An [**REDACTED**] *in our H Shares involves significant risks. In particular, we are a biotechnology company seeking to* [**REDACTED**] *on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with* [**REDACTED**] *in companies such as ours. Potential investors may lose all of their* [**REDACTED**] *in the Company given the nature of biotechnology industry. Your* [**REDACTED**] *decision should be made in light of these considerations. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the "Financial Information" section, before deciding to* [**REDACTED**] *in our H Shares. These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring.*

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 business and industry, comprising (a) risks relating to the research and development of our product candidates, (b) risks relating to sales and distribution of our product candidates, (c) risks relating to manufacture and supply of our product candidates, (d) risks relating to our cooperation with third parties, (e) risks relating to extensive government regulations, (f) risks relating to our intellectual property rights; (g) risks relating to our financial position and need for additional capital; and (h) risks relating to our general operations; (ii) risks relating to our doing business in China; and (iii) risks relating to the [**REDACTED**].

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

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to the Research and Development of Our Product Candidates

Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage product candidates, and we may be unable to successfully complete their clinical development, obtain relevant regulatory approvals or achieve their commercialization, or may experience significant delays in doing so.

Our ability to generate revenue and realize profitability depends on the successful completion of the development of our product candidates, obtaining necessary regulatory approvals, and manufacturing and commercializing our product candidates, which is contingent upon various factors. Such factors may include:

- successful enrollment in, and completion of, clinical trials, as well as completion of pre-clinical studies and favorable safety and efficacy data therefrom;
- receipt of regulatory approvals;
- enhancing our commercial manufacturing capabilities;

- the performance by CROs or other third parties of their duties to us in manner that complies with our trial protocols and applicable laws and that protects the integrity of the resulting data;

- obtaining, maintaining, protecting and enforcing patent, trade secret and other intellectual property and proprietary protection and regulatory exclusivity, and ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property and proprietary rights of third parties;

- successfully launching commercial sales;

- obtaining and/or maintaining favorable governmental and private medical reimbursement;

- efficiently and cost-effectively establishing and enhancing our marketing and distributing capabilities;

- competition with other products and product candidates; and

- continued acceptable safety profile following regulatory approval.

While we have invested a significant portion of our efforts and financial resources in the development, regulatory approval and commercialization of our existing product candidates, and expect to continue doing the same, we may not be able to achieve one or more of the foregoing factors in a timely manner or at all. As a result, we could experience significant delays or inability in obtaining approval for and/or successful commercialization of our product candidates, which would render us unable to achieve our milestones as planned and materially harm our product development prospects.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may not successfully complete clinical trials or procedures relating to our product candidates or demonstrate safety and efficacy of our product candidates to the satisfaction of regulatory authorities.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate their safety and efficacy, but there can be no assurance that such trials will be completed in a timely or cost-effective manner, due to the inherently unpredictable nature of clinical development, and there is no assurance that the results of our clinical trials, including safety and efficacy data, would be what we expect. Specifically, we may experience numerous unexpected events throughout the clinical trials, 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;

- our inability to reach agreements on acceptable terms with prospective CROs, SMOs and hospitals as trial centers;

- manufacturing issues relating to our own facilities, including problems with manufacturing, supply quality, compliance with good manufacturing practice, or GMP;

- clinical trials producing negative or inconclusive results, and additional clinical trials or abandoning product development programs being required;

- our third-party contractors' failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- our having to suspend or terminate clinical trials for various reasons, including a finding of lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks;

- the number of subjects required for clinical trials of our product candidates may be larger, enrollment may be insufficient or slower and the subjects may drop out at a higher rate than we anticipate;

- the cost of clinical trials being greater than we anticipate; and

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials being insufficient or inadequate.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates because of any of the foregoing events, the commercial prospects of that product candidate will be harmed. Specifically, we may:

- be delayed in obtaining regulatory approval;

- be required to conduct additional clinical trials or other testing beyond those that we currently contemplate;

- not obtain approval for indications that are not as broad as intended;

- be subject to additional post-marketing testing requirements;

- be subject to restrictions on how the product is distributed or used; or

- be unable to obtain reimbursement for the use of the product.

Consequentially, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commercialize our product candidates after obtaining marketing approval and generate related revenues.

Results of earlier clinical trials may not be predictive of results of later-stage clinical trials.

The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Our product 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. Future clinical trial results may not be favorable for these and other reasons. For example, in the BALB/c mice study, LZ901 has induced a stronger cellular

immune response with higher expression of multiple types of immune cell activating biomarkers as compared Shingrix®. However, there is no assurance that results on animal-based studies will be predicative of the results on the clinical trials.

In some cases, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the subject populations, including genetic and biological differences and other trial protocols. As product candidates are developed through pre-clinical to early-to late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. 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. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, which could delay completion of clinical trials, delay approval of our product candidates and/or jeopardize our ability to commence commercialization of our product candidates.

We may be unable to identify, discover, or develop new product candidates, or to identify additional therapeutic opportunities for our product candidates, in order to expand or maintain our product pipeline.

Although we continue to design, evaluate and select optimal candidates and continue to enrich our pipeline, we cannot guarantee that we will be successful in identifying potential product candidates. Research programs to pursue the development of our product candidates for additional indications and to identify new product candidates and product targets require substantial technical, financial and human resources and there is no assurance that we may have the depth and breadth in expertise to deliver each of the pipeline product candidates efficiently. Our research programs may initially show promising results in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons. Accordingly, there can be no assurance that we will be able to identify new product candidates or additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially and adversely affect our future growth and prospects.

The data and information that we gather in our research and development process could be inaccurate or incomplete.

We collect, aggregate, process, and analyze data and information from our preclinical studies and clinical programs. Because data in the healthcare industry is fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we may discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our product candidates may be materially harmed.

We also engage in the procurement of regulatory approvals necessary for the development and commercialization of our product candidates, for which we manage and submit data to governmental entities. These processes and submissions are governed by complex data processing and validation

policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a customer, court or government agency that concludes that our storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on third-party collaborators, such as CROs, to monitor and manage data for some of our ongoing preclinical and clinical programs and control only certain aspects of their activities. If any of our CROs or other third party collaborators does not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. Please see "— Risks Relating to Our Cooperation with Third Parties — As we work with various third parties to conduct a certain number of our pre-clinical studies and clinical trials, we may not be able to obtain regulatory approval for, or commercialize, our product candidates, or experience delay in doing so if these third parties do not successfully carry out their contracted duties or meet expected deadlines" below for more details.

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

The timely completion of clinical trials in line with their protocols depends additionally and specifically on our ability to enroll a sufficient number of subjects who remain in the trial until its conclusion. However, we may experience difficulties in subject enrollment for a variety of reasons, including our product candidates' targeting diseases, the size and nature of the patient population for such diseases, the public awareness of the infection rates of targeted infectious diseases and the size of population at risks of infection, the subject eligibility criteria defined in the protocol, our investigators or clinical trial sites' efforts to screen and recruit eligible subjects, the accessibility of trial sites for the subjects, and the subjects' perceptions as to the potential advantages and side effects of the product candidates being studied in relation to other available products, product candidates or therapies. Moreover, our clinical trials will likely compete with other clinical trials for product candidates that are in the same therapeutic areas as ours, which will reduce the number and types of patients available to us.

Even if we are able to enroll a sufficient number of subjects, delays in subject 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 product candidates.

We rely on third-party testing agencies to obtain testing results of clinical trials of our product candidates, and we may experience delay or obtain inaccurate data due to factors beyond our control.

We rely on third-party testing agencies, such as clinical trial institutions, to monitor and manage data for some of our ongoing clinical trials and control only certain aspects of their activities. If any of our testing agencies fails to complete testing on time, we may experience delay in obtaining testing results of clinical trials and disclosing data from such clinical trials. For example, we experienced delay in serum sample testing by the NIFDC of the NMPA to obtain exploratory endpoint data to preliminarily

explore the immunogenicity of LZ901 for the Phase I clinical trial due to the COVID-19 outbreak. We cannot guarantee that we will not experience similar delay in sample testing by the NIFDC of the NMPA to obtain exploratory endpoint data in relation to the Phase II clinical trial of LZ901, or any other clinical trials for our product candidates.

In addition, due to the testing uncertainty of the testing agencies in terms of data accuracy or completeness, exploratory endpoint data from those clinical trials may be compromised, and such data of clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials.

Our product candidates may cause AEs or undesirable side effects, which 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.

AEs caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the regulatory authority. Results of our clinical trials, including the ongoing Phase II clinical trial for LZ901 in China and planned clinical trials for LZ901 and K3, could reveal a high and unacceptable seriousness or prevalence of AEs. In such an event, our clinical trials could be suspended or terminated and the relevant regulatory authority could order us to cease further development of, or deny approval of, our product candidates for any or all targeted diseases. AEs related to our product candidates could affect subject recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims.

Additionally, if one or more of our product candidates receive regulatory approval, and we or others later identify undesirable adverse events caused by such products, a number of potentially significant negative consequences could result, including the following:

- we may suspend the marketing of the product;
- regulatory authorities may withdraw approvals or revoke licenses of an approved product candidate;
- regulatory authorities may require additional warnings on the label of an approved product candidate or impose other limitations on an approved product candidate;
- we may be required to develop a risk evaluation mitigation strategy for the product candidate, or to incorporate additional requirements under the risk evaluation mitigation strategy;
- we may be required to conduct post-market studies; and
- we could be subject to litigation proceedings and held liable for harm caused to patients.

In any such events, we may suspend, delay or alter development or marketing of our product candidates, and the costs thereof may be substantially higher than anticipated.

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

We face an inherent risk of product liability as a result of clinical trials, if our product candidates cause, are perceived to cause injury, or are found to be otherwise unsuitable during clinical testing. Regardless of the merits or eventual outcome, such liability claims may, among others, result in:

- decreased demand for our product candidates after commercialization;
- 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; and
- substantial monetary awards to trial participants or patients.

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

Our efforts in research and development in order to develop, enhance or adapt to new technologies and methodologies may fail to materialize ultimately.

The global pharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. 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 also intend to continue to strengthen our technical capabilities in vaccine and therapeutic biologics discovery, development, and manufacturing, which are capital and time intensive. However, there can be no assurance that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could harm our business and prospects.

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

Due to limited financial and managerial resources, we focus our product pipeline on product candidates that we identify for specific indications, and, as a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Risks Relating to Sales and Distribution of Our Product Candidates

The recession or eradication of the infectious diseases that our vaccine candidates target and the availability of alternative vaccines or treatment technologies may adversely affect our sales.

According to Frost & Sullivan, the eradication of the infectious diseases that our vaccine candidates target are highly unlikely. However, if the diseases that any of our vaccine candidates are indicated recess or are effectively eradicated, market demand for the relevant vaccine products will consequently diminish. Moreover, medical technologies are evolving and new vaccines or treatment technologies for the diseases that our vaccine candidates target may emerge. If these competing new vaccines or technologies are perceived by vaccines to be more effective than our vaccine candidates, market demand for our vaccines candidates may decline.

