivery networks;

---

## RISK FACTORS

---

- addressing any competing technological and market developments;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trademarks, trade secrets, and know-how;
- identifying, assessing, acquiring and/or developing new drug candidates, intellectual property and technologies;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; and
- attracting, hiring, and retaining qualified personnel.

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

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

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

---

## RISK FACTORS

---

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

[REDACTED] in pharmaceutical drug development is highly speculative. Drug development entails substantial upfront capital expenditures and significant risk that a drug candidate fails to obtain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. We have incurred losses in each period since our inception. In 2021 and 2022, we recorded loss of RMB749.0 million and RMB781.6 million, respectively. Substantially all of our losses incurred during the Track Record Period resulted from costs incurred in connection with our research and development programs, administrative expenses and fair value losses on financial instruments issued to [REDACTED].

We expect to continue to incur significant losses for the foreseeable future, and we expect our operating losses to increase as we continue to expand our development of, and seek regulatory approvals for, our drug candidates, and continue to build up our manufacturing capability, commercialization and sales workforce in anticipation of the future roll-out of our drug candidates. Typically, it takes many years to develop one new drug from the drug-discovery stage to when it is available for treating patients. In addition, we will continue to incur costs associated with operating as a public company and in support of our growth as a development-stage or commercial-stage company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues, and the timing and amount of milestones and other payments we make or receive with or through arrangements with third parties. If any of our drug candidates fails in clinical trials or does not obtain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we become profitable in the future, we may not be able to remain profitable in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. As a result, you may lose substantially all or part of your [REDACTED].

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

We had net cash used in operating activities of RMB198.0 million and RMB306.3 million in 2021 and 2022, respectively. While we believe we have sufficient working capital to fund our current operations for the next 12 months, we expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. If we are unable to maintain adequate working capital, we may default on our payment obligations such as the milestone payments under our licensing agreements, be unable to meet our capital expenditure requirements, be forced to scale back our operations, and/or experience other negative impacts on our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

---

## RISK FACTORS

---

***We recorded net liabilities during the Track Record Period and may continue to incur net liabilities going forward, which can expose us to liquidity risk.***

We had net liabilities of RMB1,111.2 million and RMB1,905.1 million as of December 31, 2021 and 2022, respectively. Our net liabilities are primarily attributable to our financial instruments issued to investors we recorded as non-current liabilities, which amounted to RMB1,500.5 million and RMB2,277.3 million as of December 31, 2021 and 2022, respectively. Although we expect our net liability position to be reversed after the automatic conversion of the Preferred Shares into Shares upon the [REDACTED], a 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 external debt, which may not be available on terms favorable or commercially reasonable to us or at all. Any difficulty or failure to meet our liquidity needs as and when needed can have a material adverse effect on our prospects.

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

We believe our current cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED] will be sufficient to meet our anticipated cash needs for at least the next 12 months from the date of this document. We may, however, require additional cash resources to meet our continued operating cash requirements in the future, especially to fund our research and development activities. Our net cash used in operating activities mainly consists of (i) research and development costs including staff costs, discovery research expenses and clinical development expenses and (ii) workforce employment costs. In 2021 and 2022, we incurred total net cash used in operating activities of RMB198.0 million and RMB306.3 million, respectively. For further details of our net cash used in operating activities, please see “Financial Information – Cash Operating Costs.” We expect our net cash used in operating activities will increase significantly in light of our expanding clinical trial programs. Additionally, we are exposed to credit risk on the cash and cash equivalents deposited in financial institutions. In the event that any of them becomes insolvent and is taken into receivership by the relevant government agencies, there will be uncertainty as to the timing and extent to which we will be able to recover our cash on deposit at such financial institution. If the financial resources available to us after the [REDACTED] are insufficient to satisfy our cash requirements, we may seek additional funding through equity [REDACTED], debt financings, collaborations and licensing arrangements. It is uncertain whether financing will be available in the amounts or on terms acceptable to us, if at all. If we were not able to obtain additional capital to meet our cash requirements in the future, our business, financial condition, results of operations and prospects could be materially and adversely affected.

