

## RISK FACTORS

*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. These risks could materially and adversely affect our business, financial condition and results of operations. The [REDACTED] price of our Shares could significantly decrease due to any of these risks, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations. You should seek professional advice from relevant advisors regarding your prospective [REDACTED] in the context of your particular circumstances.*

We believe there are certain risks and uncertainties involved in our operations and the industry, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) key risks relating to our business and industry; (ii) risks relating to our services and products, including (a) risks relating to the development of our candidate products and services, (b) risks relating to extensive government regulations, (c) risks relating to the commercialization of our products and services, (d) risks relating to manufacture and supply of our products and services, and (e) risks relating to our intellectual properties; (iii) risks relating to our operations; (iv) risks relating to our financial position and need for additional capital; (v) risks relating to conducting business in China and related regulations; (vi) risks relating to our corporate structure and contractual arrangements; and (vii) risks relating to the [REDACTED].

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

### KEY RISKS RELATING TO OUR BUSINESS AND INDUSTRY

**We may not be able to continue the expansion of our business lines to successfully launch innovative testing service and product offerings, or effectively develop and commercialize our new molecular testing services and products, or at all, which may harm our operations, financial conditions and growth prospects.**

We intend to continue to expand our business lines by innovating our testing services and products. Over the past years, we have commercialized various clinical molecular testing services and related equipment, such as our Youxinan NIPT and NIPT Plus LDT services, our Youyi hereditary cancer susceptibility testing service and our USCISEQ-200 and USCISEQ-2000 lines of DNA sequencers. In the near future, we expect to launch several IVD test kits after their approval, including our Youxu ctDNA test kit for NSCLC in 2023. However, to expand our business lines and develop and market our new service and product offerings successfully and in a timely manner will depend on several factors, including but not limited to:

- the successful pursuit of our dual-track business model;

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- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- successful pursuit of market opportunities in scientific research services;
- favorable safety and efficacy data from our clinical trials and other studies;
- regulatory approvals;
- establishing and expanding commercial manufacturing capabilities;
- expanding our testing capabilities including expanding our laboratories;
- keeping up with industry and technology developments;
- successfully launching our product candidates, if and when approved;
- accurately assess and meet end-user needs;
- make significant capital expenditures;
- optimize our service processes to predict and control costs;
- hire, train and retain the necessary personnel;
- obtain required regulatory clearances or approvals;
- increase marketing efforts to raise end-user awareness and acceptance of our services;
- provide services of a high quality and in a timely manner;
- price our services competitively;
- compete effectively with our competitors; and
- effectively integrate end-user feedback into our business planning and improvement.

If we fail to effectively develop and commercialize new services or products, our future business, including our results of operations, financial condition, cash flows, growth opportunities and prospects, could be materially and adversely affected.

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**Our business may be adversely affected by the uncertainties and changes in the regulation of LDTs in the PRC, and any lack of requisite approvals, permits, registrations or filings in relation to our business may have a material adverse effect on our business, results of operations and prospects.**

The vast majority of our revenues during the Track Record Period were derived from providing LDT services. Our revenue from medical detection amounted to RMB229.7 million, RMB244.7 million and RMB387.9 million in 2020, 2021 and the nine months September 30, 2022, respectively. We believe it is common in the molecular testing industry that laboratories, including ours, provide testing services in the form of LDTs with self-developed testing kits. As there is a relatively short history of the LDT industry in China, a comprehensive regulatory framework governing the LDT industry has not been established. However, according to the applicable PRC laws, genetic diagnostic devices are treated as medical devices and shall be registered as medical devices with NMPA. The use and sale of medical devices are clearly regulated and registration of the medical devices is required. However, while the use of LDTs is diagnostic in nature, it is difficult to ascertain whether LDTs fall under the definition of “medical devices” under relevant PRC regulations and thus need to be registered with NMPA. According to Frost & Sullivan, it is consistent with market practice that medical companies conducting LDTs similar to our in the PRC to not conduct any registrations or filings with governmental authorities for the use of LDTs, the technologies involved or for the provision of LDT services. If the competent PRC governmental authorities take a rigid view and apply the related laws and regulations fully to LDTs, we could be subject to administrative penalties for providing LDT services without product registrations with NMPA. Such penalties include suspension of use of LDTs, confiscation of LDTs, monetary penalties and suspension of overall operations. Further, the local NMPA may refuse to accept the application for registration of medical devices from the violating laboratories for the following ten years.