Failure to secure cooperation with qualified cold-chain logistics providers may cause great risk of damage to our future vaccine products and damage our reputation and business.

Vaccines are sensitive biological products. Some vaccines are sensitive to freezing, some to heat and others to light. To maintain quality and potency, vaccines must be stored in good conditions through cold-chain logistics providers. The Vaccine Administration Law of the PRC (《中華人民共和國疫苗管理法》) requires cold-chain transportation and storage in the entire delivery process of vaccines in order to ensure constant monitoring and control of temperature, with a record system implemented to keep proper records of the temperature of vaccines during transportation and storage. In order to maintain a reliable vaccine cold chain at manufacture level before delivery to our customers, we need to secure cooperation with qualified cold-chain logistics service providers to store our future vaccine products and diluents within the approved temperature range at all sites, pack and transport vaccines to and from outreach sites according to recommended procedures, and perform regular oversight and monitor on the delivery process to our customers. If we or third parties we cooperated with fail to do so, our future vaccine products may be exposed to inappropriate temperatures or other improper storage conditions and subject to potency diminishment or even potency loss. In that case, all the vaccine products are subject to quality damage and may need to be destroyed.

We expect to sell most of our future vaccine products to CDCs in China, which exposes us to uncertainties associated with the government funding and budgeting process.

We expect to derive a substantial portion of our revenue directly or indirectly from sales of our future vaccine products to CDCs, which are affiliated with the PRC government. We are accordingly exposed to various risks relating to conducting business with the government. As CDCs are generally required to seek approvals from local governments before making any purchase of vaccines, their demand for our products and their ability to make timely payment may be affected by government budgetary cycles, fluctuating availability of public funds and changes in policy. In addition, we have no influence over government procurement decisions, and CDCs may request to reduce or even cancel orders, or demand price adjustments or other changes under certain conditions. Funding reductions, delays in payment or unilateral demands by CDCs could adversely impact our business and make it difficult for us to allocate resources or anticipate demand for our products.

Our product candidates may be excluded or removed from national, provincial or other government-sponsored medical insurance programs.

Under medical insurance programs in the PRC, patients are entitled to reimbursement of all or a portion of the cost of pharmaceutical products listed in the National Reimbursement Drug List, the NRDL, the relevant provincial reimbursement drug lists, the PRDLs, or other medical insurance reimbursement lists. However, such inclusion is based on a variety of factors, including clinical needs, use frequency, efficacy, safety and price, which may be outside of our control. Moreover, the relevant PRC government authorities may also, from time to time, review and revise, or change the scope of reimbursement for, the products that are included in the medical insurance reimbursement lists. Currently herpes zoster vaccine, varicella and rabies vaccines are prophylactic vaccines which are not included in the NRDL. K193, K333, K1932 are Class A innovative biological products. There is no similar products in this category covered by NRDL. Therefore, our vaccine product candidates, K193, K333 and K1932 are unlikely to be included in the NRDL. Not being included under the NRDL would not affect the pricing of our product candidates as we would price our products candidates at market price. However, if peer products are included in the NRDL, our peer products will gain market competitive advantage in mark penetration, which would cause market pressure on our product candidates.

There can be no assurance that our future approved products will be included in any medical insurance reimbursement list. Similarly, to the extent that our future approved product are not included in any medical insurance reimbursement list or if any such insurance schemes are changed or canceled which result in any removal of products from medical insurance catalog, patients may choose, CDCs and hospitals may recommend alternative treatment methods, which would reduce demand for our products, and our sales may be adversely impacted.

We may need to lower our product price in order to qualify for medical insurance reimbursement or due to market competition.

We may need to lower the prices of our future approved products in order to have them included in the medical insurance reimbursement lists, while such price cut and reimbursement may not necessarily lead to increased sales. As a result, even if they were so included, our potential revenue from the sales thereof could still decrease as a result of the significantly lowered prices.

In addition, it is typical that the prices of pharmaceutical products will decline over the life of the product as a result of, among other things, increased competition from substitute products, the tender process by CDCs, hospitals or government authorities, pricing policies of the relevant government authorities, or voluntary price adjustments by pharmaceutical companies. Any downward adjustments or pricing pressure of our existing or future approved products could have a material and adversely effect on our business and results of operations.

Our future approved products may fail to achieve the degree of market acceptance by CDCs, local vaccination sites and clinics, physicians, KOLs, patients, third-party payers and others in the medical community necessary for commercial success.

The commercial success of our future approved products depends upon the degree of market acceptance they can achieve, particularly among CDCs, patients, hospitals and physicians, which is contingent upon a number of factors. Such factors may include:

- the clinical indications for which the product are approved;
- the safety and efficacy of the product;
- the potential and perceived advantages and disadvantages of the product, relative to competing products or treatments;
- treatments compared to alternative products and treatments; and
- the effectiveness of our sales and marketing efforts.

If our future approved products fail to achieve or maintain widespread market acceptance, or if new products introduced by our competitors are perceived more favorably by healthcare practitioners and patients, are more cost-effective or otherwise render our products obsolete, the demand for our products may decline.

Because some of our vaccine candidates are intended to prevent diseases of major public health concerns, we are at risk of governmental actions detrimental to our business, such as price controls or waivers on vaccine patent.

In response to infectious diseases or the perceived risk of infectious diseases, governments in China and other countries may take actions to protect their citizens, including but not limited to, intellectual property expropriation, compulsory licenses and/or strict price controls. These actions could affect our ability to control the production and our ability to generate revenue from sales of our vaccine products, if approved, or otherwise impose burdensome regulations on our business. Additionally, we may need to, or we may be required by governmental or non-governmental authorities to, set aside our future approved vaccine products, for designated purposes or geographic areas, and subject to requirements on allocation of supply. We are also likely to face significant public attention and scrutiny over any future business models and pricing decisions with respect to our future vaccine products.

We may not bid in the public tender process successfully and we may fail to secure subsequent product orders.

We are required to participate in the public tender process held by difference levels of CDCs in order to sell our future vaccine products in the PRC. Public tenders for Class I vaccines are held by national or provincial-level CDCs. Public tenders for Class II vaccines are held by provincial-level CDCs. Once we win a public tender, we will be eligible for selling vaccine products to CDCs. For our future therapeutic biologics products, we have to submit bids in a centralized tender process to supply our products to public hospitals and other medical institutions in the PRC at specified prices. Each public medical institution in China must generally procure drugs through a provincial centralized drug purchase platform, and make substantially all of its purchases of pharmaceutical products through a centralized tender process.

Our bids during the public tender process may not be successful and our future products may not be chosen for the following reasons:

- our prices are not competitive;
- our products are perceived to be less clinically effective than competing products;
- our service quality or any other aspect of our operation is perceived not to meet relevant requirements; or
- our reputation is adversely affected by unforeseeable events.

If we fail to participate or bid successfully during any public tender process, we will not be able to sell our future approved products to the relevant CDCs, public hospitals and other medical institutions.

Even if we bid successfully, we cannot guarantee that we will be able to secure purchase orders from local CDCs. For our existing vaccine candidates, if approved, public tenders serve as an admission for entry to market, typically for one year and in certain situations two or three years, without a specified volume, and the relevant CDCs will negotiate with us on the actual supply volume based on each CDC's demand. Therefore, winning the public tender does not guarantee that we will make sales to local CDCs and we may fail to secure subsequent product orders from local CDCs after we bid successfully at the higher level of CDCs.

The actual market size of our product candidates may be smaller than we anticipate, which could render some product candidates ultimately unprofitable even if commercialized.

Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products, since the market opportunities for our product candidates may be smaller than we anticipate. The total addressable market opportunity will depend on, among other things, acceptance of the product by the medical community and patient access, product pricing and reimbursement. Moreover, the number of patients in the addressable markets may turn out to be lower than expected, patients may not be amenable to treatment with our products, or new patients may become increasingly difficult to identify or access. Further, new studies may change the estimated incidence or prevalence of the diseases that our product candidates target. Any of the above unfavorable developments could have a material adverse effect on our business, financial condition and

results of operations. For example, the growth of herpes zoster vaccine market depends on the increased public health awareness, the lack of effective treatment and other uncertain factors, and the number of patients may turn out to be lower than expected, which may have an adverse effect on the prospect of our Core Product, LZ901.

We may be unable to conduct effective academic marketing.

Effective marketing and successful sales are crucial for us to increase the market penetration of our future products, expand our coverage of CDCs, hospitals and other medical institutions and promote new products in the future. In particular, we will place a strong emphasis on academic marketing, through which we promote our products to medical professionals, CDCs and hospitals. While we will actively work with medical professionals, CDCs and hospitals and endeavor to convince them as to the distinctive characteristics, advantages, safety and efficacy of our product candidates as compared to our competitors' products, we may not be able to successfully enhance our product awareness and receive recognition from them.

We may fail to establish and maintain a qualified sales and marketing force.

Sales efforts of pharmaceutical products necessitates our sales and marketing force to possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication skills. However, there is no assurance that there will be a sufficient amount of competent sales professional with the relevant disease knowledge, academic KOLs or doctor networks available in the market. As a result, if we are unable to effectively recruit and train our in-house sales representatives or monitor and evaluate their academic marketing performances, our sales and marketing may be less successful than desired.

When the competition for experienced marketing, promotion and sales personnel becomes intense, we may be unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals. Consequentially, sales volume of our products may be adversely affected and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

We operate in a competitive environment, and we may not be able to compete effectively against current and future competitors.

The pharmaceutical industries are characterized by rapid changes in technology, constant enhancement of industrial know-how and frequent emergence of new products, which renders our targeted markets highly competitive. For example, our Core Product, LZ901, if approved, will be primarily competing against existing commercialized vaccine products, such as Shingrix® developed by GlaxoSmithKline plc and other herpes zoster vaccine candidates under development by domestic competitors. Many of our competitors, including foreign pharmaceutical companies and large state-owned pharmaceutical companies, may have substantially greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we have. Certain of our competitors may be actively engaged in research and development in areas where we have products or where we are developing product candidates. Other companies may discover, develop, acquire or commercialize products more quickly or more successfully than we do. Moreover, there may also be significant consolidation in the pharmaceutical industry among our competitors, or alliances developed among competitors that may rapidly acquire significant market share. Furthermore, our competitors may apply for and obtain marketing approvals in China or other countries for products with the same intended use as our product candidates more rapidly than we do. The capacity of the relevant authorities, such as the

NMPA, to concurrently review multiple marketing applications for the same type of innovative drug may be limited, therefore such authorities' schedule to review our product candidates may be delayed when our product candidates are under the authorities' concurrent review with our competitors' products, and the registration process of our product may be prolonged.

Counterfeits of our product candidates could negatively affect our sales, damage our reputation and brand names, and expose us to liability claims.

Our product candidates are subject to the risk of being imitated by certain products distributed or sold in the pharmaceutical markets that are manufactured without proper licenses or approvals, or fraudulently mislabeled with respect to their content or manufacturer, i.e., counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as the PRC, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products.