---

## RISK FACTORS

---

*Raising additional capital may cause dilution to our shareholders’ interest, restrict our operations or, when licensing of intellectual property rights is deployed as a means of financing our operations, require us to relinquish rights to our technologies or drug candidates.*

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

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

We adopted the Laekna Inc. Employee Stock Option Plan for the benefit of our employees (including directors) and non-employees as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our Company. For further details, please see the section headed “Appendix IV – Statutory and General Information – D. [REDACTED] Share Option Scheme” in this document. In 2021 and 2022, we incurred equity settled share-based payment expenses of RMB12.0 million and RMB26.5 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a negative effect on our financial performance.

*Intangible assets represent a significant portion of the assets on our consolidated balance sheet. If we determine our intangible assets are impaired, our results of operations and financial condition may be adversely affected.*

As of December 31, 2022, we had intangible assets of RMB123.6 million which comprised of RMB118.7 million related to in-licensed rights and RMB4.9 million related to software. Our intangible assets are primarily related to the patents and licenses we in-licensed from our collaboration partners. The value of intangible assets is based on a number of



---

## RISK FACTORS

---

assumptions made by the management. For a detailed discussion on the intangible assets, see Note 11 to the Accountants’ Report in Appendix I to this document. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, we may be required to have a significant decrease in the value of our intangible assets and record a significant impairment loss. Furthermore, our determination on whether intangible assets are impaired requires an estimation of the carrying amount and recoverable amount of an intangible asset.

If the carrying amount exceeds its recoverable amount, our other intangible assets may be impaired. The impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations. For more information regarding our impairment policy in relation to intangible assets, see Note 2 “Significant Accounting Policies – Intangible assets” and Note 3 “Accounting Judgments and Estimates – Impairment of intangible assets not ready for commercial use” to the Accountants’ Report in Appendix I to this document.

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

Our fair value changes on financial instruments issued to [REDACTED] resulted from changes in fair value of Preferred Shares and a warrant issued to [REDACTED]. In 2021 and 2022, our fair value changes on financial instruments issued to investors were RMB522.4 million and RMB387.1 million. Since 2018, we have issued a series of Series Seeds Preferred Shares, Series A Preferred Shares, Series B Preferred Shares, Series C Preferred Shares, and Series D Preferred Shares to our Series Seeds investors, Series A investors, Series B investors, Series C investors, and Series D investors, respectively. For more details regarding Preferred Shares, please see “History, Development and Corporate Structure – [REDACTED] Investments” in this document. We have designated the entire instrument of the Preferred Shares as financial liabilities at fair value through profit or loss. On January 31, 2019, we entered into a warrant agreement with an individual investor pursuant to which we issued a warrant to such investor for a cash consideration of RMB11.7 million. Pursuant to such warrant agreement, the warrant holder may exercise the warrant to purchase 1,166,525 ordinary shares and 338,273 Series Seeds Preferred Shares for nil consideration on or before the 90th day after our board approves to initiate an [REDACTED] of our shares. The warrant is initially recognized at fair value on the date of issuance and is subsequently re-measured to the fair value at the end of each reporting period. We have engaged an independent qualified professional valuer to determine the fair value of Preferred Shares and the warrant. For additional information, see Note 21(b) of the Accountants’ Report set out in Appendix I to this document. The respective fair value is determined by applying certain valuation techniques. Key valuation assumptions used to determine the fair value of the financial instruments are subject to various uncertainties. Any change in the assumptions may lead to different valuation results and, in turn, changes in the fair value of financial instruments issued to [REDACTED]. Fair value changes in our financial instruments issued to [REDACTED] and related valuation uncertainty may materially affect our financial condition and results of operations.

---

## RISK FACTORS

---

*The impairment of our prepayments and other receivables may affect our business operations.*

Our prepayments and other receivables were RMB12.5 million and RMB11.6 million as of December 31, 2021 and 2022, respectively. Our current prepayments and other receivables include advances to third parties, deposits, interest receivables, VAT recoverable and other receivables. For more details, please see Note 15 of the Accountants’ Report set out in Appendix I to this document. We conduct assessments on the recoverability of prepayments and other receivables based on, among others, our historical settlement records, our relationship with relevant counterparties, payment terms, current economic trends and to a certain extent, the larger economic and regulatory environment, which involve the use of various judgments, assumptions and estimates by our management. However, there is no assurance that our expectations or estimates will be entirely accurate, or any precautions we take to prevent an impairment will be effective, as we are not in control of all the underlying factors affecting such prepayments and other receivables. If we are not able to recover the prepayments and other receivables as scheduled, our financial position and results of operations may be adversely affected.

