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

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

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to the Development of Our Product Candidates

Our future growth depends substantially on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval, commercialize our product candidates, or keep up with industry and technology developments, or if we experience significant delays in doing so, our business will be materially harmed.

Our business substantially depends on the successful development, regulatory approval and commercialization of our product candidates, most of which are still in design or design verification stage, type/safety and performance testing stage or early commercialization stage, and other products we may develop in the future. Whether we can generate profit from our operating activities largely depends on the successful commercialization of our product candidates. The successful commercialization of our product candidates will depend on several factors, including but not limited to:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies and success of other development stages including design, verification and type/safety and performance testing;
- favorable safety and efficacy data from our clinical trials and other studies;
- regulatory approvals;
- establishing and expanding commercial manufacturing capabilities;
- the performance by any third parties, such as CROs or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the clinical data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;

- keeping up with industry and technology developments;
- successfully launching our product candidates, if and when approved for marketing; and
- competition with other molecular diagnostics and gene sequencing products.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to obtain approval for and/or to successfully commercialize our product candidates, which would have a material adverse impact on our business and we may not be able to generate sufficient revenue and cash flows to continue our operations.

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

The global life science tools market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. Our foundational life science technology platform represents emerging and complex technologies spanning integrated circuit chips, synthetic biology, electrochemistry, microfluidics, and artificial intelligence. The inherent complexity of synchronizing these rapidly evolving disciplines presents substantial risks, including meeting high precision requirements, system integration challenges, and keeping pace with shifting industry standards. We have invested significant amounts of human and capital resources into our research and development activities. In 2023 and 2024, our research and development expenses were US$15.3 million and US$11.4 million, respectively and we did not begin generating revenue until 2024. We must continue to invest in developing or acquiring technologies that will allow us to enhance the application scenarios, functions, performance and quality of our products. However, we cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies in a timely manner, or at all. Any failure to do so may make our techniques and products obsolete, which could significantly reduce demand for our products and have a material adverse impact on our business and prospects.

Developing new technologies and improving existing technologies requires a significant amount of capital investment and involves substantial uncertainties. Even if we are able to successfully develop new technologies or optimize existing technologies after we spend significant time and efforts on research and development, we cannot guarantee you that we will definitely be able to generate sufficient return on our initial investment to maintain cost-effectiveness or achieve profitability. As a result, we may incur substantial losses from our investment in research and development activities and our future business, results of operations, financial condition and prospects could be materially and adversely affected.

We may not be able to develop new or improved products that are competitive in the market, in a timely manner or at all.

The life science tools market is characterized by technological changes, frequent new product introductions, and evolving industry standards. Without the timely introduction of new and improved products, our products could become technologically obsolete or more susceptible to competition and our results of operations and financial condition would suffer. Even if we develop new or improved products, our ability to market them could be limited by various factors such as regulatory clearance and market demands. We plan to upgrade our AxiLona EL-100 to enable protein detection and continue exploring its potentials in overseas markets. Additionally, we may develop an all-in-one molecular diagnostic POCT device based on AxiLona EL-100. For our EL-NGS gene sequencer AxiLona AXP-100, we will continuously iterate and upgrade it to enhance its capabilities and performance. In addition, we plan to develop AxiLona AXP-1000, which would feature a higher throughput sequencing chip. Although we devote significant financial and other resources to our research and development activities, we cannot guarantee that our efforts will yield favorable results and the new or improved products will be introduced successfully in a timely manner, or at all.

Technical innovations often require substantial time and investment before we can determine their commercial viability. We may not have the financial resources necessary to fund all of our existing and future product development projects. In addition, even if we are able to successfully develop new or improved products, they may not produce revenue in excess of the costs of development or achieve the desired financial return, and they may be rendered obsolete or less competitive by changing customer preferences or the introduction by our competitors of products with advanced technologies or features or other factors.

If clinical trials of our product candidates fail to demonstrate positive results to the satisfaction of regulatory authorities, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approval for the commercialization of our product candidates, we may be required to conduct extensive clinical trials, and, depending on the type of our relevant product candidates, the clinical trials may require large prospective clinical study that is far more rigorous and expensive than other existing pipeline products. For AxiLona EL-100, we completed its clinical trial in March 2025 and received the Class II medical device registration certificate from Jiangsu MPA in April 2025. We also received the CE marking for AxiLona EL-100 in July 2023. We may initiate a clinical trial for our AxiLona EL-100 in the U.S. as well. For AxiLona AXP-100, we expect to complete its type testing in the second half of 2025 in China and subsequently initiate a clinical trial for it. We may also conduct clinical trials for our other product candidates. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including but not limited to:

- regulators, institutional review boards, or IRBs, or ethics committees may not authorize 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 and hospitals as trial centers, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and hospitals as trial centers;

- manufacturing issues, including problems with manufacturing, quality of supplies, or obtaining sufficient quantities of a product candidate for use in a clinical trial;

- insufficient capabilities to meet the requirements for clinical trials;

- failure of our product candidates to demonstrate superior results than competing or alternative products, if applicable;

- clinical trials of our product candidates may fail to demonstrate the sensitivity and specificity as anticipated, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

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

- our consultants or other third parties involved in the clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics; and

- the initial or interim results of the clinical trial may not be predictive of the final results.

There can be no assurance that these trials will be completed in a timely or cost-effective manner or result in a commercially viable product. If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates, the commercial prospects of that product candidate will be harmed, and our ability to generate revenue from any of those product candidates will be delayed. In addition, 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 commence product sales and generate revenue for that candidate. Any of these occurrences may have a material adverse impact on our business, financial condition, results of operations and prospects.

If we encounter difficulties procuring requisite test samples or collect samples in our clinical trials, our research and development activities could be delayed or otherwise adversely affected.

The clinical trials of our product candidates may involve test samples from human subjects. The timely completion of clinical trials in accordance with protocols depends, among other things, on our ability to procure a sufficient number of test samples for our clinical trial. We may experience difficulties in doing so for a variety of reasons, including but not limited to:

- the number and nature of the samples;
- the qualified samples defined in the protocol;
- the size of the study required for analysis of the trial's primary endpoints;
- perceived risks and benefits of our product candidates;
- the design of the trial; and
- our ability to obtain and maintain required consent to use the samples.

If we are unable to procure enough test samples in our clinical trials, any delays in sample collection 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 may be unable to develop our product candidates as anticipated if the third parties with which we contract for clinical trials do not perform in an acceptable manner or if these third parties do not successfully carry out their contractual duties or meet expected deadlines.

We rely on third parties, including clinical trial institutions and CROs, to assist us in designing, implementing and monitoring our clinical trials. If any of these parties terminates its agreements with us, we may not be able to enter into arrangements with alternative third parties that meet our standards in a timely manner, or on commercially reasonable terms, or at all, and the development of our product candidates covered by those agreements could be substantially delayed.

In addition, we are responsible for ensuring that each of our non-clinical and clinical 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 from our regulatory responsibilities. However, these third parties may not successfully carry out their contractual obligations, meet expected deadlines or follow clinical and manufacturing guidelines and protocols. If any of these parties fails to perform their obligations under our agreements with them in the manner specified in those agreements, the regulatory authorities may not accept the data generated by those studies or 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 candidates. If any of the 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, financial condition, results of operations and prospects.

Risks Relating to the Commercialization of Our Product Candidates

We have limited experience in marketing and sales of our products. There can be no assurance that we will be able to successfully commercialize our products, and as a result, our revenue and profitability could be materially and adversely affected.

Our operations to date have been largely focused on the research and development of our product candidates. As of the Latest Practicable Date, we have only received the registration approval for AxiLona EL-100 and other pipeline products have not entered the clinical stage. We are actively preparing for the commercial launch of AxiLona EL-100 for clinical applications, and AxiLona AXP-100 for research applications in the future. As a result, we have relatively limited experience in launching and commercializing our products. For example, we have limited experience in building a commercial team, conducting a comprehensive market analysis, or managing sales force for our products. Therefore, our ability to successfully commercialize our products may involve more inherent risks, take longer and cost more than it would if we were a company with sufficient experience launching products.

We will continue to strengthen our in-house commercialization team to carry out our direct sales strategy, which will allow us to build strong customer relationships and deliver customized solutions. We also plan to establish a distributor network to penetrate specific market segments, leveraging local partnerships to enhance accessibility and expand our reach. However, there can be no assurance that we will be able to establish or maintain such relationship with our customers or distributors, or, if we are able to do so, that effective sales forces and network will be established. Any revenue we receive will partially depend on the efforts of our in-house team and such distributors, which may not be successful. We have limited control over our employees and we may have little or no control over the marketing and sales efforts of such third parties. We will also face competition in our search for sales personnel with commercialization experiences and other reputable third parties to assist us with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in-house sales and marketing capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

Our success depends on our ability to provide reliable, high-quality products and services and to rapidly evolve to meet our customers' needs. If our products or services, or similar molecular diagnostics and gene sequencing services and products available in the market in general, do not meet the expectations of customers, our results of operations, reputation and business could suffer.