Since counterfeit pharmaceutical products are generally sold at lower prices than authentic pharmaceutical products, and are in some cases very similar in appearance to authentic pharmaceutical products, counterfeit products imitating our product candidates can quickly erode our sales volume of the relevant products or product candidates. Moreover, counterfeit products may or may not have the same chemical composition as our product candidates, which may make them less effective than our product candidates, entirely ineffective or more likely to cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in litigation against us. Moreover, the continuing presence of counterfeit pharmaceutical products may reinforce the negative image of distributors and pharmacies among consumers in general, and may severely harm the reputation and brand names of our product candidates in specific.

Our vaccine candidates, once approved, may not to be included in the National Immunization Program, which could put our product candidates at a competitive disadvantage.

According to Frost & Sullivan, our vaccine candidates, once approved, are not likely to be included in the National Immunization Program, which primarily aims to protect children in China. When determining the types of vaccines to be included in the National Immunization Program, the government would consider various factors, such as the prevalence of infectious diseases, disease burden, effectiveness and safety of the vaccine, the supply capacity of vaccine manufacturers, adequate government funds and social benefits. LZ901 is mainly for adults aged 50 years and older, therefore, it is unlikely to be included in the National Immunization Program in China or similar programs in the U.S. in the foreseeable future. Human rabies vaccine aims to help protect people at risk of being exposed to rabies, regardless of their age, and therefore, it is unlikely that recombinant human rabies vaccine will be included in the National Immunization Program in China. For varicella vaccine, although several economically developed cities in China, such as Beijing, Tianjin and Shanghai, have implemented policies to provide free varicella vaccination for children, it is less likely to be included in the National Immunization Program in the next three to five years since the costs will be very high for the nation to provide free varicella vaccination. Not being included under the National Immunization Program or regional equivalent immunization programs would not affect the pricing of our product candidates as we would price our products candidates at market price. However, if peer products are included under the National Immunization Program or regional equivalent immunization programs, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. For details, please see "Business — Our Core Product and Clinical-Stage Product Candidates".

Risks Relating to Manufacture and Supply of Our Product Candidates

Manufacturing pharmaceutical products on a large commercial scale is highly exacting and complex, and we may encounter problems during the process.

The manufacturing of pharmaceutical products is highly exacting and complex, and problems may arise during manufacturing for a variety of reasons, including but not limited to:

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

If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to 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.

Furthermore, manufacturing methods and formulation are sometimes altered through the development of product 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, and any of these changes could cause the product 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 our product 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 regulatory approvals and jeopardize our ability to commence product sales and generate revenue.

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

In addition, the quality of our product 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, there is no assurance that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, or not in compliance with the relevant requirements of the GMP and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

Any failure to perform proper quality control and quality assurance would have a material adverse effect on our business and financial results.

Our product candidates and manufacturing processes are subject to applicable laws, regulations and GMP requirements. These regulations and laws govern the manufacturing processes and procedures, such as record keeping, operating and implementing the quality management systems to control and assure the quality of products approved for sale and investigational products. We have established a comprehensive and robust quality control system in our production and sales process. Please see "Business — Quality Control and Assurance" in this document for details. Despite our quality control system and procedures, errors, defects or failures may still occur. Quality defects may be attributable to a number of reasons, including:

- quality issues with the raw materials we purchase or produce;
- manufacturing errors;
- technical or mechanical malfunctions in the production process;
- human error or malfeasance by our quality control personnel;
- tampering by third parties; and
- other failure to comply manufacturing procedures and quality control requirements under applicable laws and GMP.

We have an R&D and pilot manufacturing facility located in Beijing, China to supply materials for our pre-clinical studies and early-stage clinical trials. In addition, we are currently building new manufacturing facilities in Zhuhai to expand our production in preparation for commercialization of our pipeline candidates, which are expected to meet the GMP requirements of the NMPA, the FDA, the EMA and related ICH guidelines Please see "Business — Manufacturing" in this document for more details. We may not be able to ensure consistent quality control in such new facilities after they come into operation. If we acquire manufacturing facilities from other biotechnology or pharmaceutical companies in the future, we may not be able to immediately ensure that their manufacturing facilities and processes will meet our existing quality standards. Failure to detect and cure quality defects in our future products or to prevent such defective products from being released for sale, failure to comply with relevant quality control requirements under applicable laws or GMP, or failure or deterioration of our quality control system and processes, could result in vaccinees or patients' injury or death, product destroy, recalls or withdrawals, suspension or disruption in product manufacturing, license revocation or regulatory fines, or other problems that could disrupt our business, seriously harm our reputation, expose us to liability, and adversely affect our results of operations.

Delays in completing and receiving regulatory approvals for our manufacturing facilities could delay our development plans or commercialization efforts.

Our existing and planned manufacturing facilities as well as our manufacturing process will be subject to ongoing, periodic inspection by the NMPA or other comparable regulatory agencies to ensure compliance with GMP, which is usually the pre-requisite to obtain marketing approval. Moreover, for our manufacturing facilities and other premises, we must obtain various permits, certificates and other approvals from the relevant administrative authorities at various stages of property development, including, for example, planning permits, construction permits, land use rights certificates, certificates for passing environmental assessments, certificates for passing fire control assessments, certificates for passing construction completion inspections and ownership certificates. Failure to comply with applicable regulations could lead to increased expense and result in sanctions being imposed on us, including fines, injunctions, civil penalties, requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of products or product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

We may encounter substantial disruption to our production sites on problems in manufacturing our product candidates.

We are dependent on our manufacturing facilities in Beijing and Zhuhai. The continued operation of our manufacturing facilities and our production safety may be substantially interrupted due to a number of factors, many of which are outside of our control. These may include fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars, or other natural disasters, as well as loss of licenses, certifications and permits. In addition, changes in governmental planning for the land underlying these facilities or their vicinity and regulatory changes, could also disrupt our operations, including relocation of our existing office and manufacturing facilities to a different site. If the operation of any of our manufacturing facilities is substantially disrupted, we may not be able to replace the equipment or inventories at such facilities or use different sites or a third party contractor to continue our production in a legal, timely and cost-effective manner or at all. Although we maintain property insurance for certain properties, machinery and equipment and other assets owned,

operated or deemed important for us, in line with industry practice in China, we do not have certain types of insurances, such as business interruption insurance. Thus, the amount and nature of our insurance coverage may not be sufficient to cover any substantial losses in the event of a significant disruption to any of our manufacturing facilities.

Our future vaccine and therapeutic biologics products, like any other biologic product, may involve risks of contamination.

Vaccine and therapeutic biologics products manufacturing usually requires cultivation steps, including growth of the appropriate organism and the use of substances of animal origin, which makes it easy to introduce a contaminant and to amplify low levels of contamination. In addition, cross-contamination could result from manufacturing activities at shared equipment and facilities, which are common. Other activities such as diagnosis and research are frequently linked to manufacturing, which may create opportunities for cross-contamination. Furthermore, improper actions during the long-distance transportation, storage and delivery services may also result in contamination.

In the event of contamination or injury resulting from such contamination, we could be subject to liabilities for any resulting damages to vaccinees and patients, product recalls, confiscation and/or destroy. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with laws and regulations. In addition, contamination of our products could cause customers or other third parties with whom we conduct business to lose confidence in our products' quality and the reliability of our manufacturing procedures, which could adversely affect our sales and profits. In addition, contaminated products that are unknowingly distributed could result in harm on patients, threaten the reputation of our products and expose us to product liability claims, criminal charges and administrative sanctions.

We may not be able to meet the increasing demand for our product candidates by ensuring that we have adequate manufacturing capacity, or to successfully manage our anticipated growth.

To produce our increasing number of product candidates, if approved, in the quantities that we believe will be required to meet anticipated market demand, we may need to increase, or "scale up," our production capacity over the initial level of production by constructing new manufacturing facilities and production lines. However, our ability to successfully implement our expansion plan for increasing production capacities is subject to a number of risks and uncertainties, including, but not limited to, the risk of construction delays and delays in equipment procurement, and our ability to timely recruit sufficient qualified staff to support the increase in our production capacity. If we are unable to do so, are delayed, the cost of this scale up is not economically feasible for us, or we cannot find a third-party manufacturer, we may not be able to product our future approved product candidates in sufficient quantities to meet future demand. Moreover, our plans to increase our production capacities require significant capital investment, and the actual costs of our expansion plan may exceed our original estimates, which could adversely affect the return on our expenditure.

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

Fluctuations in prices of our raw materials may have a material adverse effect on us.

In order to manufacture our product candidates, if approved, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner, which exposes us to risks associated with fluctuations in prices of raw materials. The prices of our raw materials 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 the outbreak of COVID-19 and the global economic and political conditions. We may have limited capability to transfer the increasing costs of raw materials to our customers in a timely manner, and a significant increase in the costs of raw materials may increase our cost of sales and negatively affect our profit margins.

If we fail to obtain regulatory approval in any targeted jurisdictions outside of China, we will not be able to market our products in those jurisdictions. If we obtain approval to commercialize our product candidates outside of China, we could face a variety of risks associated with international operations.

We are subject to the laws and regulations in relation to obtaining regulatory approval in China. In addition, we may decide to market certain of our product candidates, if approved, in jurisdictions outside of China, such as the U.S. Penetration in any overseas market will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary among regions and countries which may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain NMPA approval. Our limited experience in overseas markets may expose us to risks and uncertainties, including but not limited to the risks associated with the following:

- dealing with regulatory regimes, regulatory bodies and government policies which may differ materially from those in the PRC or with which we may be unfamiliar;
- substantial time which may be required for us to obtain approval for registering and selling our products;
- commercializing our approved product candidates in new markets where we have limited experience with the dynamics and no sales and marketing infrastructure;
- higher costs for product development and reliance on overseas partners for the development, commercialization and marketing of our product candidates;
- products related and professional liability litigation and regulatory scrutiny arising from the marketing and sale of products in overseas markets and the costs incurred dealing with such procedures, as well as our ability to obtain insurance to adequately protect us from any resulting liabilities;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness and inflation;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;

- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

In addition, in many countries outside China, the prices that we intend to charge for our products may also be subject to approval. Approval by the NMPA does not ensure approval by regulatory authorities in other countries or other jurisdictions. Similarly, approval by one foreign regulatory authority does not imply the approval by regulatory authorities in other foreign countries or by the NMPA. The foreign regulatory approval process may include all of the risks associated with obtaining NMPA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our vaccines in any market.

In addition, if we obtain such regulatory approval and decide to market certain of our product candidates in international markets, we expect that we will be subject to additional risks in commercializing our product candidates outside of China, including:

- different regulatory requirements for vaccines and biologics in foreign countries;
- weakened protection for our intellectual property rights, or more aggressive protection of our competitors' intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations and remittance limitations; workforce uncertainty in countries where labor unrest is more common than in China;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

Risks Relating to Our Cooperation with Third Parties

We may not realize any or all benefits of collaboration, alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our existing product candidates and any future product candidates that we may develop. Our strategic collaboration with partners involves numerous risks. First, we may not achieve the revenue and cost synergies expected from the transactions, as such synergies are inherently uncertain and subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. Also, the synergies from our collaboration with our 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.