### **RISKS RELATING TO DOING BUSINESS IN CHINA**

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

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

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

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide

---

## RISK FACTORS

---

the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

On November 19, 2021, the CDE launched 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》), or the Clinical Principles, for anti-tumor drugs, which state that the fundamental purpose of the drug market is to address the needs of patients, and emphasize that drug research and development should be based on patient needs and clinical value. The Clinical Principles discourage repetitive research and development of “me-too drugs” (drugs with identical mechanisms of actions) and disorderly waste. If we are unable to comply with, or are deemed to be in violation of the Clinical Principles’ detailed provisions and principles, our clinical development activities and overall business operations may be materially adversely affected.

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

A large portion of our operations are conducted in China through our PRC subsidiaries, and are governed by PRC laws, rules and regulations. Our PRC subsidiaries are subject to laws, rules and regulations applicable to foreign investment in China. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

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

---

## RISK FACTORS

---

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

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

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

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

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

---

## RISK FACTORS

---

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

The PRC Foreign Investment Law (《中華人民共和國外商投資法》), or the FIL, was enacted by the NPC on March 15, 2019 and became effective on January 1, 2020, which replaces a trio of previous laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law (《中外合資經營企業法》), the Sino-foreign Cooperative Joint Venture Enterprise Law (《中外合作經營企業法》) and the Wholly Foreign-invested Enterprise Law (《外資企業法》), together with their implementation rules and ancillary regulations. This law has become the legal foundation for foreign investment in the PRC. The FIL embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Implementation Rules to the Foreign Investment Law 《外商投資法實施條例》 were promulgated by the State Council on December 26, 2019 and became effective on January 1, 2020. However, uncertainties exist with respect to interpretation and implementation of the FIL and its Implementation Rules, which may adversely impact our corporate governance practice and increase our compliance costs. For instance, the FIL imposes information reporting requirements on foreign investors or foreign-invested enterprises. Failure to take timely and appropriate measures to cope with any of these or other regulatory compliance requirements under the FIL may lead to rectification obligations, penalties or other regulatory sanctions on us.

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

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

---

## RISK FACTORS

---

exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

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

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage research and development activities. We recorded government grants of RMB0.1 million and RMB0.3 million in 2021 and 2022, respectively, which represent subsidies from local governments. The local governments have the discretion in deciding the timing, amount and criteria of government financial incentives and thus we cannot predict with certainty whether or how much financial incentive will be granted to us even if we apply for such funding. We generally do not have the ability to influence local governments in making these decisions. Government authorities may also decide to reduce or eliminate incentives or may amend or terminate the relevant financial incentive policies at any time. In addition, some of the government financial incentives are granted to us on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

**We may be required to complete filing procedures with the CSRC for the [REDACTED] and [REDACTED] of our Shares on the Hong Kong Stock Exchange.**

On August 8, 2006, six PRC regulatory authorities, including the MOFCOM, the SASAC, the STA, the SAIC, the CSRC, and the SAFE, jointly issued the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》) (the “M&A Rules”), which became effective on September 8, 2006, and amended on June 22, 2009. The M&A Rules include, among other things, provisions that purport to require that an offshore special purpose vehicle formed for the purpose of an overseas listing of securities in a PRC company obtain the approval of the CSRC prior to the listing and trading of such special purpose vehicle’s securities on an overseas stock exchange. However, uncertainty remains regarding the scope and applicability of the M&A Rules to offshore special purpose vehicles.



---

## RISK FACTORS

---

On July 6, 2021, the relevant PRC government authorities issued Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》). These opinions emphasized the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies.