Our success depends on our ability to provide reliable, high-quality products and services and to rapidly evolve to meet our customers' needs. However, there is no assurance that our products will perform as expected at all times and our customers will be satisfied with our services. If our products fail to accurately and completely detect or identify specific indicators for the purposes of the testing or make other errors, or if we fail to satisfy or respond to the requirements of our customers for our services, our customers may be unsatisfactory about our products or services, reduce their purchase or even turn to our competitors' comparable products or services, which may materially and adversely affect our business, financial condition, results of operations and reputation.

In addition, our success depends on the market's confidence in molecular diagnostics and gene sequencing services and products in general. If other molecular diagnostics and gene sequencing products or services do not perform to expectations, it may result in lower confidence in our industry in general and will then adversely affect the demand of our products and/or services and our business.

Failure to achieve broad market acceptance or maintain a good reputation necessary for our products would have a material adverse impact on our results of operations and profitability.

The commercial success of our existing and future products depends upon their market acceptance, particularly among our customers. Our products may fail to receive broad acceptance from target customers and end-users as anticipated. If our products fail to gain sufficient market acceptance by customers and others in the industry, the sales of our products will be adversely affected. In addition, customers may prefer other novel products to ours. If our products do not achieve an adequate level of acceptance, we may not generate significant revenue to become profitable. Failure to achieve an adequate level of acceptance or to improve market awareness of our products may have a material adverse impact on our business, financial condition and results of operations. The degree of market acceptance of our products, if approved for commercial sale, will depend on a number of factors, including:

- customers considering our products as safe and effective;
- the potential and perceived advantages of our products over alternative products;
- our continuing collaborations with the established commercialization channels;

- our ability to further validate our products through clinical research and accompanying publications;
- the timing and scope of approval by regulatory authorities for our product candidates;
- the impact of negative publicity regarding our or our competitors' products and technologies resulting from defects or errors;
- changes of governmental policies or guidelines in respect of molecular diagnostics and gene sequencing products and services;
- accelerated research and development progress of our competitors; and
- the effectiveness of our sales and marketing efforts.

Even after we successfully achieve commercialization of our products for clinical applications, if any of our products fails to achieve market acceptance among customers or if we fail to maintain good relationships with them, we will not be able to generate significant revenue. Our ability to market our products could be limited by the need for regulatory clearance, restrictions imposed on approved applications, entrenched patterns of clinical practice, uncertainty over third-party reimbursement, or other factors. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than ours, are more cost effective or render our products obsolete.

We believe that maintaining and enhancing our brand identity and increasing market awareness of our company and products is critical to achieving widespread acceptance of our products, strengthening our relationships with our existing customers and our ability to attract new customers. The successful promotion of our brand will depend largely on our ability to continue to offer high-quality products and our research and development efforts. However, there is no assurance that our brand promotion activities and research and development efforts may be successful or contribute to our growth. In addition, even if these activities increase revenue, the revenue may not be enough to offset the increased expenses we incur.

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

Our estimates of the total addressable markets for our current product candidates are based on a number of internal and third-party estimates, including, without limitation, the size of target customers and the assumed prices at which we can sell the relevant product candidates for markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the total addressable markets for our

product candidates may be proved to be incorrect. If the target population who would benefit from our product candidates, the price at which we can sell our product candidates or the total addressable markets for our product candidates is smaller than we have estimated, our sales growth may be impaired and there may be an adverse impact on our business, financial condition and results of operations.

Even if we are able to commercialize any products, the pricing of such products may be subject to downward changes, which may have a material adverse effect on our business, financial condition and results of operations.

We may face downward change in pricing of our products due to increasing market competition, launch of competitive products or evolving regulatory regime which may impose pricing control or other restrictive measures. A critical differentiator of our business is our ability to balance technological sophistication with cost-effectiveness in our products, which is pivotal to adoption by our customers and end-users. Although we have formulated a reasonable and comprehensive pricing strategies, our pricing strategies still face inherent challenges. We may not have sufficient bargaining power in negotiating with suppliers, potentially requiring higher-than-anticipated production costs. Our customers may gain more bargaining power depending on the availability of alternative products, demands of customers and the preference of doctors. If our customers lower the order prices of our products and therefore reduce our profitability, it will have a material adverse impact on our results of operations.

More competing molecular diagnostics and gene sequencing products may become available, which will offer alternatives for our customers. Any price reductions by our competitors with scaled manufacturing capabilities could force us to lower prices, which may have a material adverse effect on our business, results of operations and financial condition. In addition, as of the Latest Practicable Date, there was no pricing guidance or centralized procurement set by the PRC government on our products. If the PRC government issues price guidance for our products, it may impose downward pressure on our current pricing strategies. Furthermore, our international commercialization strategy will subject us to additional risks in maintaining our products at appealing or competitive prices in the overseas markets. Countries to which we make export sales may take restrictive measures, such as trade tariffs, or anti-dumping duties and other non-tariff barriers, to protect their home markets. Any imposition of tariffs, anti-dumping duties, or other non-tariff barriers in one or more markets could result in additional costs to us and negatively affect our ability to price our products at appealing or competitive rates. Any downward change in pricing of our products may have a material adverse effect on our business, financial condition and results of operations.

We plan to rely on our in-house marketing force and third-party distributors to promote and market our products. If we are unable to develop, expand and maintain adequate sales and commercial distribution capabilities, our business and results of operations could be adversely affected.

Under our strategic marketing model, we plan to rely on both our in-house sales and marketing force and third-party distributors to promote and sell our products. For details, please refer to "Business — Sales and Marketing." The success of our marketing model depends on our ability to maintain and expand our relationships with qualified distributors and our ability to attract, motivate and retain qualified and professional employees in our sales and marketing teams who have, among other things, the sufficient expertise in the molecular diagnostics and gene sequencing and other relevant areas and are able to communicate effectively with medical professionals. However, we would have little or no control over the marketing and sales efforts of the third-party distributors, and our revenue from product sales may be lower than if we had commercialized our products by ourselves. We also face competition in our search for distributors to assist us with the sales and marketing efforts for our products. There can be no assurance that we will be able to develop and successfully maintain our commercial distribution capabilities or establish or maintain relationships with medical device distribution companies, hospitals and other third parties to successfully commercialize our products. If we are unable to maintain and expand our relationships with those third parties, or to attract, motivate and retain a sufficient number of qualified sales personnel to support our marketing model, sales volumes or margin of our existing and future products may be adversely affected and we may be unable to extend our market coverage and deepen our market penetration as contemplated.

Risks Relating to the Manufacturing of Our Product Candidates

The manufacture process of our products is highly complex and subject to strict quality controls. Our business could suffer if our products are not produced in compliance with all the applicable quality standards.

The manufacturing process of our products is highly complex and subject to strict quality controls, partly due to rigorous regulatory requirements. In addition, quality is extremely important due to the serious and costly consequences of a product failure. Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, raw material problems, software problems, or human error. Stability failures and other issues relating to the manufacturing of our products could occur in the future. Although closely managed, disruptions can occur during implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions. As we increase our market penetration and launch our pipeline products over time, we may face unanticipated surges in demands for our products which could strain our production capacity. If these problems arise or if we otherwise fail to meet our internal quality standards or those of the NMPA or other applicable regulatory body, which include detailed record-keeping requirements, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product and professional liability and other costs, product approvals could be delayed, and thereby our business

could otherwise be adversely affected. In addition, our manufacturing and warehousing facilities, as well as those of our suppliers and logistics partners, could be materially damaged by earthquakes, hurricanes, volcanoes, fires, and other natural disasters or catastrophic circumstances, which could have a material adverse effect on our business.

If we fail to expand our commercial manufacturing capacity after we launch our future approved products, or if our manufacture capacity fails to meet the market demand, our business prospects could be materially and adversely affected.

We manufacture, assemble and test our products mainly at our 4,100 square-meter manufacturing center in Wuxi. To expand our manufacturing capability to capture the growing market demand, we plan to build a new production line for our instruments and test kits, with a total planned capacity of up to approximately 1,000 units of instrument and 100,000 sets of test kits per year. Companies manufacturing medical devices in China are required to obtain permits and licenses issued by various government authorities, including but not limited to the medical device production permit (醫療器械生產許可證) and the medical device operation permit (醫療器械經營許可證) if such manufacturing companies store and sell medical devices in places other than their domiciles and the places of production of medical devices. We have received the medical device production permit for AxiLona EL-100 from Jiangsu MPA in April 2025. Such permits, licenses and certificates are subject to periodic reviews and renewals by the relevant government authorities, and the standards of such reviews and renewals may change from time to time. There can be no assurance that the relevant authorities will approve our applications in the future. Any failure by us to obtain, maintain or renew the necessary permits, licenses and certificates could disrupt our business, which in turn may have a material adverse effect on our business and operating results.