We out-licensed Inactivated EV71 Vaccine to Zhifei Biopharma and out-licensed K11 to Beijing Science Sun. Please see "Business — Our Products and Product Candidates — Our Other Historically Developed Products" for details. Under relevant licensing arrangements, we will receive royalties or other payments from Zhifei Biopharma and Beijing Science Sun based on how they commercialize the products they develop under the licensing arrangement. In addition, we do not have plans or intention for out-licensing of any product candidate in China. However, for overseas market, we plan to collaborate with multinational pharmaceutical companies who have a robust sales and marketing network to rapidly commercialize LZ901 globally and may develop corresponding out-licensing or collaboration strategies in the global market outside China and Southeast Asia for the commercialization of LZ901. Please see "Business — Commercialization" for details. Although we carefully select business partners that have the financial resource and capability to develop products when seeking out-licensing or transfer, and after the out-licensing or transfer we communicate with our collaboration partners, approximately once a quarter and on an irregular basis for related technologies for Beijing Science Sun and from time to time for Zhifei Biopharma, to monitor the progress of product development, we may still be subject to the following risks under licensing arrangements:

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

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

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

Moreover, disputes may arise between us and our current or future collaboration partners. Such disputes or our partners' failure to fully perform their obligations may cause delay or termination of the research, development or commercialization of our product candidates, or result in costly litigation or arbitration that diverts management attention and resources. In specific, international business relationships subject us to additional risks that may materially and adversely affect our ability to attain or sustain profitable operations, including: (i) difficulty of effective enforcement of contractual provisions in local jurisdictions; and (ii) third-party collaborators may not properly obtain, maintain, protect or enforce our patent, trade secret and other intellectual property rights and regulatory exclusivity for our product candidates or may use our intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our intellectual property or expose us to potential litigation or other intellectual property-related proceedings.

As we work with various third parties to conduct a certain number of our pre-clinical studies and clinical trials, we may not be able to obtain regulatory approval for, or commercialize, our product candidates, or experience delay in doing so if these third parties do not successfully carry out their contracted duties or meet expected deadlines.

We rely on third parties, including clinical trial institutions, public hospitals, CROs and SMOs, to assist us in designing, implementing and monitoring our clinical trials. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. If any of these parties terminates its agreements with us, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all, and the development of the product candidates covered by those agreements could be substantially delayed. In addition, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocols, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. However, these third parties may not successfully carry out their contractual obligations, meet expected deadlines or follow regulatory requirements, including clinical and manufacturing guidelines and protocols. Moreover, if any of these parties fail to perform their obligations under our agreements with them in the manner specified in those agreements, the NMPA, the FDA and/or other comparable regulatory authorities may not accept the data generated by those studies or relevant regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, which would increase the cost of and the development time for the relevant product candidate. If any of the preclinical studies or clinical trials of our product candidates is affected by any of the above-mentioned reasons, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business and prospects.

We are exposed to various supply chain risks as we depend on a stable, adequate and quality supply of raw materials, technical services, equipment and infrastructure construction services, and any price increases or interruptions of such supply may have a material adverse effect on our business.

Our business operations are exposed to various supply chain risks. During the Track Record Period, we relied on third parties to supply raw materials and technical, construction and other services. We expect to continue to rely on third parties to supply such raw materials and services for the research, development, manufacturing and commercialization of our product candidates. See "Business — Suppliers."

Currently, the raw materials and the services are supplied by multiple source suppliers. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our product candidates.

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

We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In the event of significant price increases for such materials, there is no assurance that we will be able to raise the prices of our future products sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability. Additionally, although we have implemented quality inspection on the materials before using them in the manufacturing process, there is no assurance that we will be able to identify all of the quality issues.

In addition, there can be no assurance that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which, in turn, may result in shortage of the services, materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or the recall of our products. The noncompliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of noncompliance, which may have a material and adverse effect on our business, financial condition and results of operation.

Risks Relating to Extensive Governmental Regulations

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

All jurisdictions in which we intend to conduct our research, development, manufacturing and commercialization activities regulate these activities in great depth and detail. Obtaining regulatory approvals and maintaining compliance with applicable laws and regulations is a lengthy, expensive and uncertain process, which requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include but are not limited to a regulator's refusal to approve pending applications, withdrawal of an approval, 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.

The regulatory approval processes of the NMPA, FDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable.

The process to obtain approval by the NMPA, FDA other comparable regulatory authorities typically takes years following the commencement of pre-clinical studies and clinical trials, and is inherently unpredictable. Specifically, we could fail to receive regulatory approval for our product candidates for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate a product candidate's safety and efficacy;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- government authority's disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- government authority's requirement of additional information, including pre-clinical and clinical data, to support approval; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

All these factors, among others, 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 there is no assurance that we will be able to meet regulatory requirements of different jurisdictions. Also, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries.

Approval pathway for biosimilars in China remains fluid, which may adversely affect the regulatory approval of our biosimilar product candidate.

The Guidelines for the R&D and Evaluation of Biosimilar Drugs (for Trial Implementation) (《生物類似藥研發與評價技術指導原則(試行)》) and Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》) (collectively, the "**Biosimilar Guidelines**"), which are the prevailing PRC guidelines on biosimilar evaluation, outline the technical guidance for biosimilars, aiming to move toward a clear industry structure for the research and development and evaluation of biosimilars. The Biosimilar Guidelines do

not offer an alternative pathway for launching biosimilar products in China; rather, under Biosimilar Guidelines, biosimilars are essentially subject to the same approval pathway as novel biologics, only with a different set of data requirements. Applicants must mark in their IND applications and NDAs that submissions are intended to be reviewed as biosimilars. In addition, various uncertainties surrounding the application and interpretation of the Biosimilars Guidelines could adversely affect the regulatory approval of our existing biosimilar product candidate, K3, as well as other biosimilars we may develop in the future. Uncertainties surrounding the approval pathway for biosimilars in China include:

- the Biosimilar Guidelines serve as a technical guidance only and cannot address several fundamental issues for the administration of biosimilars in the absence of a clear legislative authorization, such as interchangeability with reference products, naming rules and labeling requirements for biosimilars;

- although the Biosimilar Guidelines adopt a stepwise comparability approach, they do not contain sufficient details to be regarded as overarching guidelines and it is also not clear whether the NMPA will take further steps to develop product-specific guidelines on our biosimilars candidates and guidelines addressing issues such as immunogenicity assessment;

- while under the Biosimilar Guidelines, biosimilars are subject to the same approval pathway as innovative biologics with a different set of technical review criteria, it remains unclear if the time to market for biosimilars will be reduced compared with the lengthy review process for innovative biologics; and

- since changes in regulatory requirements and guidance may occur, it is unpredictable whether the NMPA and other regulatory authorities will issue updated policies or guidelines on biosimilars to replace or supplement the Biosimilar Guidelines, or whether such updated policies or guidelines will bring additional compliance costs or substantial impediments for our biosimilar candidates to obtain regulatory approvals.

As such, there is no assurance that our biosimilar candidate will be approved under the Biosimilar Guidelines or any further updated policies or guidelines in the future, in a timely manner or at all, and we may not ultimately be able to develop and market any or all of them successfully.

After we receive regulatory approvals for our product candidates, we will be subject to ongoing or additional regulatory obligations and continued regulatory review.

If any of our product candidates receives regulatory approval in the future, it will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China and/or other countries in which we commercialize our products candidates. Also, following an approval for commercial sale of any product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA and/or comparable regulatory authorities. Accordingly, we must continue to devote time, money and effort in all areas of regulatory compliance. For details of other potential consequences in the event that we fail to maintain compliance with such ongoing or additional regulatory requirements, see "— Risks Relating to Extensive Governmental Regulations — All material aspects of the research, development, manufacturing and commercialization of our product candidates are heavily regulated" in this section.

The recently enacted PRC Vaccines Administration Law may impose unprecedented regulatory compliance challenges encompassing our business.

On June 29, 2019, the Standing Committee of the National People's Congress of the PRC promulgated the PRC Vaccines Administration Law (《中華人民共和國疫苗管理法》) (the "**Vaccines Administration Law**"). The Vaccines Administration Law, together with the newly revised PRC Drug Administration Law (《中華人民共和國藥品管理法》) promulgated on August 26, 2019 (the "**Revised Drug Administration Law**"), came into effect on December 1, 2019. With this new enactment, vaccines development, production and circulation, vaccination and supervision and management within the territory of the PRC are all subject to this Vaccines Administration Law. Among others, the Vaccines Administration Law imposes us obligations on manufacturing, safekeeping of sales records, setting up electronic traceability system of vaccines, purchasing compulsory vaccines liability insurance, post-market management of vaccines, mandatory disclosure system as well as increasingly severe regulatory punishment in cases of non-compliance. Under the Vaccine Administration Law, the State implements a vaccination-related abnormal reaction compensation system. Relevant compensation shall be paid in the case of any in-vaccination or post-vaccination death, severe disability or damage such as organ tissue injury to a recipient that is identified as or cannot be ruled out as being a vaccination-related abnormal reaction. The compensation scope shall be subject to management by catalog and dynamical adjustment in light of the actuality.

Adhering to strong safety awareness, stringent risk management and control methods, concurrent scientific supervision, as well as a societal co-governance scheme, this Vaccines Administration Law is considered as, arguably, the strictest regulatory framework for vaccine business in China. As we strive to provide the utmost protection to human safety while conducting our business, our compliance cost under the current vaccine regulatory framework may be unprecedentedly high. For example, under the new Vaccines Administration Law, we will be required to establish vaccines electronic traceability system to be linked with the national vaccine electronic traceability collaboration platform, for the purpose of integrating whole process traceability information on vaccine production, circulation and vaccination so as to realize the traceability of vaccines. Setting up and maintaining the smooth running of such a system would cause us additional costs in not only gathering resources and developing the system, but also sourcing data and statistics management experts. As of the Latest Practicable Date, we had not set up such system as we are not a vaccine marketing authorization holder at the current stage, which, according to our PRC Legal Advisor, does not contravene the Vaccines Administration Law. Our management and in-house experts might need to spend additional time on decoding and integrating the new rules into our day-to-day operations, which could potentially distract their attention on ongoing essential corporate affairs.

We may be unable to obtain or renew certain approvals, licenses, permits and certificates required for our business.

Pursuant to the relevant laws, regulations and relevant regulatory practice by governmental authorities, we are required to obtain and maintain various approvals, licenses, permits and certificates from relevant authorities to operate our business and construct our facilities. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations and construction of our facilities, such as construction work commencement permit, environmental protection inspection, and fire safety approvals, may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities ceasing our operations, and may include corrective

measures requiring capital expenditure or remedial actions. Furthermore, if the interpretation or implementation of existing laws and regulations changes, or new regulations come into effect requiring us to obtain any additional approvals, permits, licenses or certificates that were previously not required to operate our existing businesses, there is no assurance that we will successfully obtain such approvals, permits, licenses or certificates.