Our PRC Legal Advisor and the PRC legal advisor to the Sole Sponsor consulted the Beijing NMPA in July 2022 and the BMHC in February 2023 regarding the regulatory practice of our LDT services (“Governmental Consultations”). Although pursuant to the Governmental Consultations with the Beijing NMPA and the Governmental Consultations with the BMHC, (i) provision of LDT services by using self-developed testing reagents shall not be deemed as distribution and sale of these unregistered testing reagents by Beijing NMPA; (ii) we may continue our provision of LDT services in the PRC until the NMPA and NHC promulgate new and specific regulations in this regard; and (iii) the possibility of being penalized by Beijing NMPA and BMHC for use of our unregistered testing reagents in our provision of LDT service is remote, we cannot rule out the possibility that our provision of LDT services may be deemed to be non-compliant conduct under laws, regulations or standards that may be introduced in the future, which may have a material adverse effect on our operational and financial performance. See “– Risks Relating to Our Services and Products – Risks Relating to Extensive Government Regulations – We may be adversely affected by the lack of regulatory supervision on our provision of LDT services in the PRC, and our provision of such services may be deemed as non-compliant conduct under laws, regulations or standards that may be introduced in the future and such non-compliance may have a material adverse effect on our operational and financial performance” for details.

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However, given the PRC laws and regulations in relation to medical devices and, in particular, LDT services are still evolving, and that it is uncertain whether new legislation, regulations or interpretations may be promulgated or adopted in the future, we cannot assure you that our provision of LDT services will not be interpreted as non-compliance with the applicable laws and regulations in the future. If the PRC government promulgates clear requirement for approval of LDT services, we intend to take necessary actions to meet such requirements. Any failure to meet existing or future requirements or us being identified to have other non-compliance in conducting our businesses may adversely affect our business and results of operations.

**We have a relatively limited experience in marketing and sales of our products and services, particularly our IVD products.**

There can be no assurance that we will be able to successfully commercialize our products and services. As a mature platform-based genetic technology company, we have established a comprehensive products and services portfolio that meets the diversified needs of our customers, while our ability to successfully market our products and services may involve more inherent risks, requiring longer time and more resources than it would if we were a company with sufficient experience launching such products and services. As of the Latest Practicable Date, we only commercialized 19 LDT services and two IVD equipment. We have limited experience in building a commercial team, conducting a comprehensive market analysis, or managing sales force for our product candidates and services under development, especially for our IVD product candidates.

The success of our sales and marketing efforts depends on our ability to attract, motivate and retain qualified and professional employees in our sales and marketing team who have, among other things, the sufficient expertise in the oncology molecular diagnostics and testing industry and are able to communicate effectively with professionals. Furthermore, even though we expect to hire more employees with relevant experience and knowledge to strengthen our marketing and sales workforce. Due to the intense competition for experienced personnel, we may be unable to attract, motivate and retain a sufficient number of qualified sales and marketing employees to support our business development and expansion, and our sales revenue and results of operations may be negatively affected.

**We have incurred net losses during the Track Record Period and may incur net losses for the foreseeable future, and you may lose substantially all your [REDACTED] in us given the high risks involved in the medical testing and device business.**

Historically, we incurred net profit of RMB18.1 million in 2020, net losses of RMB27.2 million and RMB179.1 million for 2021 and for the nine months ended September 30, 2022, respectively, during the Track Record Period. The majority of our operational expenditure was resulted from expenses incurred in connection with our research and development programs and from selling, administrative expenses associated with our operations. We expect to incur significant net loss for the year ending December 31, 2022 for the same reason. The net losses incurred during the Track Record Period were primarily due to the fair value changes of

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convertible redeemable preferred shares, which were one-off in nature since the preferred shares shall be converted immediately before the completion of the [REDACTED]. 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 many 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 public company 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 programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive with 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.