Other than the risks relating to application of requisite licenses and permits, we could also face other risks in implementing our commercial manufacturing plan, including construction delays, failure to adopt new manufacturing techniques, implement effective quality control, recruit a sufficient number of qualified staff to support the increase in production capacity, or engage qualified subcontractors with sufficient manufacturing capacity in a cost-effective manner and on terms acceptable to us. Given the complexity of our product candidates, competition for qualified manufacturing staff is intense. New manufacturing staff are generally required to undergo sufficient training before they can commence work on our production lines. In addition, in the event of any significant increase in market demand, we may not be able to find sufficient external subcontractors to help produce our products, and even if we could engage third parties to produce a portion of our products, we would be exposed to the risks that the third parties may not manufacture products meeting our specifications or in sufficient volumes to meet market demand. Therefore, we cannot assure you that we will be able to establish or increase our commercial manufacturing capacity, develop advanced manufacturing techniques, process controls in the manner we contemplate, recruit a sufficient number of qualified manufacturing staff, or engage qualified subcontractors with sufficient production capacity, or at all.

In the event of any aforementioned failure, we may not be able to capture the expected growth in demand for our products, which could materially and adversely affect our business prospects. Moreover, our plans to establish and increase our commercial manufacturing capacity require significant capital investment, and the actual costs of our commercial manufacturing plan may exceed our original estimates, which could materially and adversely affect the realization of expected return on our expenditures.

We depend on third-party suppliers to supply raw materials to be used in manufacture our products. If these suppliers can no longer provide satisfactory products with high quality to us on commercially reasonable terms, our business, financial condition and results of operations could be adversely affected.

We purchase raw materials, which primarily include (i) printed circuit board assembly, wafers, pumps, valves, plastic parts, and metal processing components for our products, and (ii) enzymes, probes, primers, conventional chemical reagents, and screw-cap tubes for test kits. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material difficulties in procuring our major raw materials and had not experienced significant fluctuations in the prices of our supplies.

General economic conditions could adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products in a timely manner or at all. While we work closely with suppliers to monitor their financial viability, assure continuity of supply, and maintain high quality and reliability, these efforts may not be successful. Moreover, we expect our demand for raw materials to increase as we expand our business scale and commercialize more product candidates, and we cannot guarantee that current suppliers have the capacity to meet our future demand. We are also exposed to the possibility of increased raw material costs, which we may not be able to pass on to customers, and as a result, lower our profitability. In addition, although we have implemented quality inspection procedures on the raw materials and components before they are used in our manufacturing process and require our suppliers to maintain high quality standards, we cannot guarantee that we will be able to detect all quality issues in the supplies we use. These third parties may not 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 supplies to us.

Besides, due to the rigorous regulations and requirements of the NMPA and/or foreign regulatory authorities regarding the manufacture of our products (including the need for approval of any change in supply arrangements), we may have difficulty establishing additional or replacement sources in a timely manner or at all if the need arises. Certain suppliers may also elect to no longer service medical device companies due to the high number of requirements and regulation. Although we consider alternative supplier options, a change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology, and the loss of any existing supply contract could have a material adverse effect on us.

In the event of any aforementioned failure, we may have to delay manufacturing and sales, recall our products, be subject to product liability claims, fail to comply with continuing regulatory requirements and incur significant costs to rectify such issues, which may have a material and adverse effect on our business, financial condition and results of operations.

We mainly rely on our own production facilities for the manufacturing of our products. Any disruptions to the operation of our production facilities could adversely affect our business and results of operations.

We manufacture, assemble and test our products mainly at our 4,100 square-meter manufacturing center in Wuxi. The facilities may encounter unanticipated expenses due to a number of factors, including regulatory requirements. Our manufacturing facility is designed to be in compliance with GMP requirements of China and applicable regulations in the U.S. and the EU. We are also accredited in accordance with the ISO 13485 quality standard. Our manufacturing facilities will be subject to ongoing, periodic inspection by the NMPA and/or its local counterpart or other comparable regulatory agencies to ensure compliance with relevant laws and regulations. Failure to comply with applicable regulations could also result in sanctions being imposed on us, which could disrupt the operation of our production facilities and have a material adverse impact on our business.

Our facilities may be harmed or rendered inoperable by physical damage from fire, floods, earthquakes, typhoons, tornadoes, power loss, telecommunications failures, break-ins, and similar events. If our manufacturing facilities or the equipment are damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party in a timely manner, or at all. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our product candidates in a timely manner could materially and adversely affect our business, financial condition and results of operations.

Currently, our principal insurance policies cover property and general liability. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for all the expenses or losses we may suffer from disruption to our operations. We may suffer expenses or losses, and may be unable to meet our requirements for our product candidates if there were a catastrophic event or failure of our manufacturing facilities or processes.

If our experimental facilities fail to comply with applicable experimental license requirements, or become contaminated, damaged, destroyed or inoperable, or we are required to vacate the facility, our ability to operate our business may be jeopardized.

As of the Latest Practicable Date, we have strategically established four R&D centers across Silicon Valley, Shenzhen, Tianjin, and Wuxi, each equipped with cutting-edge experimental facilities to fuel our innovative R&D endeavors. Our experimental facilities are subject to various regulatory requirements, and failure to comply with applicable regulations could result in sanctions being imposed on us, which could have a material adverse impact on our business. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including pandemic, pollution, fires, earthquakes, flooding, power outages and other defects, which may render it difficult or impossible to operate for some period of time and result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation or such relationships in the future. Furthermore, our experimental facilities and the equipment used to perform our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves the collection of biological samples from patients or test subjects for the development of our product candidates. In some cases, these samples are difficult to obtain. If the parts of our experimental facility where we store these biological samples were damaged or compromised, our ability to pursue our research and development projects, operate our business, as well as our reputation, could be materially and adversely affected.

Risks Relating to Our Intellectual Property Rights

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

The success of our business operation depends in 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 technology and product candidates that we consider commercially important by filing patent applications in China and other jurisdictions, relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in a timely manner or at all. Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior deficiencies in the patent application or the lack of novelty of the underlying invention or technology. We may also fail to identify patentable aspects of our research and development 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.

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 research and development output, such as our employees, consultants, advisors and other third parties, 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. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries. Patent applications in China and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all.

Furthermore, China has adopted the "first-to-file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under China's first-to-file patent system, we may still risk unknowingly infringing third-party intellectual property rights even after conducting reasonable investigations. This is because competitors could file patent applications during our product development phase without our knowledge, and crucially, patent protection begins from the filing date rather than the grant date. Consequently, if another party files a patent application before us for the same or substantially similar technology, their patent – even if granted later – would take priority over our issued patents or pending applications in terms of validity and applicability. Furthermore, we may be involved in claims and disputes of intellectual property infringement in other jurisdictions (for example, in China and the United States). In addition, under the Patent Law of the PRC, 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 China National Intellectual Property Administration, or the CNIPA, for confidentiality examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention.

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

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 a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications may be co-owned with third parties due to joint development agreements or collaborative research arrangements. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products

and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may not be able to effectively protect our intellectual property rights in China and overseas.

Filing, prosecuting, maintaining and defending patents on our product candidates in jurisdictions throughout the world could be prohibitively expensive for us, and our intellectual property rights in some jurisdictions can have a different scope and strength from those in some other jurisdictions. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of certain other jurisdictions do. Consequently, we may not be able to prevent third parties from practicing our inventions in all jurisdictions, or from selling or importing medical products made using our inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to certain jurisdictions where we have patent protection but where enforcement rights are not as strong as those in certain other jurisdictions. These products may compete with our product candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

As of the Latest Practicable Date, we owned 40 patents and 28 patent applications in China, and 13 patents and 11 patent applications overseas, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the same. In addition, if we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and may delay us from developing or commercializing our product candidates.

Competitors may infringe our intellectual property rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An unfavorable result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

Defendant counterclaims alleging invalidity or unenforceability are commonplace, and a third party can assert invalidity or unenforceability of a patent on numerous grounds. Third parties may also raise similar claims before administrative bodies in China or overseas, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we, our patent counsel, and the patent examiner could be unaware of invalidating prior art during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business. In addition, we may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as we expect.

If third parties claim that we infringe upon or misappropriate their intellectual property rights, such proceedings could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications globally belonging to third parties that exist in fields in which we are developing our product candidates. We may also be unaware of third-party patents or patent applications, and given the dynamic area in which we operate, additional patents are likely to be issued that relate to aspects of our business. There are a substantial amount of litigation and other claims and proceedings

involving patent and other intellectual property rights in the medical device industry generally. As the medical device industry expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

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

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

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

Periodic maintenance fees 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. The CNIPA and various governmental patent agencies require compliance with a number of procedurals, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Intellectual property and other laws and regulations are subject to change, which could diminish the value of our intellectual property in general, thereby impairing our ability to protect our current and any future products.