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

If we obtain approval from the NMPA or other comparable regulatory authorities approval for any of our product candidates and begin commercializing those product candidates in China and our other target markets, our operations may be subject to various fraud and abuse laws of various jurisdictions, including but not limited to, the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), the PRC Criminal Law (《中華人民共和國刑法》), the Federal Anti-Kickback Statute and the Federal False Claims Act, and the physician payment sunshine laws and regulations. There are ambiguities as to what is required to comply with any of these requirements, and violations of such fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the relevant government. Moreover, as law enforcement authorities have been increasingly focused on enforcing these laws, efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs.

Changes in government regulations or in practices relating to healthcare industry, including healthcare reform and compliance with new regulations may result in additional costs.

The policies of the NMPA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our products. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or abroad, where the regulatory environment is constantly evolving. For instance, changes in regulatory requirements and guidance that require us to amend clinical trial protocols submitted to the regulatory authorities may also occur, and amendments thereto to reflect such changes may impact the costs, timing or successful completion of a clinical trial. In addition, there could be changes in government regulations specifically on pharmaceutical product registrations and approvals, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures which will lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements.

Also, in recent years, there have been and will likely continue to be efforts to enact administrative or legislative measures which may result in more rigorous coverage criteria and downward pressure on the price that we fix for any approved product. For details of the risks associated with such downward pricing pressure, see "— Risks Relating to Sales and Distribution of Our Product Candidates — We may need to lower our product price in order to qualify for medical insurance reimbursement or due to market competition" in this section.

Finally, it is also possible that the Chinese government or other government authorities in countries where we plan to sell our products could adopt new or different regulations affecting the way in which pharmaceutical products are sold to address bribery, corruption or other concerns. Any such new or different regulations could possibly increase the costs incurred by us, or our employees in selling our products, or impose restrictions on sales and marketing activities, which could in turn increase our costs.

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related 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 jurisdictions in which we may operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill. While 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 setting internal rules requiring our employees and business partners to maintain the confidentiality of our subjects' medical records, these measures may not be always effective.

Risks Relating to Our Intellectual Property Rights

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

Our success depends in a large part on our ability to protect our proprietary technology and product candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technologies and product candidates that we consider commercially important by, among others, filing patent applications in the PRC, and other countries. As of the Latest Practicable Date, we had four invention patents granted, including two relating to LZ901, nine registered trademarks and we had filed eight patent applications worldwide. For more details, please see "Business — Intellectual Property Rights" in this document. Although there is no substantive legal impediment for each of our pending patent applications of being granted according to our IP Legal Adviser, there is no assurance that our patent applications will be approved eventually. However, applying for patent protection is an expensive and time-consuming process, and we may not be able to successfully file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may however fail to identify patentable aspects of our R&D output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Specifically, patents may be invalidated and patent applications may not be granted not only because of known or unknown prior deficiencies in the patent applications, but also due to the lack of novelty or inventiveness of the underlying invention or technology. Although we enter into non-disclosure and confidentiality agreements or include such provisions in our relevant agreements with parties who have access to confidential or patentable aspects of our R&D output, any of these parties may breach such agreements and disclose such output before a patent application is filed, jeopardizing our ability to seek patent protection. As of the Latest Practicable Date, seven of our patent applications relating to our Core Product were pending approval, and our patent applications may not be granted for a number of reasons. For instance, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. We cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications partially because of the oftentimes postpone of publications of discoveries in the scientific or patent literature in relation to the actual discoveries and patent applications filings. Furthermore, under the "first-to-file" system adopted by the PRC, and recently, the United States, even after reasonable investigation we may still be unable to determine with certainty whether any of our products, product candidates, processes, technologies, improvement and other related matters has already become unpatentable as any third party might have filed a patent application for the inventions thereunder that are the same or substantially similar to ours early than we do.

In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the National Intellectual Property Administration, or NIPA, for confidentiality examination. Otherwise, if such application is later filed in China, the patent right will not be granted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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.

The China National Intellectual Property Administration (the "**CNIPA**") and various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. For instance, periodic maintenance fees on any issued patent are due to be paid to the CNIPA and other patent agencies in several stages over the lifetime of the patent. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Such non-compliance events may 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 addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the CNIPA for confidentiality examination; otherwise the patent right will not be granted, if an application is later filed in China.

The scope of our patent protection may be uncertain, and our current or any future patents may be challenged and invalidated even after issuance.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned patents may be challenged in the courts or patent offices in the PRC and other jurisdictions. For instance, we may be subject to a third-party submission of prior art to the CNIPA or other related intellectual property offices or become involved in post-grant proceedings such as opposition, derivation, revocation, invalidation, re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging the priority of our invention or other features of patentability of our patents and patent applications. Moreover, any claims that we assert against competitors who are perceived to infringe our patent rights or misappropriate or otherwise violate our intellectual property rights could assert against us invalidity or unenforceability of our patents on numerous grounds. Any abovementioned submission, proceeding or litigation may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. More importantly, an adverse determination therein may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies and product candidates.

Even if we are able to obtain patent protection for our products candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights.

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As such, even if we successfully obtain patent protection for a product candidate, such product candidate may face competition from generic or biosimilar medications once the patent has expired. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

The absence of data exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition for our product candidates in China.

In China, there is no currently effective law or regulation providing data exclusivity. Therefore, a lower-cost generic product can emerge onto the market much more quickly. While Chinese regulators have set forth a framework for integrating data exclusivity into the Chinese regulatory regime, such a framework will require adoption of regulations in order to be implemented. To date, no regulations have been issued, which results in weaker protection for us against generic competition in China than could be available to us in other jurisdictions where data exclusivity is available.

We may become involved in lawsuits to protect or enforce our intellectual property or being sued for infringing, misappropriating or other violating the intellectual property rights of third parties, which could be expensive, time-consuming and unsuccessful.

Our commercial success depends in part on our ability to avoid infringing, misappropriating, or otherwise violating intellectual property rights of third parties. However, our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Defending ourselves against third parties' intellectual right infringement allegations, meritorious or not, would be expensive and time consuming, and would be a substantial diversion of our resources and our management team's attention. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation. In June 2022, our IP Legal Adviser conducted freedom-to-operate (FTO) searches and analyses in target country(s) and/or region(s) in relation to our Core Product (LZ901), K3 and K193, and did not identify any substantial risk of infringement by all of the current key technologies and features of our Core Product, K3 and K193 against active patents in such country(s) and/or region(s). FTO analysis is a patent search commonly used to determine whether there are any existing patents covering a company's product, and whether such product would infringe any existing patents. However, the potential scope of an FTO search can be immense and all patent databases have limitations. Further, patent applications generally remain unpublished within 18 months after its earliest filing, and hence an earlier-filed, unpublished patent application could potentially present an infringement risk. Therefore, we cannot guarantee that our FTO search and analysis have exhaustively reviewed all the existing and future patents that potentially cover our products. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to issue that relate to aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the pharmaceutical industries generally. As the pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others. FTO analysis is technically complicated and involves significant judgement as to the scope, validity and enforceability of patents. There can be no assurance that a court would agrees with our analysis or find in our favor on questions of infringement, and the outcome following legal claims of patent infringement is unpredictable.

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

Our owned patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings, and we or our collaboration partners may be unsuccessful in any of these proceedings, therefore requiring us to obtain licenses from third parties that 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 product candidates we may develop.

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

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our pipeline products.

Depending on decisions by the National People's Congress of the PRC and the CNIPA, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The United States has enacted and is currently implementing wide-ranging patent reform legislation. In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. 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. As the laws and regulations governing patents continue to evolve in China, the U.S. and other jurisdictions, we cannot guarantee that any other changes would not have a negative impact on our intellectual property protection.

We may fail to protect the confidentiality of our trade secrets, as we may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, or that asserting ownership of what we regard as our own intellectual property.

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our product candidates. Specifically, we seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or including such undertakings in the agreement with parties that have access to them. However, non-disclosure agreements with employees, consultants, contractors and other parties may not adequately prevent disclosures of our trade secrets and other proprietary information. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can also be difficult, expensive and time-consuming, and the outcome is unpredictable.

Furthermore, some of our employees, including our senior management, might have previously been employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees might have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. In the event that litigation is necessary to defend against such claims, we may be subject to monetary damages and lose valuable intellectual property rights or personnel.

We may fail to protect our trademarks and trade names well to build brand recognition in our markets of interest.

We currently hold issued trademark registrations and have trademark applications pending, which we need to build name recognition among potential partners or customers in our markets of interest but subjects us to risks of trademark invalidity, dilution and infringement, and etc. First, any of our trademark registrations and applications may be the subject of a governmental or third-party objection, so as to be challenged, infringed, circumvented or declared generic, which could prevent the registration or maintenance of the same. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, but we may be 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. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdiction where we seek protection.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Consequentially, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and sell or import products made using our inventions in and into our markets of interest. These products may compete with our products, and our existing patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any of our product or product candidates or utilize similar technology that are not covered by the claims of our owned patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- the proprietary technologies on which we rely may not be patentable; and
- we may choose not to file a patent for certain trade secrets or know-how, yet a third party may subsequently file a patent covering such intellectual property.

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

Risks Relating to Our Financial Position and Need for Additional Capital

We incurred net losses and net operating cash outflows during the Track Record Period, and we may continue to incur net losses and net operating cash outflows.

Investment in human vaccine and therapeutic biologics product development is highly speculative. It entails substantial upfront capital expenditures and significant risks and a product might fail to demonstrate sufficient efficacy or safety to gain regulatory approval or become commercially viable. Our ongoing operations bring significant expenses. As a result, we have incurred losses in each period during the Track Record Period. We experienced a loss of RMB539.4 million and RMB725.2 million in 2021 and 2022, respectively. As of December 31, 2021 and 2022, we had an accumulated loss attributable to owners of RMB795.3 million and RMB1,520.5 million. We also had net cash used in operating activities of RMB19.2 million and RMB77.3 million in 2021 and 2022, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development expense, administrative expenses and fair value loss of financial liabilities at FVTPL.

The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or additional grants. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, our ability to achieve sufficient market acceptance, secure procurement from CDCs or hospitals in China and other factors.

We may continue to incur net losses for the foreseeable future, and these losses may increase as we continuously expand our development, including:

- conducting clinical trials and advancing pre-clinical studies of our current product candidates;
- recruiting highly skilled and qualified research and development personnel to further expand our research and development team;
- maintaining and expanding our own manufacturing facilities;
- seeking regulatory approvals for our product candidates that successfully complete clinical trials;
- commercializing our product candidates for which we have obtained marketing approval;
- building up our commercialization, distribution, and sales workforce in anticipation of the future roll-out of our product candidates;
- initiating pre-clinical studies, clinical trials or other research and development activities for new product candidates;
- maintaining, protecting and expanding our intellectual property portfolio; and
- creating additional infrastructures to support our operations as a [**REDACTED**] company, our product development, and planned future commercialization efforts.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials, is a very time consuming, expensive and uncertain process that takes years to complete. During the process, we may encounter unforeseeable expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend partially on the number and scope of our vaccine and therapeutic biologics development programs and the associated costs, the rate of the future growth of our expenses and the commercialization costs of any approved products. If any of our product candidates fails during clinical trials or does not gain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and Shareholders' equity.