**A limited number of customers accounted for a substantial portion of our revenue during the Track Record Period, and any decreases in our future sales to them could adversely affect our financial condition and results of operations.**

In 2020, 2021 and for the nine months ended September 30, 2022, the aggregate revenue generated from our five largest customers were RMB62.8 million, RMB52.3 million and RMB251.5 million, respectively, representing 25.5%, 19.7% and 62.9% of our revenue, respectively. Sales to our largest customer for the same periods were RMB22.2 million, RMB15.3 million and RMB191.0 million, respectively, representing 9.0%, 5.7% and 47.8% of our revenue, respectively. Our five largest customers during the Track Record Period included hospitals, biotechnology companies and government agencies. It is likely that we will continue to be dependent upon a limited number of customers for a significant portion of our revenues for the foreseeable future and, in some cases, the portion of our revenues attributable to one single customer may increase in the future. The loss of one or more major customers or a reduction in purchase from any major customer would reduce our revenues.

**Our business operations and financial performance have been materially affected by the COVID-19 pandemic, may in the future continue to be affected by the COVID-19 pandemic, and may be affected by other force majeure events, natural disasters, pandemic, outbreak of epidemics, and other unforeseeable catastrophes.**

An outbreak of a respiratory disease COVID-19 was first reported in December 2019 and continues to expand across the PRC and globally. In March 2020, the World Health Organization characterized the COVID-19 outbreak as a global pandemic. In response to the COVID-19 pandemic, we began to offer our COVID-19-related testing services in 2020. With

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COVID-19 remaining a threat to public health, we turned our COVID-19-related testing services into a regular line of service and continue to offer testing services for those who are in need. During the Track Record Period, the vast majority of our pathogenic detection revenue was derived from COVID-19 testing. The circumstances that have accelerated the growth of our COVID-19-related testing service stemming from the effects of the COVID-19 pandemic are unlikely to continue in the future once the impact of the COVID-19 pandemic tapers. With recent changes by the Chinese government to loosen up its COVID-19 prevention and testing policies, we expect our revenue from COVID-19-related testing service will decline in future periods. We may not be able to expand our other molecular testing businesses as expected to offset the decline in revenue from COVID-19-related testing services, our business and financial conditions and prospects may be materially and adversely affected.

The COVID-19 pandemic has caused, and may continue to cause, a long-term material impact on the economy and social conditions in China and other affected countries, which may have caused direct and indirect impact on our industry and cause temporary or permanent shutdowns of our customer’s businesses and shortage of labor and raw materials, which would severely disrupt our operations and affect our prenatal and oncology businesses. In addition, any future occurrence or recurrence of force majeure events, natural disasters or outbreaks of epidemics and contagious diseases, including COVID-19, which in the past has affected the operation of our clinical testing business and our research and development efforts, avian influenza, severe acute respiratory syndrome, swine influenza caused by the H1N1 virus, or H1N1 influenza or the Ebola virus, may result in temporary or permanent shutdowns of our laboratory or our customer and supplier’s operations, which would materially and adversely affect our business, financial condition and results of operations. Moreover, in the past few years, the PRC has experienced natural disasters such as earthquakes, floods, droughts and pandemics. Any future occurrence of severe natural disasters in China may materially and adversely affect its economy and our business. We cannot assure you that any future occurrence of natural disasters or outbreaks of epidemics and contagious diseases or the measures taken by the Chinese government or other countries in response to such contagious diseases will not seriously disrupt our operations or those of our customers, which may materially and adversely affect our business, financial condition and results of operations.



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### RISKS RELATING TO OUR SERVICES AND PRODUCTS

#### Risks Relating to the Development of our Candidate Products and Services

**We invest substantial resources in research and development in order to develop our products and services and enhance our technologies, which we may not be able to do successfully.**

The molecular diagnostics and testing industry is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. In 2020, 2021 and for the nine months ended September 30, 2022, our R&D expenses amounted to RMB29.9 million, RMB51.3 million and RMB32.0 million, respectively. We expect to continue to invest significant amounts of human and capital resources to develop our products and services and enhance our technologies that will allow us to advance our product candidates and services under development. We intend to continue to strengthen our technical capabilities in the research and development and manufacture of our products, which are capital and time intensive. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products and services to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products and services or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products and services are introduced, that those products and services will achieve or maintain market acceptance. Any failure to do so may render our efforts obsolete, which could significantly reduce demand for our products and services and harm our business and prospects.