Obtaining and enforcing patents in the biotechnological industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biotechnological patents is costly, time consuming and inherently uncertain. In addition, there are periodic proposals for changes to the patent laws in China, the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Changes in either the patent laws or in the interpretations of patent laws in China, the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our future patents or in third-party patents.

Patent terms may not be sufficient to effectively protect our products and business.

In most countries in which we plan to file applications for patents, the term of an issued patent is generally ten to 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords are limited. Even if patents covering our product candidates are obtained, we may be open to competition from other companies once our patent rights expire. Furthermore, there is no currently effective law or regulation providing patent term extension in China for medical devices.

As of the Latest Practicable Date, we had been granted 40 patents in China. Our patents have expiration dates ranging from August 2029 to September 2042. We also have 28 patent applications in China and 2 international patent applications under the Patent Cooperation Treaty, or PCT, as of the Latest Practicable Date. Upon expiration of our issued patent or patents that may issue from our pending patent application, we will not be able to assert such patent rights against potential competitors and our business, financial condition and results of operation may be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

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. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. However, 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 be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, including our senior management, were previously employed at other medical device companies, including our competitors or potential competitors. 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. We are not aware of any material threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and other third parties involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

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

We currently hold issued trademark registrations and have pending trademark applications, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our product candidates mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

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

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.

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

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

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

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

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

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

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

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

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

- the patents of others may harm our business; and

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

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

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant operating losses since our inception and anticipate that we may continue to incur operating losses for the foreseeable future.

Investment in life science tools development entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. As a result, we incurred net losses of US$22.9 million and US$23.7 million in 2023 and 2024, respectively. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development activities and our general business operations.

We may continue to incur losses for the foreseeable future, and the losses may increase as we expand our development of, and seek regulatory approvals for, our product candidates, and commercialize our products. Typically, it takes several years to develop one new product between the time when it is designed and when it is available for commercialization. In addition, we will start incurring costs associated with being and maintaining the status of a [**REDACTED**] in Hong Kong after the [**REDACTED**]. We will also incur costs in support of our further development and growth. The size of our future net losses will depend, in part, on the number and scale of our product development and the associated costs of our research and development activities, the cost of commercializing any approved products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive with arrangements with third parties. If any of our product candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital,

maintain our research and development efforts, expand our business or continue our operations as well as the price of our Shares.

We had net operating cash outflows during the Track Record Period and we may need to rely on revenue generated from our product candidates once commercialized and additional financing to fund our operations.

Our product candidates will require completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can generate revenue. Our operations have consumed substantial amounts of cash since inception. We cannot assure you that we will be able to generate positive cash flows from operating activities in the future. Our liquidity and financial condition may be materially and adversely affected by negative net cash flows, and we cannot assure you that we will have sufficient cash from other sources to fund our operations. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that we will be able to obtain the financing on terms acceptable to us, or at all, and if we raise finance by issuing further equity securities, your interest in our Company may be diluted. If we continue to have negative operating cash flows in the future, our liquidity and financial condition may be materially and adversely affected.

We expect to continue to spend substantial amounts on research and development, advancing the clinical development of our product candidates, and launching and commercializing any product candidates for which we receive regulatory approval. Our existing cash and cash equivalents may not be sufficient to enable us to complete all global development or commercially launch all of our current product candidates for the anticipated uses and to invest in additional research and development activities. Accordingly, we may require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. We cannot assure you that our financial resources will be adequate to support our operations. Our future funding requirements will depend on many factors, including:

- revenue and cash generated from our product candidates once commercialized;
- selling and marketing expenses associated with approved product future product candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll subjects in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our product candidates;
- the number and characteristics of product candidates that we may develop;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;

- cash requirements of any future acquisitions and/or the development of other product candidates;

- the cost and timing of development and completion of commercial-scale internal or outsourced, if any, manufacturing activities; and/or

- our headcount growth and associated costs.

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development activities or future commercialization efforts.

We had net current liabilities and net liabilities during the Track Record Period, which may adversely affect our liquidity.

We had net current liabilities of US$38.1 million and US$63.0 million and net liabilities of US$33.3 million and US$58.3 million as of December 31, 2023 and 2024, respectively, and may have net current liabilities and net liabilities in the future. For details, see "Financial Information." A net current liabilities position may expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources including the [**REDACTED**], and/or other sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all. Any difficulty or failure to meet our liquidity needs as and when needed may have a material adverse effect on our business, financial condition, results of operations and prospects.

We have incurred and may continue to incur share-based payments. The issuance of share-based payment awards may cause dilution to our existing Shareholders and may affect the* [REDACTED] *of our Shares.

We have granted share options to certain eligible employees in recognition of their contributions to our Company. In 2023 and 2024, we incurred share-based payments of US$1.1 million and US$1.2 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares with respect to such share-based compensation may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based compensation may also increase our operating expenses and therefore have a negative effect on our financial performance and may affect the [**REDACTED**] of our Shares.

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

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

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

While we use U.S. dollars as our reporting currency, our operations in the PRC primarily transact and maintain our financial records in RMB. Renminbi has fluctuated against the Hong Kong dollar and U.S. dollar, at times significantly and unpredictably. We have recorded net foreign exchange gains in 2023 and 2024. There is no assurance that we will continue to incur foreign exchange gains in the future or our foreign exchange losses will not incur in the future. The value of Renminbi against the U.S. dollar and other currencies is affected by changes in political and economic conditions and by foreign exchange policies, among other things. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the Hong Kong dollar or U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between Renminbi and the Hong Kong dollar or U.S. dollar in the future.

In addition, the [**REDACTED**] from the [**REDACTED**] will be received in Hong Kong dollars. As a result, any appreciation of Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [**REDACTED**] from the [**REDACTED**]. Conversely, any depreciation of Renminbi may adversely affect the value of, and any dividends payable on, our Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to complete filings with and obtain approvals from the SAFE before converting significant sums of foreign currencies into Renminbi. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our Shares in foreign currency terms.

RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATIONS

If we are not able to obtain, complete or maintain, or experience delays in obtaining, completing or maintaining, required regulatory approvals, permits, registrations or filings, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

All material aspects of the research, development and commercialization of our product candidates are heavily regulated. The process of obtaining regulatory approvals and compliance with appropriate laws and regulations require substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The failure to comply with these regulations could have a material adverse effect on our business, financial condition, results of operations and prospects.

Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate its effectiveness in well-controlled clinical trials, and, with respect to approval in China, to the satisfaction of the NMPA that the product candidate is safe and effective for the intended use and that the manufacturing facilities, processes and controls are adequate. Obtaining regulatory approvals is a lengthy, expensive and uncertain process, and approvals may not be obtained. When we submit a registration application to the NMPA, the NMPA will decide whether to accept or reject the submission for registration. We cannot be certain that any submissions will be accepted for registration and review by the NMPA. The NMPA may also slow down, suspend or cease review of our applications and any of these could prolong the registration process of our product candidates.

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

- failure of clinical trial results to meet the level of statistical significance required for approval or failure to conduct a clinical trial in accordance with regulatory requirements or clinical trial protocols;

- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;

- regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our product candidates or other products; and/or

- rejection by the relevant authorities to approve pending applications or supplements to approved applications filed by us or suspension, revocation or withdrawal of approvals.

Changes in regulatory requirements and guidance may also occur, and we may, among other things, need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The process to develop, obtain regulatory approval for and commercialize medical device product candidates is long, complex and costly both domestically in China and overseas. Even if our product candidates were to successfully obtain approval from the regulatory authorities, such approval might significantly limit the approved use, or require that precautions or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other product candidate in the future.

All material aspects of the research, development and commercialization of our products are heavily regulated. Any failure to comply with relevant laws and regulations may adversely affect our business, financial condition, results of operations and prospects.

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

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. For example, the United States and other jurisdictions or organizations, including the European Union, the United Kingdom, the United Nations and Australia, have, through executive order, legislations or other government means, implemented measures that impose economic sanctions against certain countries, regions or targeted industry sectors, group of companies or persons, and/or organizations within such countries. Failure to comply with the applicable requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions. On March 29, 2024, members of the U.S. House Select Committee on the Strategic Competition Between the United States and the Chinese Communist Party submitted a letter (the "Letter") to the U.S. Department of Defense, proposing the inclusion of certain biotechnology companies, including us, in the List of Entities Identified as Chinese Military Companies Operating in the United States in Accordance with Section 1260H of the National Defense Authorization Act for Fiscal Year 2021 (the "1260H CMC List"). After gaining knowledge of this event, we promptly initiated an internal review and risk assessment to evaluate potential implications for our operations. Importantly, the proposal remains at the suggestion stage and has not resulted in our formal inclusion in the 1260H CMC List. Therefore, it did not have any material adverse impact on our business operations. As of the Latest Practicable Date, we were not included in the 1260H CMC List. However, U.S. export controls and economic sanctions are subject to change beyond our control, and we cannot guarantee that we will not face such restrictions in the future. These sanctions could include a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Failure to comply with these regulations could therefore materially and adversely affect our business, financial condition, results of operations and prospects.