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

As of December 31, 2021 and 2022, we had net liabilities of RMB584.5 million and net assets of RMB937.5 million, respectively. Our deficit position was largely due to the accounting treatment for our preference shares, which are classified as financial liabilities at FVTPL. Our obligations with respect to special rights granted to [**REDACTED**] Investors, other than information rights, were terminated in June 2022. Therefore, the preference shares were reclassified from financial liabilities to equity at their fair value. Please see "Financial Information — Financial Liabilities at FVTPL" and Note 27 to the

Accountants' Report in Appendix I to this document for further details of our financial liabilities at FVTPL during the Track Record Period. We cannot guarantee that we will not incur net liabilities in the future. If we are to record net liabilities again, it will affect our liquidity, as well as our ability to raise funds, obtain bank loans and pay debts when they become due and declare and pay dividends.

We may need to obtain additional financing to fund our expansion of research and development and our operations, and we may not have access to sufficient funding.

Our business operations and our implementation of our strategies will require significant funding, including:

- promoting the clinical development of certain of our pipeline candidates, including LZ901, K3 and K193;
- advancing the development of other pipeline candidates;
- expanding our production capacity to meet growing market demands;
- laying out plans to strategically promote commercialization at home and abroad; and
- seeking global collaboration to expand our product pipeline.

In addition, many aspects of our general business operations have on-going funding requirements that may increase over time. While we expect that the implementation of our strategies and business plans will require us to rely in part on external financing sources, our ability to obtain additional capital on commercially reasonable terms is subject to a variety of factors, many of which are outside of our control, including our future financial condition, results of operations and cash flows, the global economic conditions, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government policies on lending. If we cannot do so successfully, our strategies and business plans will not be carried out as currently contemplated.

We have historically received government grants and we may not receive such grants or subsidies in the future.

We have historically received government grants and recognized government grants as other income of RMB1.9 million and RMB11.6 million in 2021 and 2022, respectively. We also recorded deferred government grants of RMB47.3 million and RMB36.8 million as of December 31, 2021 and 2022, respectively. However, there is no assurance that you of the continued availability of the government grants currently enjoyed by us, any reduction or elimination of which would have an adverse effect on our financial condition. Our eligibility for government grants depends on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, the availability of funding at different granting authorities, and the research and development progress made by other peer companies. In addition, the timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. Also, some of the government financial incentives may be subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein, which we may fail to satisfy, and the governmental authorities may reduce or discontinue such grants, or require us to repay part or all of the government grants we previously received.

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

We adopted employee incentive plans for the benefit of our employees as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our Company. For more details, please see "History, Development and Corporate Structure — Employee Incentive Scheme" and Note 31 to the Accountants' Report set out in Appendix I in this document. In 2021 and 2022, we incurred expenses for share-based payments of RMB76.2 million and RMB111.4 million, respectively. To further incentivize our employees to contribute to us, we may grant additional share-based payments in the future. Issuance of additional Shares with respect to such share-based payments may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payments may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

We are exposed to credit risks associated with our investment in certain wealth management products.

As part of our treasury management, we invest in certain wealth management products to better utilize excess cash when our cash sufficiently covers our ordinary course of business. As of December 31, 2021 and 2022, our financial assets at FVTPL amounted to RMB532.4 million and RMB512.7 million, respectively, and we recorded fair value gains on financial assets at FVTPL of RMB10.8 million and RMB13.9 million in 2021 and 2022, respectively. Pursuant to the Guidance on Regulating Financial Institution's Asset Management Business (《關於規範金融機構資產管理業務的指導意見》) promulgated by the People's Bank of China, the China Banking and Insurance Regulatory Commission, the China Security Regulatory Commission and the State Administration of Foreign Exchange on April 27, 2018, financial institutions selling wealth management products shall not guarantee the principals and/or returns of such products. As a result, the returns of our investments on the wealth management products were not guaranteed. We measured these financial assets at FVTPL, and we are exposed to credit risks in relation to these financial assets, which may adversely affect their fair value. Net changes in their fair value are recorded in profit or loss, and therefore directly affect our results of operations. We have implemented a series of internal control policies and rules setting forth overall principles as well as detailed approval process of our investment activities. We adopt a prudent approach in selecting wealth management products. We may continue to invest in wealth management products in the future when we believe that we have surplus cash on-hand and the potential investment returns are attractive. For more details, please refer to the paragraphs headed "Financial Information — Discussion of Certain Selected Items from the Consolidated Statements of Financial Position — Financial Assets at FVTPL" in this document. However, there can be no assurance that our internal management and investment strategy will be effective and adequate with respect to our purchased wealth management products.

Fair value changes on financial liabilities are subject to uncertainties and may affect our financial position and results of operations.

Our financial liabilities at FVTPL primarily represented the preference shares we issued in Series A Financing, Series B Financing, Series B+ Financing and Series C Financing, and the fair value change of financial liabilities at FVTPL is recognized in profit or loss. The fair value measurement of our preference shares involves estimates and assumptions that are subject to significant uncertainties and risks.

The fair value of the financial liabilities at FVTPL is established by using valuation techniques, including the backsolve method and hybrid method. Valuation techniques are certified by an independent qualified professional valuer before being implemented for valuation and are calibrated to ensure that outputs reflect market conditions. Valuation models established by the valuer make the maximum use of market inputs and rely as little as possible on our specific data. However, some significant unobservable inputs, such as fair value of our ordinary shares, possibilities under different scenarios such as [**REDACTED**], liquidation and redemption, and discount for lack of marketability, require management estimates. Management estimates and assumptions are reviewed periodically and are adjusted when necessary. Should any of the estimates and assumptions change, it may lead to changes in the fair value of financial liabilities at FVTPL. In addition, the valuation methodologies may involve a significant degree of management judgment and are inherently uncertain, which may result in material adjustment to the carrying amounts of certain liabilities and in turn may materially and adversely affect our results of operations. Our fair value of financial liabilities at FVTPL as of December 31, 2021 and 2022 amounted to RMB1,237.5 million and nil, respectively. For more details, please refer to the paragraphs headed "Financial Information — Discussion of Certain Selected Items from the Consolidated Statements of Financial Position — Financial Liabilities at FVTPL" in this document.

Risks Relating to Our General Operations

We may fail to sufficiently and promptly respond to clinical demand and market changes in the pharmaceutical industry.

Clinical demand and market conditions for pharmaceutical products may change rapidly and significantly, and our success depends on our ability to anticipate product offering lead-time and demand, identify customer preferences and adapt our products to these preferences. We may need to adjust our research and development plan, production scale and schedule, product portfolio, and future inventory levels based on customer demand, sales trends and other market conditions. However, there can be no assurance that we will be able to sufficiently and promptly respond to changes in clinical demand and purchasing patterns in the future.

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

Our operations, and those of our suppliers, research institution collaborators and other business partners, could be subject to natural or man-made disasters, health epidemic, or business interruptions, for which we are predominantly self-insured. Damage or extended periods of interruption to our and our partners' administration, development, research, manufacturing or storage facilities due to fire, natural disaster, health epidemic, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our product candidates, seriously harm our and our partners' operations and financial condition, and increase our and their costs and expenses.

Our success depends on our key senior management members and our ability to attract, train, motivate and retain highly skilled scientists and other technical personnel.

Our success depends heavily upon the continued services of the Board members and senior management to manage our business and operations, and on our key research and development personnel to develop new products, technologies and applications and to enhance our existing products. Our ability

to attract, hire, retain and motivate qualified scientific, technical, clinical, manufacturing, and sales and marketing personnel, as well as other consultants and advisers, is also crucial for us. Although we have entered into employment agreements and consulting agreements with each of our executives, employees, consultants and advisers, they may terminate their agreements with us at any time. As such, we will have to compete for qualified personnel with other pharmaceutical and biotechnology companies, universities and research institutions. The pool of suitable candidates is limited, and we may not be able to hire and retain enough skilled and experienced scientists or other technical personnel at the current level of wages, and need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations.

We may encounter difficulties in managing our growth and expanding our operations successfully.

Our success will depend upon our ability to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose additional responsibilities on members of management. Our ability to commercialize our product candidates and our future financial performance will depend heavy on whether we are able to manage the future growth effectively. Therefore, hiring, training and integrating additional management, administrative and sale and marketing personnel is crucial in further ensuring the effective clinical trials developments in future. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Our business, results of operations and financial position could be adversely affected by the ongoing COVID-19 pandemic.

COVID-19, an outbreak of a novel strain of coronavirus since December 2019 that was declared by the World Health Organization to be a pandemic in March 2020, has already resulted in a high number of fatalities and is likely to continue having an adverse impact on the livelihood of the people both in China and globally, which in turn will have a negative impact on the global economy. Our business operation has also been, and may continue to be, negatively affected by the outbreak. For instance, any temporary suspension of productions, shortage of labor and raw materials or disruption of local and international travel and economic may affect imports and exports as related to our business. Also, the development progress of product candidates could be slightly delayed due to the prolonged process of subject enrollment for our ongoing clinical trials, delay of construction of our facilities in Zhuhai, and the slow-down of the responses from the relevant governmental authorities reviewing our clinical trial applications, among other reasons.

There is great uncertainty around the future of the COVID-19 outbreak and how it will impact our operations. In particular, we cannot accurately forecast the potential impact of additional outbreaks as to government restrictions including further shelter-in-place or other government restrictions implemented in response to such outbreaks, or the impact on the ability of our suppliers and other business partners to remain in business as a result of the ongoing pandemic or such additional outbreaks. With the uncertainties surrounding the COVID-19 outbreak until a cure or vaccine has been discovered, the threat to our business and the related financial impact remains.

We may become a party or are subject to litigation, legal disputes, claims, administrative proceedings or other administrative measures, which may divert our management's attention and results in costs and liabilities, and there is no assurance that the results of such legal proceedings would favor us.

We may from time to time become subject to various litigation, legal or contractual disputes, investigations or administrative proceedings arising in the ordinary course of our business, including but not limited to various disputes with or claims from our suppliers, customers, contractors, licensors, business partners, employees and other third parties that we engage for our business operations. Ongoing or threatened litigation, legal disputes, claims, investigations or administrative proceedings may divert our management's attention and consume their time and our other resources. Furthermore, any such matters 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. If any verdict or award is rendered against us or if we settle with any third parties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business projects. During the Track Record Period, we did not register and/or fully contribute to certain social insurance and housing provident funds for two of our employees. As of the Latest Practicable Date, we had rectified such incidents. Our Directors, having consulted our PRC Legal Adviser, are of the view that such isolated incidents will not have material impact on our business. In any event, negative publicity arising from litigation, legal disputes, investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products.

If we, our employees, agents, suppliers or affiliates engage, or are perceived to engage, in misconduct or breaches, including corrupt practices or leakage of confidential information, we could be exposed to regulatory investigations, costs and liabilities.