**We may not be able to successfully complete product registration testing or clinical trials in a timely manner and at acceptable costs, or at all.**

All of our IVD product candidates are classified as medical devices in the catalog issued by the NMPA. To obtain product registrations for medical devices, we may need to conduct, at our own expense, adequate and well-controlled clinical trials to demonstrate the safety and efficacy of our product candidates. Such testing is or will be conducted either by ourselves or by third-party testing institutions recognized by the NMPA. The product registration testing schedule of third-party testing institutions is beyond our control, and we cannot assure you that our product candidates will pass these tests in a timely manner, or at all.

Before obtaining regulatory approval for the sale of our IVD test kit products, we must conduct clinical trials to demonstrate their safety and effectiveness. Clinical testing is expensive and can take multiple years to complete, and its outcome is inherently uncertain. There can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication. We may experience numerous unexpected events, including but not limited to:

- regulators or ethics committees may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

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- our inability to reach agreements on acceptable terms with prospective hospitals as trial centers, the terms of which can be subject to extensive negotiation and may vary significantly among different hospitals as trial centers;
- manufacturing issues, including problems with manufacturing, supply quality, or obtaining sufficient quantities of a product for use in a clinical trial;
- failure of our product 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;
- our third-party contractors 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 products for various reasons, including a finding of a lack of clinical response or other unexpected characteristics;
- regulators or ethics committees may require that we suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements; and
- the cost of clinical trials of our products may be greater than we anticipate.

If we are required to conduct additional clinical trials or other testing of our products beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our products or other testing, if the results of these trials or tests are not positive or are only modestly positive, we may (i) be delayed in obtaining regulatory approval for our products; (ii) not obtain regulatory approval at all; (iii) obtain approval for indications that are not as broad as intended; (iv) have the product removed from the market after obtaining regulatory approval; (v) be subject to restrictions on how the product is distributed or used; and/or (vi) be unable to obtain reimbursement for use of the product.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our products, the commercial prospects of that product may be harmed, and our ability to commence commercial sales of products will be delayed. Any of these occurrences may harm our business, financial condition and prospects significantly.



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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the trial until its conclusion. We may experience difficulties in subject enrollment in our clinical trials for a variety of reasons, including the size and nature of the subject population and the subject eligibility criteria defined in the protocol.

Our clinical trials will likely compete with other clinical trials which will reduce the number and types of subjects available to us, because some subjects who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by others. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of subjects who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of subjects in our clinical trials, delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

**Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could result in delay or failure to develop our products and services.**

We are exposed to the risk that our employees, collaborators, service providers, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in fraudulent or other illegal activities with respect to our business. See “– Risks Relating to Our Operations – We rely on our employees, third-party suppliers, consultants and commercial partners to not engage in misconduct or other improper activities, and their misconduct or other improper activities may have a material adverse effect on our business, financial condition and results of operations” for details.

We may not be able to identify and deter employees’ and third parties’ misconduct, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and defending ourselves or asserting our rights, those actions could severely delay our research and development programs, or result in failure to obtain regulatory approvals for our product candidates. Without the timely introduction of new and innovative products caused by the slowdown of our product candidate development and approval process, our products may become technologically obsolete or more susceptible to competition, thereby jeopardizing our ability to commence product sales and generate related revenues for that candidate. In addition, our employees and third parties who are responsible for the claims, disputes or legal proceedings against us due to their misconduct

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may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings. The regulatory authorities may also impose civil, criminal and administrative penalties, damages and monetary fines on us, which could materially and adversely affect our reputation and business operation.

### **Risks Relating to Extensive Government Regulations**

**We conduct our business in a heavily regulated industry. We may be adversely affected by the uncertainties and changes in PRC regulations with respect to genetic testing service industry, and any lack of the requisite approvals, permits, registrations, or filings in relation to our business may have a material adverse effect on our business, results of operations and prospects.**

Our testing laboratories, technology platforms, R&D operations and marketing network are primarily in China, which we believe confers clinical, commercial and regulatory advantages. We are required to obtain, maintain and renew the requisite approvals, permits, registrations, or filings in relation to our business in China. See “Regulatory Overview” for a discussion of regulatory requirements that are applicable to our current business activities in China.

Any changes or amendments of our regulatory environment may result in increased compliance costs on our business, or cause delays in or prevent the success of the development or commercialization of our services in China and reduce the current benefits currently available to us through developing genetic testing services in China. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China.