On February 17, 2023, the CSRC promulgated the Overseas Listing Trial Measures and five supporting guidelines, which has become effective on March 31, 2023. The Overseas Listing Trial Measures require, among others, that PRC domestic enterprises that seek to offer and list securities in overseas markets, either directly or indirectly, to file the required documents with the CSRC within three business days after its application for overseas listing is submitted. On the same date, the CSRC promulgated the Arrangement for Filing-based Administration. According to the Arrangement for Filing-based Administration, PRC domestic enterprises shall not be required to complete the filing procedures if all of the following conditions are met: (i) the application for indirect overseas offering or listing shall have passed the hearing for a contemplated offering and/or listing in Hong Kong prior to the effective date of the Overseas Listing Trial Measures; (ii) it is not required to re-perform the overseas regulatory procedures for overseas securities offering and listing; and (iii) such overseas securities offering or listing shall be completed before September 30, 2023. We have passed the hearing before [REDACTED] and if our [REDACTED] can be completed before [REDACTED], as advised by our PRC Legal Advisor, we will not be required to file with the CSRC with respect to this [REDACTED].

Furthermore, we cannot assure you that any new rules or regulations promulgated in the future will not impose additional requirements or restrictions on us or our financing activities. If it is determined in the future that approval from or filing with the CSRC or other regulatory authorities or other procedures are required, we may fail to obtain such approval, perform such filing procedures or meet such other requirements in a timely manner or at all. We may face sanctions by the CSRC or other PRC regulatory authorities for failure to seek CSRC approval or other government authorization, or perform filing procedures, for this [REDACTED] or our future financing activities, and these regulatory authorities may impose fines and penalties on us, limit our operating activities in the PRC, limit our ability to pay dividends outside of the PRC, delay or restrict the repatriation of the [REDACTED] from the [REDACTED] into the PRC or take other actions to restrict our financing activities, which could have a material adverse effect on our business.

***We are subject to PRC tax laws and regulations.***

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. Although we believe that in the past we had acted in compliance with the requirements under the relevant PRC tax laws and regulations in all material aspects and had established effective internal control measures in relation to accounting regularities, we cannot assure you that future examinations by PRC tax authorities

---

## RISK FACTORS

---

would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC government from time to time adjusts or changes its tax laws and regulations. Such adjustments or changes, together with any uncertainty resulting therefrom, could have an adverse effect on our business, financial condition and results of operations.

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

Most of our operating subsidiaries are incorporated in China. Some of our management reside in China. Almost all of our assets are located in China. Therefore, it may not be possible for [REDACTED] to effect service of process upon us or our management inside China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions. On July 14, 2006, the mainland China and 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**”), pursuant to which a party with an enforceable final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with an enforceable final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a Chinese court is expressly designated as the court having sole jurisdiction for the dispute.

On January 18, 2019, the Supreme People’s Court and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “**New Arrangement**”), which seeks to establish a mechanism with further clarification on and certainty for recognition and enforcement of judgments in a wider range of civil and commercial matters between the Hong Kong Special Administrative Region and the China. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court and the completion of the relevant legislative procedures in the Hong Kong Special Administrative Region. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in China if the parties in the

---

## RISK FACTORS

---

dispute do not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for [REDACTED] to effect service of process against our assets or management in China in order to seek recognition and enforcement of foreign judgments in China.

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

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

SAFE has promulgated several regulations associated with offshore investment such as Circular of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by Domestic Residents in China via Special-Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) or SAFE Circular 37, issued and effective on July 4, 2014, and the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments (《國家外匯管理局關於發佈〈境內機構境外直接投資外匯管理規定〉的通知》) (SAFE Circular 30). Failure to comply with the various SAFE regulations might result in liability under PRC laws for evasion of applicable foreign exchange restriction, including (1) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (2) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

There remains uncertainty as to the interpretation and implementation of the latest SAFE rules at practice level. We are committed to complying with the relevant SAFE rules and other regulations; however, due to the inherent uncertainty in the implementation of the regulatory requirements by PRC authorities, such registration might not be always practically available in all circumstances as prescribed in those regulations. In addition, we may not always be fully aware or informed of the identities of our beneficial owners who are PRC nationals or entities, and may not be able to compel them to comply with relevant SAFE rules and other regulations. We cannot assure you that all of our Shareholders or beneficial owners will at all times comply with, or in the future make or obtain any applicable registrations or approvals required by SAFE rules or other regulations. We cannot assure you that the SAFE or its local branches will not release explicit requirements or interpret the relevant PRC laws and regulations otherwise.