Moreover, the regulatory framework regarding the medical device industry is continuing to develop, and we cannot guarantee that amendments to the laws and regulations with regard to medical device industry would not adversely affect our business and prospects. Any such amendments may result in increased compliance difficulty and costs 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. Developments in government regulations or in practices relating to the medical device industry such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which would lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects.

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

We routinely obtain and manage clinical trial related-data through clinical research organizations, who apply de-identification methods such as coding and replacing full names with initials before transmitting these data to us. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives, regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officers and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects' private or medical records without their consent, they will be held liable for damage caused thereby. The personal information of subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. Whilst we have adopted security policies and measures to protect our proprietary data and subjects' privacy, privacy leakage incidents might not be avoided due to hacking activities, human error, employee misconduct or negligence or system breakdown.

Furthermore, our clinical trials also frequently involve professionals from third-party institutions working onsite with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including CROs, hospitals, consultants and other third parties for our clinical trials and operations. Any leakage or abuse of personal data by our third-party partners may be perceived by the enrolled subjects as our fault, negligence or a result of our failure.

In addition, any development in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Noncompliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other personal data, could have a material adverse effect on our business, financial condition and results of operations.

Even after we obtain regulatory approval for the marketing and distribution of our product candidates, our products and any future products will continue to be subject to ongoing or additional regulatory obligations and continue to be subject to regulatory review, which may result in significant additional expenses and if we fail to comply with regulatory requirements or encounter unexpected problems with our products and/or future products, we may be subject to penalties.

Even after we obtain regulatory approval for the marketing and distribution of our product candidates, our approved products will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, post market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China and/or other jurisdictions. Our manufacturing facilities are required to comply with extensive regulatory requirements from the NMPA and/or other comparable authorities. As such, we are and will be subject to continual review and inspections by the regulators in order to assess our compliance with applicable laws and requirements and adherence to commitments we made in any application materials with the NMPA or other authorities. Accordingly, we must continue to devote time, money and effort in all areas of regulatory compliance.

The regulatory approvals for our product candidates may be subject to limitations on the uses for which our products may be marketed. The approvals we obtain may also be subject to other conditions which may require potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of our product candidates. Such limitations and conditions could adversely affect the commercial potential of our product candidates.

Following an approval for commercialization of our product candidates, certain changes to the products, 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. Regulatory approvals for any of our product candidates may also be withdrawn. The NMPA or comparable regulatory authorities may seek to impose a consent decree or withdraw approval if we fail to maintain compliance with these ongoing regulatory requirements or if problems occur after the product reaches the market. Later discovery of previously unknown problems with product candidates or with our manufacturing processes may result in revisions to the approved labeling or requirements to add new safety information; imposition of clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the products from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our products and product candidates; and/or
- injunctions or the imposition of civil or criminal penalties.

The NMPA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of medical products and services placed on the market. Our product candidates may be promoted only for their approved use in accordance with the provisions of the approved label. The NMPA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. 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. 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. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

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

China has adopted management and administration measures of the import and export of technology and software products. Under the Regulations on Administration of

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

We may in the future enter into agreements with CROs in the United States for their technical support to assist us with the development of our product candidates, which may be deemed to constitute the import of technology under the regulations. As a result, such transfers are required to be registered with applicable PRC governmental authorities. We are also subject to regulatory supervision over genetics and data-related operations. To carry out clinical trials, as a foreign-invested enterprise, we may be required, as applicable, to obtain approval from the Office of Human Genetic Resources Management under the Ministry of Science and Technology (科學技術部人類遺傳資源管理辦公室) who will conduct genetics and data safety review. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all. In addition, we may also be subject to similar requirements of overseas regulatory authorities.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the "Scientific Data Measures"), which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret or individual privacy may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent our research and development of product candidates will be subject to the Scientific Data Measures and any relevant laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad. If we are unable to obtain necessary approvals or fail to obtain such approvals in a timely manner, our research and development of product candidates may be hindered, which may materially and adversely affect our business, financial condition, results of operations and prospects. If the transmission of our scientific data is found to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

We and our third-party collaborators may be subject, directly or indirectly, 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 expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

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

There is no definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations.

RISKS RELATING TO OUR OPERATIONS

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

We started our journey as a biotechnological company founded in 2016. Our operations to date have focused on raising capital, establishing our intellectual property portfolio, product development and conducting pre-clinical studies and clinical trials of our product candidates. For these reasons, particularly in light of the rapidly evolving biotechnology industry, it may make it difficult to evaluate our current business and reliably predict our future performance. There is inherent risk in using our historical financial information to project or estimate our financial performance in the future, as it only reflects our past performance under particular conditions. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors in our general business operations, the research and development of product candidates or the commercialization of our approved product. In addition, our financial and operating results may not meet the expectations of public market analysts, which

could cause the future price of the shares to decline. If we do not address these risks and difficulties successfully, our business will suffer.

Our future success depends on our ability to retain key executives and to attract, hire, retain and motivate other qualified and highly skilled personnel.

Our future success is dependent on our ability to attract a significant number of qualified employees and retain existing key employees. We are highly dependent on the continued contributions of our founders and other senior management, as well as other key clinical and scientific personnel. The loss of the services of any of our executive officers or other key employees could materially harm our business.

Competition for qualified employees in the biotechnology industry is intense and the pool of qualified candidates is limited. We believe that there will continue to be intense competition for highly skilled management, technical, sales and other personnel with experience in our industry. Our need to significantly increase the number of our qualified employees and retain key employees may cause us to materially increase compensation-related costs, including share-based compensation. Despite an increase in staff costs, we may still not be able to retain the services of experienced senior management or key clinical and scientific personnel in the future. The departure of one or more of our key employees may disrupt our product development progress and have a material and adverse effect on our business, financial condition, results of operations and prospects. Moreover, to the extent we hire personnel from competitors, we also may be subject to allegations that they have been improperly solicited or divulged proprietary or other confidential information. In addition, our senior management team has limited experience in running public companies, which will require us to expend additional resources in hiring additional support staff and incur additional costs and expenses. If we are unable to retain and motivate our existing employees and attract qualified personnel for important positions, we may be unable to manage our business effectively, including the development, marketing and sale, which could adversely affect our business, financial condition and results of operations.

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

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

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

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

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

Changes in U.S. and international trade policies, particularly with regard to China, may cause disruptions to our clinical development, manufacturing processes and other aspects of our business and operations.

The U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies towards China. It remains unclear what additional actions, if any, will be taken by the U.S. or other governments with respect to international trade agreements, the imposition of tariffs on goods imported into the United States, tax policy related to international commerce, or other trade matters. For example, recently, the United States has proposed to impose multiple rounds of tariffs on a wide range of goods imported from multiple countries, including China. The decisions made by the U.S. government led to significant market volatility and economic uncertainty. Although, other than in the case of China, most of the tariffs were later suspended and replaced by a base tariff of 10% for a period of 90 days, it is uncertain if and to what extent the tariffs may be reimposed. It is also unknown whether new tariffs will be imposed by the U.S. or other governments, or whether new laws and regulations will be enacted, or the effect that any such actions would have on us or our industry. Any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the import or export of raw materials and disrupt our product development

and the manufacturing of our product candidates. Such unfavorable policies may also negatively impact the hiring of scientists and other research and development personnel, the demand for and competitiveness of our products, or prevent us from selling our products in certain countries. If any new tariffs, policies, legislation and/or regulations are announced or implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition, results of operations and prospects.

We may be exposed to potential product liability claims if our products contain significant defects, and our insurance coverage may be inadequate to protect us from all the liabilities we may incur.

Some of our existing or future product candidates may be classified as Class II or Class III medical devices. Such classifications denote medical devices with significant clinical implications that require a high level of supervision to ensure safety and effectiveness. We may be subject to product liability claims if our products have quality issues. For example, we may face product liability claims if our product candidates are defective and thus are unable to deliver accurate results, which could lead to inaccurate diagnosis. Any such product liability claims may include allegations of defects in design, component failure, inaccurate diagnosis, a failure to warn of dangers inherent in the medical device product, negligence or strict liability. Further, we cannot ensure that doctors will strictly and accurately follow our instructions on the proper usage of our product candidates. If our product candidates are used incorrectly by doctors, quality issues, incorrect diagnosis and injury may result, which could require review and corrective action by us or even give rise to product liability claims against us.