Due to the relatively short history of the clinical molecular testing service industry in the PRC, a comprehensive regulatory framework governing our industry has not been established. We cannot rule out the possibility that some common practices in the industry which we also adopt might be viewed as not being in full compliance with the existing PRC laws and regulations.

According to the Administrative Measures for Clinical Gene Amplification Test Laboratories of Medical Institutions (“Circular 194”), a clinical gene amplification testing laboratory shall not conduct the clinical testing items that have not been registered or filed with the relevant health administrative authority in accordance with the Catalogue of Clinical Laboratory Items for Medical Institutions (2013) (the “Testing Items Catalogue”). The scope of the Testing Items Catalogue is limited and has not been updated since 2013. Many of our genetics testing services are beyond the scope of the Testing Items Catalogue, so that we are not able to register or file such services with the applicable health administrative authority. Meanwhile, pursuant to the Notice on Issues Related to the Management of Clinical Laboratory Items (“Circular 167”), promulgated by the National Health and Family Planning Commission (“NHFPC”) on February 25, 2016, the services which are not included in the Testing Items

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Catalogue, but with clear clinical significance, relatively high specificity and sensitivity, and reasonable price, are required to be validated in time to meet clinical needs. We believe that medical institutions could conduct certain testing items which fall within Circular 167, but beyond the scope of Testing Items Catalogue after validation. However, it remains unclear as to how to validate such services based on Circular 167, nor does Circular 167 specify which services are “with clear clinical significance, relatively high specificity and sensitivity and reasonable price.” According to the Governmental Consultations of the BMHC, clinical laboratories, including us, can in practice carry out testing items that are beyond the scope of the Testing Item Catalogue in accordance with Circular 167, and no administrative penalties would be imposed on us with respect to such issues provided that we validated such testing items according to Circular 167. If the government promulgates clear guidelines for validation under Circular 167, we intend to take necessary actions to meet such requirements. Any failure to meet existing and future requirements may prevent us from providing genomic testing services, and result in adverse effect on our business operation.

On February 9, 2014, the General Office of NHFPC and the General Office of China Food and Drug Administration, predecessor of the National Medical Products Administration (“NMPA”), jointly issued the Notice of Strengthening the Administration of Products and Technologies Relating to Clinical Genomic Testing (“Notice No. 25”), to specifically govern products and technologies used in genetic testing service. In accordance with Notice No. 25, the pilot enterprises designated by the NHFPC may use genetic testing products on trial and no medical institutions may apply genetic testing technologies or products for clinical use before the issuance of relevant access standards and management regulations. Subsequently, in March 2014, the Medical Affairs and Hospital Administration Bureau of the NHFPC issued a notice to start the pilot scheme on clinical use of NGS. The companies that are not pilot enterprises, including us, may be prohibited from conducting genetic testing service and specifically from using NGS technology. According to the Governmental Consultations of the BMHC, (i) after the first batch of pilot enterprises were promulgated, no other enterprises entered into the pilot list and the Notice No. 25 were not implemented in practice, (ii) we have been registered and obtained a Practice License for Medical Institutions and have the approval to conduct clinical gene, as such, we are allowed to continue our NGS-based testing services without being required to obtain additional approval, registration or filings before the access standard or other implementation rules are promulgated, and (iii) no administrative penalties would be likely to be imposed on us by BMHC with respect to our historical provision of NGS-based testing services. If the government promulgates a clear requirement for NGS technology approval, we intend to take necessary actions to meet such requirements. Any failure to meet existing and future requirements may result in adverse effect on our continuous business operation of NGS technology utilization.