We are subject to risks in relation to actions taken by us, our employees, agents, suppliers or affiliates that constitute violations of anti-corruption and other related laws in jurisdictions where we conduct business. Any allegations of corrupt practices against us, our employees, agents or affiliates or the pharmaceutical industry in general could generate negative publicity and materially and adversely affect our reputation and business prospects. Despite our procedures and controls to monitor compliance with applicable anti-corruption laws, we may still be held liable for actions taken by us, or our employees, in which case the government authorities may seize the products involved in any illegal or improper conduct engaged in by us, or our employees. We may also be subject to claims, fines or suspension of our operations.

Furthermore, if we are involved in criminal, investigational or administrative procedure for commercial bribery, we will be included on the negative list of commercial briberies by provincial health and family planning administrative department, as a result of which our products cannot be purchased by public medical institutions as well as medical and health institutions receiving financial subsidies of specific territorial scope in two years, pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》).

Negative publicity and allegations involving us, our Shareholders, Directors, management personnel, employees and business partners may affect our reputation, business and growth prospects.

We, our Shareholders, Directors, management personnel, employees and business partners may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our employees and business partners were not compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our investors and customers.

Negative publicity on the overall vaccine industry may impact the public confidence in our future vaccine products or vaccine products in general, lead to lower demand of vaccination, and result in more stringent regulations.

We and the vaccine industry were, and may be in the future, subject to the implications of negative publicity regarding vaccine products or the vaccine industry in general. For example, in March 2016, media reported on improperly stored vaccines illegally sold by distributors in the Shandong province and all across China. The illegal distribution resulted in sales to CDCs of a large amount of vaccine products, including rabies vaccines, that might be ineffective or less effective due to improper storage in distributions. Although this scandal was a result of illegal distributions and had no indication of any quality issues of vaccine manufacturers, this caused panic and public concerns over the safety of vaccines in general. Such incidents led to an overall downturn in the vaccine market in China, and promoted the PRC government to introduce more stringent legislations and regulations for the vaccine industry.

Any such negative publicity may shake the public confidence in vaccine products or industry in general, including our future vaccine products, and lead to lower demand for vaccines in the PRC, which in turn could affect our business and performance adversely. Investigations or more stringent governmental regulations after such negative publicity, if any, may require time and attention of our management team that would otherwise be devoted to operation of our business, or may cause more compliance expenses. In the event that any negative publicity is regarding our own products or our own business, the adverse impact on our financial condition or results of operation will be more significant. The [**REDACTED**] of our H Shares could also suffer dramatically as a result of such negativity.

We may be subject to product liability claims that could expose us to costs and liabilities.

We are exposed to product liability risks as a result of developing, producing, marketing, promoting and selling pharmaceutical products in the PRC and other jurisdictions in which our pharmaceutical products may be marketed and sold. Such claims may arise if any of our products are deemed or proven to be unsafe, ineffective, defective or contaminated or if we are alleged to have engaged in practices such as insufficient or improper labeling of products or providing inadequate warnings or insufficient or misleading disclosures of side effects. A product liability claim brought against us, may, regardless of merit or outcome, result in damages to our reputation, strain our financial resources and consume the time and attention of our management. If we are unable to defend ourselves against such claims, we may, among others, be subject to product recalls, civil liability for physical injury, death or other losses caused by our products, criminal liability and the revocation of our business licenses. We have not purchased product liability insurance and we may be unable to acquire such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We may grow our business in part through acquisitions, which may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities and have material adverse effect on our ability to manage our business, and we may fail to successfully complete such acquisitions or enhance post-acquisition performances in the future.

To enhance our growth, we may acquire businesses, products, technologies or know-how or enter into strategic partnerships that we believe would benefit us in terms of product development, technology advancement or distribution network, among others. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- inability to identify suitable acquisition targets and reach agreement on acceptable terms;
- lack of access to financing for acquisitions on acceptable terms or at all, or otherwise assumption of additional indebtedness or contingents and issuance of our equity securities;
- failure to obtain or secure the governmental approvals and third party consents necessary to consummate any proposed acquisition;
- increased operating expenses, including research and development expenses due to an increased number of product candidates, administrative expenses as well as selling and distribution expenses;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- difficulty in 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 products and product candidates;
- 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; and/or
- deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in the acquired business we discover after such acquisition.

In any such event, our plan to grow our business through such acquisitions may not materialize as expected.

Our internal risk management and control system may not be so adequate or effective to detect potential risks in our business as intended.

We have an internal control system in place to monitor and control potential risk areas relevant to our business operations. However, due to the inherent limitations in the design and implementation of our internal control system, it may not be sufficiently effective in identifying, managing and preventing all risks if external circumstances change substantially or extraordinary events take place. Further, integration of various business operations from potential future acquisitions may give rise to additional internal control risks that are currently unknown to us, despite our efforts to anticipate such issues. Our risk management and internal controls also depend on effective implementation by our employees. There can be no assurance that such implementation by our employees will always function as intended, or such implementation will not be subject to human errors, mistakes or intentional misconduct.

Breach, failure or disruption in or to our information system could compromise sensitive information related to our business and expose us to liability or reputational harm, and our ability to effectively manage our business operations could be adversely affected.

Our information system may fail and is vulnerable to breakdown, breach, interruption or damage from computer viruses, computer hackers, malicious code, employee error or malfeasance, theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromise. Any system damage or failure that interrupts data input, retrieval or transmission or increases service time could disrupt our normal operations, including the loss of clinical trial data from completed or future clinical trials that could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. There can be no assurance that we will be able to effectively handle a failure of our information systems, or that we will be able to restore our operational capacity in a timely manner to avoid disruption to our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate use, disclosure of or access to confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be hindered or delayed.

Specifically, we may collect and store sensitive personal data in the ordinary course of our business. For more details, please see "— Risks Relating to Extensive Governmental Regulations — We are subject to stringent privacy laws, information security polices and contractual obligations related to data privacy and security, and we may be exposed to risks related our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information" in this section. If such personal data are compromised due to a material breach of our information system, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. More importantly, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations.

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

As our operations involve the use of potentially harmful biological materials and other hazardous chemical materials and may produce hazardous waste, we are subject to numerous environmental, health and safety laws and regulations, including those governing air emissions, discharge of water, and the handling, use, storage, treatment and disposal of hazardous materials and wastes. While we have entered into hazardous waste disposal agreements with third parties for the disposal of these materials and wastes, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and incur significant costs associated with civil or criminal fines and penalties. Further, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of hazardous materials.

Increased labor costs negatively affect our ability to operate efficiently and have an adverse impact on our revenues and profitability.

Many aspects of our strategies and business growth may require us to have additional employees, and we may also have additional employees as a result of acquisitions or organic growth of our business. The average cost of labor in the PRC has been steadily increasing over the past years as a result of inflation, government-mandated wage increases and other changes in PRC labor laws, as well as competition for talents and qualified employees among pharmaceutical companies. As a result, increased labor costs could slow down our growth and affect our profitability.

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 operate in the pharmaceutical industry, which involves numerous operating risks and occupational hazards. The insurance policies we maintain are required under the applicable laws and regulations as well as based on our assessment of our operational needs and industry practice. For more details, please see "Business — Insurance" in this document. However, there is no assurance that the existing insurance coverage is sufficient to compensate for actual losses suffered or incurred. In line with industry practice in the PRC, we have elected not to maintain certain types of insurance, such as business interruption insurance or insurance to cover product and professional liability claims or lawsuits against us. In addition, there are certain types of losses, such as losses from war, acts of terrorism, health or public security hazards, earthquakes, typhoons, flooding and other natural disasters, as for which we cannot obtain insurance at a reasonable cost or at all. Should an uninsured loss or a loss in excess of insured limits occur, our business, results of operations and financial condition may be materially and adversely affected by such losses and associated liabilities. For details of the specific risks of inadequate insurance coverage in the event of product liability claims and environmental liabilities, see "— Risks Relating to Our General Operations — We may be subject to product liability claims that could expose us to costs and liabilities" and "— Risks Relating to Our General Operations — If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially and adversely affect the success of our business", respectively, in this section.

We are subject to risks associated with leasing space.

As of the Latest Practicable Date, we leased two real properties in Zhuhai and one real property in Beijing as our office, manufacturing and/or research and development facilities. As our lease expires, we may fail to obtain renewals, either on commercially acceptable terms or at all, which could compel us to close such office and manufacturing facility. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

Further, as of the Latest Practicable Date, the lease agreements of the aforementioned real properties in Zhuhai and Beijing were not registered with the relevant municipal land and real estate administration department in accordance with applicable PRC laws and regulations. As registration of the lease agreement will require the cooperation of the landlord, there is no assurance that you that we can complete the registration of such lease agreement in a timely manner or at all. Our PRC Legal Adviser advised us that the failure to register the lease agreement for our leased property in the PRC will not affect the validity of this lease agreement, but if we fail to complete the registration within the prescribed time frame as required by competent municipal land and real estate administration departments in the PRC, a penalty for the Company ranging from RMB1,000 to RMB10,000 may be imposed for each non-registered lease. During the Track Record Period and up to the Latest Practicable Date, we had not received any such request or suffered any such fine from the relevant PRC government authorities.

Changes in the U.S. and international trade policies, particular 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 of the jurisdictions in which we operate, or the perception that these changes could occur, could adversely affect the financial and economic conditions of the jurisdictions in which we operate, as well as our overseas expansion, our financial condition and results of operations.

For instance, it is notable that the United States government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs which have led to other countries, including China and members of the European Union, imposing tariffs against the United States in response. It is also unknown whether and to what extent any such actions would have any significant effect on us or our industry.

RISKS RELATING TO OUR DOING BUSINESS IN CHINA

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

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new products. For details of a discussion of regulatory requirements that are applicable to our current and planned business in China, see "Regulatory Overview" in this document. We believe our strategy and approach are consistent with the PRC government's policies, but we cannot ensure that our strategy and approach will continue to be consistent. Additionally, 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 product candidates and reduce the current benefits we believe are available to us from developing and manufacturing our product candidates in China. The PRC authorities have also become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us to maintain compliance with applicable laws and regulations may result in the suspension or termination of our business activities in China.

Adverse changes in political, economic and other policies of the PRC government could have a material adverse effect on the overall economic growth of China, which could reduce the demand for our products, or otherwise materially and adversely affect our business, operations or competitive position.

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, allocation of resources and an evolving regulatory system. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources, but some of these measures may have a negative effect on us. For example, our financial condition and results of operations may be adversely and affected by government control over capital investments or changes in tax regulations that are currently applicable to us. More generally, 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, and there is no assurance that future growth will be sustained at similar rates or at all. If the business environment or economic conditions in China deteriorates from the perspective of domestic or international investment, our business may also be adversely affected.