Any serious failures or defects could cause us to withdraw or recall products, and subject us to product liabilities, which may damage our brand name and may have a material adverse effect on our business, financial condition, results of operations and prospects. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material customer complaint or product return or exchange from customers. We cannot assure you that we will be able to successfully defend ourselves against, obtain indemnification from our collaborators for product liability claims if and where applicable, or acquire sufficient product liability insurance at an acceptable cost, and failure to do so would result in substantial liabilities or limitation on the commercialization of our product candidates, and our business, financial condition, results of operations and prospects may be materially and adversely affected.

Our future investments, acquisitions or strategic partnerships may have a material adverse effect on our reputation, business, financial condition, results of operations and prospects.

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

- increased operating expenses and cash requirements;

- the assumption of additional indebtedness or contingent or unforeseen liabilities;

- the issuance of our equity securities;

- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;

- the loss of key employees and personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and

- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

We may not be able to identify attractive targets, and we have limited experience in acquisitions. In addition, we may not be able to successfully acquire the targets identified despite spending a significant amount of time and resources on pursuing such acquisition. Furthermore, integration of an acquired company, its intellectual property or technology into our own operations is a complex, time-consuming and expensive process. The successful integration of an acquisition may require, among other things, that we integrate and retain key management, sales and other personnel, integrate the acquired technologies or services from both an engineering and a sales and marketing perspective, integrate and support preexisting supplier, distribution and customer relationships, coordinate research and development efforts, and consolidate duplicate facilities and functions. The geographic distance between companies, the complexity of the technologies and operations being integrated, and the disparate corporate cultures being combined may increase the difficulties of integrating an acquired company or technology. In addition, it is common in our industry for competitors to attract customers and recruit key employees away from companies during the integration phase of an acquisition. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense. For investments over which we do not obtain management and operational control, we may lack influence over the controlling partner or shareholder, which may prevent us from achieving our strategic goals in such investments. Any of the foregoing negative developments described could disrupt our existing business and have a material adverse effect on our reputation, business, financial condition, results of operations and prospects.

We, our senior management or Directors may be involved in claims, disputes, litigation, arbitration or other legal proceedings, or may be subject to governmental investigations or administrative proceedings, which could adversely affect our business, financial condition, results of operations and reputation.

From time to time, we, our senior management or Directors may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. Any claims, disputes or legal proceedings initiated by us or brought against us, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, any litigation, legal disputes, claims, administrative proceedings or other administrative measures 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. Negative publicity arising from litigation, legal disputes, claims, administrative proceedings or other administrative measures may damage our reputation and adversely affect the image of our brands and products. In addition, if any verdict or award is rendered against us or we are imposed any fines or penalties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business ventures or projects. Consequently, our business, financial condition, results of operations and prospects may be materially and adversely affected.

We may be subject to disasters, health epidemics, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Natural disasters, acts of war, terrorism or other force majeure events beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the jurisdictions where we conduct our business. Our operations, and those of our collaboration partners, suppliers and other third parties, may be under the threat of natural disasters such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, force majeure events such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or potential wars or terrorist attacks. The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments could materially disrupt our business and operations. For example, for several years since the end of December 2019, the outbreaks of a novel strain of coronavirus COVID-19 have materially and adversely affected the global economy. Many countries and regions had been affected by the COVID-19 outbreaks. There is no assurance that such kind of health epidemic or even a more severe pandemic will not occur again in the future.

There also could occur serious natural disasters, which may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, disaster, epidemics, 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. As we rely on third parties on various services and supplies, the occurrence of any of the foregoing events could seriously harm ability to obtain services or supplies if such third parties are affected by disasters, epidemics, business interruptions and other force majeure events. In addition, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. Acts of war or terrorism may also injure our employees, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition, results of operations and prospects.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. We do not operate in a highly polluting industry, but the manufacturing process of our instruments, test kits and product candidates for clinical trials and research involves the use of hazardous chemicals, flammable and toxic materials, and may exhaust gas and generate wastewater, solid waste, and other hazardous waste. We may contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials and wastes, whether arising from our own operations or those of our business partners, now or in the future. In the event of such contamination or injury, we could be held liable for any resulting damages, and such liabilities could exceed our resources. We could also incur significant costs associated with civil or criminal fines and penalties. In addition, we may incur substantial costs to ensure compliance with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees or other third parties. If we or our third-party collaborators fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses.

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Moreover,

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

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

Any failure to comply with applicable laws and regulations and industry standards or obtain various licenses and permits or any development to the applicable laws and regulations could harm our reputation, business, financial condition, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the PRC and other applicable jurisdictions impose strict rules, regulations and industry standards governing biotechnology research and development activities, which apply to us. Our or our collaboration partners' failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our reputation, business, financial condition, results of operations and prospects.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or impose fines and penalties which could materially and adversely affect our business, financial condition, results of operations and prospects. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may

develop, and there can be no assurance that we will be able to meet new criteria that may be imposed. If the interpretation or implementation of existing laws and regulations develops or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect our results of operations and prospects.

Any government investigation of alleged violations of laws could require us to expend significant time and resources in response and generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our results of operations will be adversely affected.

Our business significantly depends on our reputation, and any negative publicity on us or failure to maintain and enhance our recognition and reputation may materially and adversely affect our business, financial condition, results of operations and prospects.

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. Moreover, it may become increasingly difficult for us to effectively manage our brand reputation when we engage various third parties, such as contract sales organizations, to expand our commercialization network and increase market access for our product candidates, as we have relatively limited control over these third parties.

Our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. We, our Shareholders, Directors, officers, employees, collaboration partners, suppliers, or other third parties we cooperate with or rely on may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees, collaboration partners, suppliers or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Any negative publicity, including disputes concerning our Shareholders, Directors, officers, employees, collaboration partners, suppliers, or other third parties we cooperate with or rely on, even if untrue, could adversely affect our reputation and prospects. If we are unable to maintain a good reputation, our ability to attract and retain key employees and business partners could be harmed which, in turn, may materially and adversely affect our business, financial condition, results of operations and prospects.

Moreover, any negative media publicity about the biotechnology industry in general, including issues and allegations solely involving other companies in the industry, may also negatively impact our reputation. In the event that such negative publicity relates to our own products and business, the adverse impact on our financial condition or results of operations might be more significant. Any such negative publicity may

undermine the public confidence in our products, reputation, brand image, business prospects, and impair the development and commercialization of our product candidates, all of which may adversely affect our business operations and financial performance. Investigations and increasingly stringent regulations arising from such negative publicity, if any, may draw time and attention from our management team, which would have otherwise been devoted into our business operations, or may incur additional compliance expenses.

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

Our internal controls and risk management will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our management, operational and financial resources and systems in the foreseeable future. In order to address the issues in our internal controls and risk management and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal control procedures and risk management framework, including adopting new policies and providing training on our controls, procedures and policies to our employees. If we encounter difficulties in improving our internal controls and risk management, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls and risk management will be effective. If we fail to maintain effective internal controls and risk management in the future, our reputation, business, financial condition, results of operations and prospects may be materially and adversely affected.

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

We maintain insurance policies that are required under the PRC laws and regulations and that we believe are in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our principal insurance policies cover property and general liability. However, our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our product development and overall operations.

RISKS RELATING TO DOING BUSINESS IN THE JURISDICTION WHERE WE MAINLY OPERATE

***We are subject to the approval, filing or other requirements of the CSRC or other PRC governmental authorities in connection with overseas offerings and future capital raising activities, including this* [REDACTED].**

On July 6, 2021, the relevant PRC government authorities issued the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law (《關於依

法從嚴打擊證券違法活動的意見》). These opinions emphasized the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies.

On February 17, 2023, the CSRC promulgated the Trial Measures for Overseas Listing, which have become effective on March 31, 2023. The Trial Measures for Overseas Listing require, among others, that PRC domestic companies that seek to initially offer and list securities in overseas markets, either directly or indirectly, file the required documents with the CSRC within three business days after its application for overseas listing is submitted. We will file with CSRC within a specific time limit as required by the Trial Measures for Overseas Listing. However, we cannot assure you that we could complete such filing in a timely manner or at all, the failure of which may restrict our ability to complete the proposed [**REDACTED**] and have a material and adverse effect on our financial performance and business prospects.

On February 24, 2023, the CSRC, the MOF, the National Administration of State Secrets Protection of China, and the National Archives Administration of China published the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the "Archives Rules"), which came into effect on March 31, 2023. The Archives Rules require that, in relation to the overseas securities offering and listing activities of domestic enterprises, either in direct or indirect form, such domestic enterprises, as well as securities companies and securities service institutions providing relevant securities services, are required to strictly comply with relevant requirements on confidentiality and archives management, establish a sound confidentiality and archives system, and take necessary measures to implement their confidentiality and archives management responsibilities.

We cannot assure you that any new rules or regulations promulgated in the future will not impose additional requirements or restrictions on us or our financing activities. If it is determined in the future that additional approval from or filing with the CSRC or other regulatory authorities or other procedures are required, we may fail to obtain such approval, perform such filing procedures or meet such other requirements in a timely manner or at all.