---

## RISK FACTORS

---

Failure by any such shareholders to comply with SAFE rules or other regulations may result in restrictions on the foreign exchange activities of our PRC subsidiaries and may also subject the relevant PRC resident or entity to penalties under the PRC foreign exchange administration regulations.

*We and our Shareholders face uncertainty relating to PRC laws and regulations relating to the indirect transfer of equity interests in PRC resident enterprises by a non-PRC resident enterprise.*

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

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

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

---

## RISK FACTORS

---

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

Provisions of Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to “non-resident enterprise acquiring and disposing of the equity interests of the same offshore listed company in a public market,” or the Public Market Safe Harbor, which is determined by whether the parties, number and price of the shares acquired and disposed are not previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to 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. As stated in “Information about this Document and the [REDACTED]” in this document, potential [REDACTED] should consult their professional advisors if they are in any doubt as to the tax implications of subscribing for, purchasing, holding, disposing of and dealing in the Shares.

***Under the EIT Law, we may be classified as a “PRC resident enterprise” for PRC income tax purposes, and such classification could result in unfavorable tax consequences to us and our non-PRC shareholders.***

Under the EIT Law, an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it can be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. The Notice Regarding the Determination of Chinese-Controlled Offshore-Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) issued by STA on April 22, 2009, or Circular 82, regarding the standards used to classify resident enterprises clarified that dividends and other distributions paid by such resident enterprises which are considered to be PRC source income will be subject to PRC withholding tax, currently at a rate of 10%, when received or recognized by non-PRC resident enterprise shareholders. This circular also subjects such resident enterprises to various reporting requirements with the PRC tax authorities. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting and properties” of the enterprise. In addition,



---

## RISK FACTORS

---

Circular 82 specifies that certain China-invested enterprises controlled by Chinese enterprises or Chinese group enterprises will be classified as resident enterprises if the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. On July 27, 2011, the STA issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (《境外註冊中資控股居民企業所得稅管理辦法(試行)》), or Bulletin 45, which became effective on September 1, 2011, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

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

Despite the foregoing, the STA may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules and Bulletin 45 dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax, as the PRC foreign-exchange control authorities and tax authorities have not yet issued guidance with respect to the processing of outbound remittances to entities that are treated as resident enterprises for PRC enterprise income tax purposes but not controlled by a PRC enterprise or enterprise group like us. Finally, under the EIT Law and its implementing rules issued by PRC tax authorities dividends paid by us to our non-PRC shareholders may be subject to a withholding tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders, and gains recognized by our non-PRC shareholders may be subject to PRC tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders.



---

## RISK FACTORS

---

Any PRC tax liability on dividends or gain described above may be reduced under applicable tax treaties. However, it is unclear whether, if our Cayman Islands holding company is considered a PRC resident enterprise, non-PRC shareholders would be able to obtain in practice the benefit of income tax treaties entered into between PRC and their countries. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise. Any such tax may reduce the returns on your [REDACTED] in our Shares.

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

The PRC government imposes controls on the convertibility of foreign currencies into Renminbi. Under China's existing foreign-exchange regulations, foreign-exchange transactions under capital accounts continue to be subject to significant foreign-exchange controls and require the registration with, and approval of, PRC governmental authorities. In particular, if one subsidiary receives foreign-currency loans from us or other foreign lenders, these loans must be registered with SAFE or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be filed with or approved by certain government authorities, including the MOFCOM or its local counterparts and the SAMR through the Enterprise Registration System (企業登記系統) and the National Enterprise Credit Information Publicity System (國家企業信用信息公示系統) and the SAFE.

On March 30, 2015, SAFE released the Notice on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or SAFE Circular 19, which came into force from June 1, 2015. On June 9, 2016, SAFE further promulgated the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects (《關於改革和規範資本項目結匯管理政策的通知》), or SAFE Circular 16. SAFE Circular 19 has made certain adjustments to some regulatory requirements on the settlement of foreign exchange capital of foreign-invested enterprises. Under SAFE Circular 19 and SAFE Circular 16, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, SAFE Circular 19 and SAFE Circular 16 also reiterate that the settlement of foreign exchange shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity. For example, under SAFE Circular 19 and SAFE Circular 16, we may still not be allowed to convert foreign-currency-registered capital of our PRC subsidiaries which are foreign-invested enterprises into RMB capital for securities investments or other finance and investment except for principal-guaranteed bank products. Further, SAFE Circular 19 and SAFE Circular 16 restrict a foreign-invested enterprise from using Renminbi converted from its registered capital to provide loans to its non-affiliated company. On October 23, 2019, SAFE released the Circular on Further Promoting Cross-border Trade and Investment Facilitation (《國家外匯管理局關於