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

The PRC legal system is a civil law system based on written codes and statutes. Unlike the common law system, prior court decisions may be cited as persuasive authority but have limited precedential value. Since the late 1970s, the PRC government has promulgated a comprehensive system of laws, rules and regulations governing economic matters in general. However, as these laws and regulations are relatively new and the number of published decisions is limited, their interpretation and enforcement involve significant and certainties, and can be inconsistent and unpredictable. Specifically, since the 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 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 operation.

Furthermore, PRC laws and regulations afford significant protection to state-owned assets. Transactions that may lead to losses of state-owned assets are subject to heightened scrutiny by the competent authorities, and the competent authorities have significant discretion in interpreting and implementing the relevant laws and regulations. In the event we or our affiliates conduct transactions with state-owned enterprises or their affiliates, there might be risks and uncertainties involved that we might be found to have caused losses of state-owned assets, which may subject us to liabilities and could

materially and adversely affect our business, financial condition and results of operation. Finally, 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.

You may experience difficulties in effecting service of legal process and enforcing judgments against us and our management.

We are incorporated under the laws of the PRC with limited liability, and substantially all of our assets are located in the PRC. In addition, a majority of our Directors and Supervisors and all of our senior management personnel reside within the PRC, and substantially all their assets are located within the PRC. As a result, it may not be possible to effect service of process within the United States or elsewhere outside the PRC upon us or most of our Directors, Supervisors and senior management personnel.

When it comes to trans-jurisdictional recognition and enforcement of judgments, the PRC does not have treaties providing for the reciprocal recognition and enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in the PRC or Hong Kong of judgments of a court obtained in the United States and any of the other jurisdictions mentioned above may be difficult or impossible.

As between the PRC and Hong Kong, the new arrangement entered into between the Supreme People's Court of the PRC and the government of the Hong Kong Special Administrative Region on January 18, 2019 has lifted the requirements for a choice of court agreement in writing in a civil or commercial case under the previous regime on bilateral recognition and enforcement. However, before such new arrangement becomes officially effective, it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in PRC if the parties in the dispute do not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors seek recognition and enforcement of foreign judgments in the PRC.

Fluctuations in exchange rates may result in foreign currency exchange losses and may have a material adverse effect on your investment.

The change in the value of the Renminbi against the Hong Kong dollar and other currencies may fluctuate and is affected by, among other things, changes in China's political and economic conditions and China's foreign exchange policies, as well as supply and demand in the local market. As such, it is difficult to predict how market forces or government policies may impact the exchange rate between Renminbi, the US dollar, the Hong Kong dollar or other currencies in the future. Substantially all of our costs are denominated in Renminbi and most of our financial assets are also denominated in Renminbi. However, our proceeds from the [**REDACTED**] will be denominated in Hong Kong dollars. As a China-based company, any significant change in the exchange rates of the Hong Kong dollar against Renminbi may materially adversely affect any dividends payable on, our H Shares in Hong Kong dollars.

Our operations are subject to and may be affected by changes in 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, and there is no assurance that any such examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC government from time to time adjusts or changes its tax laws and regulations. For example, under the Individual Income Tax Law of the PRC (Revised in 2018) (《中華人民共和國個人所得税法(2018年修訂)》) and the amended *Individual Income Tax Law* (《中華人民共和國個人所得税法實施條例》) that took effect on January 1, 2019, foreign nationals have no domicile in China but have resided in the PRC for a total of 183 days or more in a tax year, would be subject to PRC individual income tax on their income gained within or outside the PRC. Should such rule be strictly enforced, our ability to attract and retain highly skilled foreign scientists and research technicians to work in China may be materially affected. Further adjustments or changes to PRC tax laws and regulations, together with any uncertainty resulting therefrom, could also have an adverse effect on our business, financial condition and results of operations.

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

Under the applicable PRC tax laws, both the dividends we pay to non-PRC resident individual holders of H shares ("**Non-Resident Individual Holders**"), and gains realized through the sale or transfer by other means of H shares by such shareholders, are subject to PRC individual income tax at a rate of 20%, unless reduced by the applicable tax treaties or arrangements. And the dividends we pay to, and gains realized through the sale or transfer by other means of H shares by non-PRC resident enterprise holders of H shares are both subject to PRC enterprise income tax at a rate of 10%, unless reduced by applicable tax treaties or arrangements. In addition, any non-resident enterprise registered in Hong Kong that holds directly at least 25% of the shares of our Company shall pay enterprise income tax for the dividends declared and paid by us at a tax rate of 5%.

With respect to Non-Resident Individual Holders in specific, income received from dividends and bonuses of a foreign-invested enterprise, as well as that from transfer of stocks of listed companies are currently exempt from individual income tax pursuant to applicable PRC regulations. However, the newly enacted regulations have stated the PRC government's plan to cancel foreign individuals' tax exemption for dividends obtained from foreign-invested enterprises, and the relevant governmental departments have been charged of making and implementing details of such plan. At present, no relevant implementation rules or regulations have been promulgated, but there is no assurance that any gains on the sales of our H Shares and the dividend thereon will not be subject to PRC income taxes in the future.

We may be restricted from transferring our scientific data abroad or using human genetic resources collected in China.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the "**Scientific Data Measures**"), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Upon approval by the competent authorities, the enterprise shall undergo the required procedures, and enter into the confidentiality agreements with the users of the scientific data. Further, any researcher conducting

research funded at least in part by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given that the term "state secret" is not clearly defined, if and to the extent any data collected or generated in connection with our R&D of product candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, there is no assurance 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 or to our foreign partners in China. As a result, we may be subject to fines and other administrative penalties imposed by those government authorities.

In addition, on July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) (the "**Service Guide**"), which became effective on July 2, 2015. According to the Service Guide, the sampling, collection or research activities of human genetic resources through clinical trials shall be required to be filled with the China Human Genetic Resources Management Office through the online system. Then, on May 28, 2019 the State Council promulgated the Regulations of PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), which became effective on July 1, 2019 (the "**Human Genetic Resources Regulation**"). The Human Genetic Resources Regulation stipulates that collecting human genetic resources of China's important genetic families and specific regions, or collecting those human genetic resources in such categories and quantities as prescribed by the administrative department for science and technology under the State Council, preserving China's human genetic resources and providing the basic platform for scientific research, utilization of China's human genetic resources for international cooperation in scientific research, as well as transporting China's materials of human genetic resources abroad shall be subject to the approval of the administrative department for science and technology under the State Council. If we are unable to obtain necessary approvals or comply with the regulatory requirements in a timely manner, or at all, our R&D of product candidates may be hindered. If the relevant government authorities consider the transmission of our scientific data or collection and usage of human genetic resources to be in violation of the requirements under applicable PRC laws and regulations, we may be subject to fines and other administrative penalties imposed by those government authorities.

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

Renminbi is currently not a fully freely convertible currency. The PRC government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. A portion of our revenue may be converted into other currencies in order to meet our foreign currency obligations, e.g., to obtain foreign currency to make payments of declared dividends, if any, on our H Shares. Under China's existing laws and regulations on foreign exchange, following the completion of the [**REDACTED**], we will be able to make dividend payments in foreign currencies by complying with certain procedural requirements and without prior approval from the State Administration of Foreign Exchange. However, in the future, the PRC government may, at its discretion, take measures to restrict access to foreign currencies for capital account and current account transactions under certain circumstances. As a result, we may not be able to pay dividends in foreign currencies to holders of our H Shares.

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

During the Track Record Period, we have relied on collaboration with entities in foreign countries and regions. We may also pursue partnerships with entities in foreign countries and regions in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. As a result, China's political relationships with those foreign countries and regions may affect development and commercialization of our product candidates.

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

RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our H Shares and there can be no assurance that an active market would develop, and the* [REDACTED] *and* [REDACTED] *of our H Shares may be volatile.

Prior to this [**REDACTED**], there has been no public market for our H Shares, and the [**REDACTED**] for our [**REDACTED**] was the result of negotiations among us, the [**REDACTED**] and the [**REDACTED**] (for themselves and on behalf of the [**REDACTED**]). However, a [**REDACTED**] on the Stock Exchange does not guarantee that an active and liquid [**REDACTED**] for the H Shares will develop, or if it does develop, that it will be sustained following the [**REDACTED**], or that the [**REDACTED**] of the H Shares will not decline following the [**REDACTED**]. In addition, the [**REDACTED**] and [**REDACTED**] of the H Shares may be subject to significant volatility in responses to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the [**REDACTED**] and [**REDACTED**] of our H Shares. Further, the [**REDACTED**] and [**REDACTED**] of our H Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting the relevant markets, 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.

You will incur immediate and significant dilution and raising additional capital may cause further dilution or restrict our operation.

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

Any possible conversion of Domestic Shares into H Shares could increase the supply of H Shares in the market, which will negatively impact the* [REDACTED] *of H Shares.

According to the stipulations by the State Council's securities regulatory authority and the Articles of Association, our Domestic Shares may be converted into H Shares and such converted H Shares may be [**REDACTED**] or [**REDACTED**] an overseas stock exchange, provided that prior to the conversion and [**REDACTED**] of such converted shares, the requisite internal approval processes (but without the necessity of Shareholders' approval by class) have been duly completed and the approval from the relevant PRC regulatory authorities, including the CSRC, have been obtained. In addition, such conversion, [**REDACTED**] and [**REDACTED**] must comply with the regulations prescribed by the State Council's securities regulatory authorities and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. We can apply for the [**REDACTED**] of all or any portion of our Domestic Shares on the Hong Kong Stock Exchange as H Shares in advance of any proposed conversion to ensure that the conversion process can be completed promptly upon notice to the Hong Kong Stock Exchange and delivery of shares for entry on the H Share register. This could increase the supply of H Shares in the [**REDACTED**], and [**REDACTED**], or [**REDACTED**], of the converted H Shares may adversely affect the [**REDACTED**] of H Shares.

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

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

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations regarding our H Shares, the* [REDACTED] *for our H Shares and* [REDACTED] *may decline.

The [**REDACTED**] for our H Shares will be influenced by research or reports that industry or securities analysts publish about us or our business. If one or more analysts who cover us downgrade our H Shares or publishes negative opinions about us, the [**REDACTED**] for our H Shares would likely decline regardless of the accuracy of the information. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the [**REDACTED**] or [**REDACTED**] of our H Shares to decline.

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

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

There can be no assurance that we will declare and distribute any amount of dividends in the future.

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

Our Controlling Shareholders have significant influence over our Company and their interests may not be aligned with the interest of our other shareholders.

Our Controlling Shareholders will, through its voting power at the Shareholders' meetings and its delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our Controlling Shareholder may not act in the best interests of our minority Shareholders. In addition, without the consent of our Controlling Shareholder, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a [**REDACTED**] of our Company and may significantly reduce the price of our H Shares.

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

Facts, forecasts and statistics in this document relating to the PRC economic and pharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Sole Sponsor, the [**REDACTED**] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and

statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the industry statistics in this document may be inaccurate and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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

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 H Shares. 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 any responsibility for the accuracy or completeness of any such press articles or other media coverage, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our H Shares, the [**REDACTED**] or us. 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 in any such press articles or media coverage. Accordingly, prospective investors 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. By applying to [**REDACTED**] our H 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.