Changes in economic, social conditions and policies in the jurisdictions where we operate may impact our business, financial condition, results of operations and prospects.

During the Track Record Period, we mainly conduct our business operations in China and the U.S. Accordingly, our future prospects, business, results of operations, and financial condition are, to a material extent, subject to economic, political and legal developments in the jurisdictions where we operate. If the macroeconomic condition in these jurisdictions experiences significant adverse changes, demand for our products and our ability to maintain our operations may suffer, which could consequently lead to a material and adverse impact on our business, financial condition and results of operations. Moreover, if foreign governments implement laws or regulations restricting

investment in Chinese entities and we are deemed to be subject to such restrictions, the investment and transactions in our Shares, our business prospects, financial condition, results of operations, and future capital raising activities may be adversely affected. China's economy has experienced significant growth over the past decades since the implementation of reform and opening-up policy. In recent years, the PRC government has implemented measures emphasizing the utilization of market forces in economic reform and the establishment of sound corporate governance practices in business enterprises. These economic reform measures may be adaptively adjusted from industry to industry or across different regions of the country. Changes in the business environment in the jurisdictions where we operate could have a material and adverse impact on our business, financial condition and results of operations.

You may have difficulties in effecting service of legal process or enforcing foreign judgments against us, our Directors and our senior management.

Most of our assets are located in the PRC. In addition, most of our Directors and senior management reside in the PRC. As a result, it may be difficult and time-consuming to effect service of process upon those persons residing in the PRC or to enforce against us or them in the PRC any judgments obtained from non-PRC courts. The PRC does not have treaties providing for the reciprocal recognition and enforcement of judgments of courts of certain other jurisdictions. As a result, recognition and enforcement in the PRC of judgments of a court in any of these jurisdictions outside the PRC may be difficult.

On July 14, 2006, the Supreme People's Court of the PRC and the Government of the Hong Kong Special Administrative Region of the PRC signed an Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters (《最高人民法院關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the "Arrangement"). Under the Arrangement, a party with an enforceable final court judgment rendered by any designated People's Court of mainland China or any designated Hong Kong Court requiring payment of money in a civil and commercial case according to a written choice of court agreement, may apply for recognition and enforcement of the judgment in the relevant People's Court of mainland China or Hong Kong Court. A written choice of court agreement is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a court of mainland China or a Hong Kong court is expressly designated as the court having sole jurisdiction for the dispute. Therefore, it may not be possible to enforce a judgment rendered by a Hong Kong court in mainland China if the parties in the dispute did not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for you to effect service of process against us in order to seek recognition and enforcement of foreign judgments in mainland China. On January 18, 2019, the Supreme People's Court of the PRC and the Government of Hong Kong Special Administrative Region of the PRC entered into an agreement regarding the scope of judgments which may be enforced between mainland China and Hong Kong (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the "New Arrangement"). The New Arrangement broadens the scope of judgments that may be enforced between mainland China and Hong Kong under the Arrangement. Whereas a choice of jurisdiction needs to be agreed in writing in the form of an agreement between the parties for the selected jurisdiction to have exclusive jurisdiction over a matter under the Arrangement, the New Arrangement

provides that the court where the judgment was sought could apply jurisdiction in accordance with the certain rules without the parties' agreement. The New Arrangement became effective on January 29, 2024, both in mainland China and in Hong Kong and replaced the Arrangement. Under the New Arrangement, any party concerned may apply to the relevant court of mainland China or Hong Kong for recognition and enforcement of the effective judgments in civil and commercial cases subject to the conditions set forth in the New Arrangement. Although the New Arrangement has become effective, the outcome and effectiveness of any action brought under the New Arrangement may still be uncertain. We cannot assure you that an effective judgment that complies with the New Arrangement can be recognized and enforced in a mainland China court.

If we are classified as a PRC resident enterprise for PRC enterprise income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC Shareholders.

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside the PRC with its "de facto management body" within the PRC is considered a "resident enterprise" and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. The SAT issued the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as People's Republic of China Tax Resident Enterprises on the Basis of De Facto Management Bodies (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) ("SAT Circular 82") on April 22, 2009, and most recently amended on December 29, 2017. SAT Circular 82 provides certain specific criteria for determining whether the "de facto management body" of an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China, and will be subject to PRC enterprise income tax on its global income only if all of the following conditions are met (i) the primary location of the day-to-day operational management is in the PRC; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC; (iii) the enterprise's primary assets, accounting books, and records, company seals, and board and shareholder resolutions are located or maintained in the PRC; and (iv) at least 50% of voting board members or senior executives habitually reside in the PRC. We believe our Company is not a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." If the PRC tax authorities determine that our Company or any of our offshore subsidiaries is a PRC resident enterprise for enterprise income tax purposes, our Company or the relevant offshore subsidiaries will be subject to PRC enterprise income on its worldwide income at

the rate of 25%. Furthermore, if we are treated as a PRC tax resident enterprise, we will be required to withhold a 10% tax from dividends we pay to our Shareholders that are non-resident enterprises. In addition, non-resident enterprise Shareholders may be subject to PRC tax at a rate of 10% on gains realized on the sale or other disposition of Shares, if such gain is treated as derived from a PRC source. Furthermore, if we are deemed to be a PRC resident enterprise, dividends paid to our non-PRC individual Shareholders and any gain realized on the transfer of Shares by such Shareholders may be subject to PRC tax at a rate of 20% (which, in the case of dividends, may be withheld at source by us). These rates may be reduced by an applicable tax treaty, but it is unclear whether our non-PRC Shareholders would, in practice, be able to obtain the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. Any such tax may reduce the returns on your [**REDACTED**] in our Shares.

Laws and regulations over currency conversion may limit our ability to pay dividends and other obligations, and affect the value of your Shares.

Renminbi is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but requires approval from or registration with appropriate government authorities or designated banks under the "capital account," which includes foreign direct investment and loans. Currently, our PRC subsidiaries, that are foreign invested enterprises, may purchase foreign currency for settlement of "current account transactions," including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Any insufficiency of foreign exchange may restrict our ability to pay dividends to our Shareholders or to satisfy any other foreign exchange requirements, capitalize our capital expenditure plans, and could ultimately have a material and adverse impact on our future prospects, business, financial condition and results of operations.

PRC regulations of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the* [REDACTED] *of the* [REDACTED] *to make loans or additional capital contributions to our PRC subsidiaries.

We are an offshore holding company conducting our operations mainly in China through our PRC subsidiaries. If we are to make available any of our offshore funds to our PRC subsidiaries, we may (i) make loans to our PRC subsidiaries, subject to the approval from governmental authorities and limitation of amount, or (ii) make additional capital contributions to our PRC subsidiaries in China. Any loans to our PRC subsidiaries, which are treated as foreign-invested enterprises under PRC law, are subject to PRC regulations and foreign exchange loan registrations. For example, loans by us to our PRC subsidiaries to finance their activities cannot exceed statutory limits and must be registered with the local counterpart of SAFE. In addition, a foreign invested enterprise shall use its capital pursuant to the principle of authenticity and self-use within its business scope. The capital of a foreign invested enterprise shall not be used for the following purposes (i) directly or indirectly used for payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; (ii) directly or indirectly used for investment

in securities investments other than banks' principal-protected products unless otherwise permitted by relevant laws and regulations; (iii) the granting of loans to non-affiliated enterprises, except where it is expressly permitted in the business license; and (iv) paying the expenses related to the purchase of real estate that is not for self-use (except for the foreign-invested real estate enterprises).

In light of the various requirements imposed by PRC regulations on loans to and direct investment in PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans to our PRC subsidiaries or future capital contributions by us to our wholly foreign-owned subsidiaries in China. As a result, uncertainties exist as to our ability to provide prompt financial support to our PRC subsidiaries when needed, including making the [**REDACTED**] available to our PRC subsidiaries in accordance with our intended usage disclosed in "Future Plans and Use of [**REDACTED**]." If we fail to complete such registrations or obtain such approvals, our ability to use the [**REDACTED**] we expect to receive from this [**REDACTED**] and to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

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

We are a Cayman Islands holding company and we rely principally on dividends and other distributions on equity from our PRC subsidiaries for our cash requirements, including for services of any debt we may incur.

Our PRC subsidiaries' ability to distribute dividends is based upon their distributable earnings. Current PRC regulations permit our PRC subsidiaries to pay dividends to their respective shareholders only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC subsidiaries is required to set aside at least 10% of its after-tax profits each year, if any, to fund a statutory reserve until such reserve reaches 50% of each of their registered capitals. These reserves are not distributable as cash dividends. If our PRC subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us. Separately, in recent years, the PBOC and SAFE have implemented a series of capital control measures, including stricter vetting procedures for PRC-based companies to remit foreign currency for dividend payments. See "— Laws and regulations over currency conversion may limit our ability to pay dividends and other obligations, and affect the value of your Shares." Any limitation on the ability of our PRC subsidiaries to distribute dividends or other payments to their respective shareholders could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our businesses, pay dividends or otherwise fund and conduct our business.