---

## RISK FACTORS

---

進一步促進跨境貿易投資便利化的通知》), or SAFE Circular 28, according to which non-investment foreign-invested enterprises are permitted to make domestic equity investments with their capital funds provided that such investments do not violate the Negative List and the target investment projects are genuine and in compliance with laws. On April 10, 2020, SAFE promulgated the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》), or SAFE Circular 8, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign loans and the income under capital accounts of overseas listing, without providing evidentiary materials concerning authenticity of each expenditure, provided that their capital use shall be authentic and in line with provisions, and conform to the prevailing administrative regulations on the use of income under capital accounts. Considering that SAFE Circular 28 and SAFE Circular 8 are often principle-oriented and subject to the detailed interpretations by the enforcement bodies to further apply and enforce such laws and regulations in practice, it is unclear how they will be implemented, and there exist substantial uncertainties with respect to its interpretation and implementation by government authorities and banks.

Violations of SAFE Circular 19 and SAFE Circular 16 could result in severe monetary or other penalties. We cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries, and conversion of such loans or capital contributions into Renminbi. If we fail to complete such registrations or obtain such approvals, our ability to capitalize on or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business.

***The M&A Rules and certain other PRC regulations establish complex procedures for some acquisitions of PRC companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.***

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》), or the M&A Rules, and relevant regulations and rules concerning mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. The M&A Rules require that the MOFCOM shall 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 an impact on the 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. The approval from MOFCOM shall be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies.

---

## RISK FACTORS

---

The Anti-Monopoly Law (《中華人民共和國反壟斷法》) promulgated by the Standing Committee of the National People’s Congress, or NPC, which became effective in August 2008, requires that when a concentration of undertakings occurs and reaches statutory thresholds, the undertakings concerned shall file a prior notification with MOFCOM. Without the clearance from MOFCOM, no concentration of undertakings shall be implemented and effected. 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 under 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》) or the Prior Notification Rules, issued by the State Council in August 2008 is triggered. If such prior notification is not obtained, MOFCOM may order the concentration to cease its operations, dispose of shares or assets, transfer the business of the concentration within a time limit, take any other necessary measures to restore the situation as it was before the concentration, and may impose administrative fines. SAMR becomes the successive authority of MOFCOM with regard to the above matters, upon the government reorganization in March 2018.

In addition, the Implementing Rules Concerning Security Review on the Mergers and Acquisitions by Foreign Investors of Domestic Enterprises (《商務部實施外國投資者併購境內企業安全審查制度的規定》), issued by the MOFCOM in August 2011, specify that mergers and acquisitions by foreign investors relating to national security are subject to strict review by the MOFCOM, and prohibit any activities attempting to bypass such security review, including by structuring the transaction through a proxy or contractual control arrangement. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the abovementioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions.

We cannot preclude the possibility that the MOFCOM or other government agencies may publish explanations contrary to our understanding or broaden the scope of such security reviews in the future, in which case our future acquisitions in the PRC, 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.

***Failure to comply with relevant regulations relating to social insurance and housing provident fund may subject us to penalty.***

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to the social insurance plans and the housing provident fund under the relevant PRC laws and regulations for our employees. For details relating to these relevant laws and regulations, please refer to the paragraph headed “Regulatory overview – Labor and social security” in this document.