In addition, the Enterprise Income Tax Law and its implementation rules provide that a withholding tax at a rate of 10% will be applicable to dividends payable by Chinese companies to non-PRC-resident enterprises unless reduced under treaties or arrangements between the PRC central government and governments of other countries or regions where the non-PRC resident enterprises are tax resident. Pursuant to the tax agreement between mainland China and the Hong Kong Special Administrative Region of the PRC, the withholding tax rate with respect to the payment of dividends by a PRC enterprise to a Hong Kong enterprise may be reduced to 5% from a standard rate of 10% if the Hong Kong enterprise (i) directly holds at least 25% of the PRC enterprise, (ii) is a tax resident in Hong Kong and (iii) could be recognized as a beneficial owner of the dividend from PRC tax perspective. Under the Notice of the State Administration of Taxation on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties (《國家税務總局關於執行税收協定股息條款有關問題的通知》) ("SAT Circular 81"), promulgated and took effect on February 20, 2009 by the SAT, a Hong Kong resident enterprise must meet the following conditions, among others, in order to apply the reduced withholding tax rate: (i) it must be a company; (ii) it must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (iii) it must have directly owned such required percentage in the PRC resident enterprise throughout the 12 months prior to receiving the dividends. Pursuant to the Announcement of the SAT on Issuing the Measures for the Administration of Treaty Benefits for Nonresident Taxpayers (《國家税務總局關於發佈〈非居民納税人享受協定待遇管理辦法〉的公告》), published in October 2019 and effective in January 2020, nonresident enterprises are not required to obtain pre-approval from the relevant tax authority in order to enjoy the reduced withholding tax. Instead, nonresident enterprises and their withholding agents may, by self-assessment and on confirmation that the prescribed criteria to enjoy the tax treaty benefits are met, directly apply the reduced withholding tax rate, and file necessary forms and supporting documents when performing tax filings, which will be subject to post-tax filing examinations by the relevant tax authorities. Accordingly, our Hong Kong subsidiary may be able to benefit from the 5% withholding tax rate for the dividends it receives from our PRC subsidiaries, if it satisfies the conditions prescribed under SAT Circular 81 and other relevant tax rules and regulations. However, if the relevant tax authorities consider the transactions or arrangements we have are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable withholding tax in the future. Accordingly, there is no assurance that the reduced 5% will apply to dividends received by our Hong Kong subsidiary from our PRC subsidiaries. This withholding tax will reduce the amount of dividends we may receive from our PRC subsidiaries.

Failure to comply with PRC regulations regarding the registration requirements for employee share ownership plans or share option plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), replacing earlier rules promulgated in 2007. Pursuant to these rules, PRC citizens and non-PRC citizens who reside in China for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register

with SAFE through a domestic qualified agent, which could be the PRC subsidiaries of such overseas-listed company, and complete certain other procedures. In addition, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. We and our executive officers and other employees (i) who are PRC citizens or who reside in the PRC for a continuous period of not less than one year, and (ii) who have been or will be granted incentive shares or options, are or will be subject to these regulations. Failure to complete the SAFE registrations may subject us and them to fines and legal sanctions, and there may be additional restrictions on their ability to exercise their stock options or remit proceeds gained from the sale of their stock into the PRC. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our Directors, executive officers and employees. See "Regulatory Overview — Relevant Laws and Regulations in the PRC — Regulation of Foreign Exchange and Dividend Distribution."

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

Pursuant to the PRC laws and regulations, we are required to participate in the employee social welfare plan administered by local governments. Such plan consists of pension insurance, medical insurance, work-related injury insurance, maternity insurance, unemployment insurance and housing provident fund. The amount we are required to contribute for each of our employees under such plan should be calculated based on the employee's actual salary level of previous year, and be subject to a minimum and maximum level as from time to time prescribed by local authorities. During the Track Record Period, we did not pay social insurance and housing provident fund in full for some of our employees based on their actual salary level. We have made full provisions in respect of the outstanding amount of the social insurance fund and housing provident fund contributions. In 2023 and 2024, our shortfall of contribution to social insurance and housing provident funds amounted to US$739.0 thousand and US$524.0 thousand, respectively. We may be required by competent authorities to pay the outstanding amount, and could be subject to late payment penalties or enforcement application made to the court. Pursuant to relevant PRC laws and regulations, the relevant PRC authorities may demand the employers failing to perform the aforesaid obligations to pay the outstanding social insurance contributions within a stipulated timeframe and such employers may be liable to a late payment fee equal to 0.05% of the outstanding amount for each day of delay. If employers fail to make such payments, they may be liable to a fine of one to three times the amount of the outstanding contributions. With respect to a failure to pay the full amount of housing provident fund as required, the housing provident fund management center may require payment of the outstanding amount within a stipulated timeframe. If the payment is not made within such time limit, an application may be made to the PRC courts for compulsory enforcement.

One lease agreement of our leased properties has not been registered with the relevant PRC government authorities as required by PRC law, which may expose us to potential fines.

We have leased certain properties in China. Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, we have one lease agreement that had not been registered. Although failure to register does not in itself invalidate the leases, we may be subject to fines if we fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease agreement, at the discretion of the relevant authority. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any penalties arising from the non-registration of our lease agreement. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our costs in the future.

RISKS RELATING TO THE [REDACTED]

There has been no prior* [REDACTED] *market for our Shares and the liquidity and* [REDACTED] *of our Shares may be volatile.

Prior to the completion of the [**REDACTED**], there has been no [**REDACTED**] for our Shares. There can be no guarantee that an active [**REDACTED**] market for our Shares will develop or be sustained after the completion of the [**REDACTED**]. The [**REDACTED**] is the result of negotiations between our Company and the [**REDACTED**] (for themselves and on behalf of the [**REDACTED**]), which may not be indicative of the price at which our Shares will be [**REDACTED**] following the completion of the [**REDACTED**]. The [**REDACTED**] of our Shares may drop below the [**REDACTED**] at any time after completion of the [**REDACTED**].

***The* [REDACTED] *and* [REDACTED] *volume of our Shares may be volatile, which could result in substantial losses for* [REDACTED] *who* [REDACTED] *our Shares in the* [REDACTED].**

The [**REDACTED**] and [**REDACTED**] volume of our Shares may be volatile and could fluctuate widely in response to factors beyond our control. In particular, the performance and fluctuation of the market price and trading volume of other companies with business operations located mainly in mainland China that have listed their securities in Hong Kong may affect the volatility in the price of and [**REDACTED**] volumes for our Shares. A number of mainland China-based companies have listed their securities, and some are in the process of preparing for listing their securities, in Hong Kong. The market price and trading volume of shares of some of these companies have experienced significant volatility, including significant price declines after their initial public offerings. The trading performances of the securities of these companies at the time

of or after their offerings may affect the overall investor sentiment toward mainland China-based companies listed in Hong Kong and consequently may impact the [**REDACTED**] performance of our Shares. These factors may significantly affect the [**REDACTED**] and [**REDACTED**] volume of our Shares, regardless of our actual operating performance.

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

The [**REDACTED**] of our Shares could decline as a result of future sales of a substantial number of our Shares or other securities relating to our Shares in the [**REDACTED**], the issuance of new shares or other securities, or the perception that such sales or issuances may occur. Future sales, or perceived sales, of substantial amounts of our securities, including any future offerings, could also materially and adversely affect our ability to raise capital at a specific time and on terms favorable to us. Equity-linked securities issued by us may also confer rights and privileges that take priority over those conferred by the Shares.

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

The [**REDACTED**] of the [**REDACTED**] is higher than the net tangible asset value per Share immediately prior to the [**REDACTED**]. Therefore, [**REDACTED**] of the [**REDACTED**] in the [**REDACTED**] will experience an immediate dilution in [**REDACTED**] consolidated net tangible asset value. To expand our business, we may consider [**REDACTED**] and issuing additional Shares in the future. [**REDACTED**] of the [**REDACTED**] may experience dilution in the net tangible asset value per Share of their Shares if we issue additional Shares in the future at a price that is lower than the net tangible asset value per Share at that time.

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

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

Our Board has complete discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your [**REDACTED**] in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [**REDACTED**] or even

maintain the price at which you [**REDACTED**] the Shares. You may not realize a return on your [**REDACTED**] in our Shares and you may even lose your entire [**REDACTED**] in our Shares.

We cannot guarantee the accuracy of facts, forecasts and other statistics obtained from official government sources or other sources contained in this document.

Certain facts, forecasts and statistics in this document relating to the PRC, the PRC economy and biotechnology industry in China are obtained from various sources including official government publications that we believe are reliable. We believe that the information originated from appropriate sources and was extracted and reproduced after taking reasonable care. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading.

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