---

## RISK FACTORS

---

As of the Latest Practicable date, we have engaged third-party human resource agency to pay social insurance premium and housing provident funds for four of our employees. Pursuant to the agreement entered into between such third-party human resources agency and us, the third-party human resources agency have the obligation to pay social insurance premium and housing provident funds for our relevant employees on behalf of us. As of the Latest Practicable Date, we had not received any administrative penalty or labor arbitration application from employees for its agency arrangement with third-party human resources agency. These four employees have confirmed in writing that they have accepted this arrangement and will not pursue any claims against us with the competent authorities. As advised by our PRC Legal Adviser, considering the facts stated above, the risk of us being subject to material penalties as a result of paying the social insurance premium or housing provident funds through third-party agency and thus have any material adverse effect on our financial condition or results of operations taken as a whole is relatively low. However, if the local governments determine the use of third-party agency to pay social insurance and housing provident funds to be non-compliant in the future or such human resource agency fail to pay the social insurance premium or housing provident funds for and on behalf of our employees as required by applicable PRC laws and regulations, we may be subject to additional contribution, late payment fee and/or penalties imposed by the relevant PRC authorities for failing to discharge our obligations in relation to payment of social insurance and housing provident funds as an employer or be ordered to rectify. This in turn may adversely affect our financial condition and results of operations.

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

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

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

There can be no assurance that such collaborators or business partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Since mid-2018, political tension has increased between China and the U.S. There can be no assurance that potential collaboration partners will not alter their perception of us or their preferences as a result of such adverse changes between China and relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions

---

## RISK FACTORS

---

may adversely affect our business, financial condition, results of operations, cash flows and prospects. It also remains unclear what actions, if any, the U.S. government will take with respect to other existing international trade agreements. If the U.S. were to withdraw from or materially modify certain international trade agreements to which it is a party, especially with respect to intellectual properties transfer, our business, financial condition and results of operations could be negatively impacted.

### **RISKS RELATING TO THE [REDACTED]**

*No public market currently exists for our Shares; an active [REDACTED] market for our Shares may not develop and the [REDACTED] for our Shares may decline or become volatile.*

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED] (for itself 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 deal in, the Shares. In addition, each existing Shareholder, including our [REDACTED] Investors, has entered into [REDACTED] undertakings in favor of our Company and/or the Sole Sponsor and/or the [REDACTED] pursuant to which they are subject to [REDACTED] arrangements ending on the date which is six months from the [REDACTED], subject to certain exceptions. As a result, a [REDACTED] on the Hong Kong Stock Exchange does not guarantee that an active and liquid trading market for our Shares will develop, especially during the period when a significant portion of our Shares are subject to [REDACTED] undertakings, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will rise following the [REDACTED].

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

The price and [REDACTED] of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and [REDACTED] of our Shares. In addition to market and industry factors, the price and [REDACTED] of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies [REDACTED] 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.



---

## RISK FACTORS

---

*The price of our Shares when trading begins could be lower than the [REDACTED].*

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

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

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

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

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] net tangible asset value. In order to expand our business, we may consider [REDACTED] and [REDACTED] 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 [REDACTED] Shares pursuant to the share incentive schemes, which would further dilute Shareholders' interests in our Company.

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

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



---

## RISK FACTORS

---

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

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

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

*Our single largest Shareholder has had and will continue to have substantial influence over the outcome of shareholder actions in our Company. The interests of our Shareholder may not be aligned with the interests of our other Shareholders.*

Upon completion of the [REDACTED] and [REDACTED], the single largest Shareholder will hold [REDACTED]% of our total issued and outstanding Shares (assuming that all of the Preferred Shares have been converted into the Shares on a one-to-one basis). As a result, the single largest Shareholder, will have significant influence over our business, including decisions regarding mergers, consolidations, liquidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions.

It may take actions that are not in the best interest of us or our other Shareholders. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could have the effect of depriving our other Shareholders of the opportunity to receive a premium for their shares as part of a sale of our Company and may reduce the price of the Shares. This concentrated control will limit your ability to influence corporate matters and could discourage others from pursuing any potential merger, takeover or other change of control transactions that other holders of our ordinary shares may view as beneficial.

---

## RISK FACTORS

---

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

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

As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management, Directors or our single largest Shareholder, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such Shareholders are located.

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

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. We believe that the sources of such information is appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. The information has not been independently verified by us, the Sole Sponsor, the [REDACTED] or any other party involved in the [REDACTED] and no representation is given as to its accuracy. The Directors and the Sole Sponsor have exercised reasonable care in selecting and identifying the named information sources, in compiling, extracting, and reproducing the information, and in ensuring that there is no material omission of the information.

---

## RISK FACTORS

---

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

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

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