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**We may be adversely affected by the lack of regulatory supervision on our provision of LDT services in the PRC, and our provision of such services may be deemed as non-compliant conduct under laws, regulations or standards that may be introduced in the future and such non-compliance may have a material adverse effect on our operational and financial performance.**

The LDT industry is relatively new in China and a comprehensive regulatory framework governing the LDT industry has not been established. Our provision of LDT services conforms to industry practice and we maintain a quality control system to assure the stability and accuracy of our testing services. However, due to the lack of regulatory supervision, there are no clear rules and standards that govern certain aspects of our provision of such services, such as certain testing procedures and quality control measures. According to Article 53 of the 2021 Rules, drug agencies in conjunction with the appropriate healthcare departments are responsible for the adoption and implementation of specific administrative measures on LDT-related matters. Our PRC Legal Advisor and the PRC legal advisor to the Sole Sponsor consulted the Beijing NMPA and the BMHC regarding the regulatory practice of our LDT services. Although pursuant to the Governmental Consultations with the Beijing NMPA and the Governmental Consultations with the BMHC, (i) provision of LDT services by using self-developed testing reagents shall not be deemed as distribution and sale of these unregistered testing reagents by Beijing NMPA; (ii) we may continue our provision of LDT services in the PRC until the NMPA and NHC promulgate new and specific regulations in this regard; and (iii) the possibility of being penalized by Beijing NMPA and BMHC for use of our unregistered testing reagents in our provision of LDT service is remote, we cannot rule out the possibility that our provision of LDT services may be deemed to be non-compliant conduct under laws, regulations or standards that may be introduced in the future, which may have a material adverse effect on our operational and financial performance.

**We face risks associated with uncertainties relating to Regulation for the Administration of Human Genetic Resources.**

The collection, preservation, usage and outbound provision of human genetic resources in the PRC are governed by Regulation for the Administration of Human Genetic Resources (the “HGR Regulation”) (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council on May 28, 2019, and effective from July 1, 2019, except for activities relating to human genetic resources conducted for some specific purposes including clinical diagnosis and treatment. We believe that our genetic testing businesses are for the purpose of clinical diagnosis and treatment, so that such activities relating to human genetic resources in our genetic testing businesses would not be governed by the HGR Regulation. However, we cannot assure you that our genetic testing businesses will be continuously deemed as conducted for the purpose of clinical diagnosis by the relevant government authority. If such business is not deemed as for the purpose of clinical diagnosis and treatment, additional regulatory requirements including regulatory approvals may be required. Meanwhile, our use of human genetic resources including human tissues and specimen in our research and development activities, including those conducted in collaboration with external institution for scientific research may be governed by the HGR Regulation.

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Pursuant to the HGR Regulation, there are certain limitations for foreign entities as well as individuals and entities established or actually controlled by foreign entities (“Restricted Entities”) to engage in activities relating to human genetic resources. For example, the Restricted Entity is not allowed to collect or preserve human genetic resources of China, and it is also prohibited from using human genetic resources in China unless that such Restricted Entity has obtained an approval from relevant government authority or have filed with relevant government authority for international cooperation with a domestic entity. According to the the HGR Regulation, although an entity controlled, directly or indirectly, by foreign persons through shareholding ownership would be deemed as a Restricted Entity, it remains unclear as to whether our PRC Consolidated Entities, which are controlled by a wholly foreign owned enterprise through contractual arrangements, would be deemed as Restricted Entities. On March 21, 2022, the Ministry of Science and Technology of the People’s Republic of China published the Implementation Measures of Regulation for the Administration of Human Genetic Resources (Draft for Comments), which provides that Restricted Entities include those entities upon which overseas organizations and individuals are sufficient to exert significant influence through contracts or other arrangements in terms of major matters such as decision-making, operation and management of the organization. We cannot assure you that our PRC Consolidated Entities will not be deemed as Restricted Entities in the future, given the lack of clear statutory interpretation regarding HGR Regulation. If our PRC Consolidated Entities are deemed as the Restricted Entities by a government authority in China, we may be subject to order to cease such activities, imposed on administrative penalties, and required to cooperate with domestic entities and be required to obtain approvals or file with relevant government authority for such cooperation which could result in additional cost and our business, financial condition and results of operations will be adversely affected. As of the Latest Practicable Date, we have not been subject to any material fines or other penalties related to our collection, preservation and usage of human genetic resources. However, prior enforcement activity, or lack of enforcement activity, is not necessarily predictive of future actions. The regulatory framework for the administration of human genetic resources is also evolving and may remain uncertain for the foreseeable future.

**We may not be able to maintain or renew all the permits, licenses and certificates required for our production.**

Medical test laboratories engaging in clinical testes shall be regulated as medical institutions in China are required to obtain permits and licenses issued by various government authorities and complete filing with competent government authorities, including but not limited to the Medical institution practice license (醫療機構執業許可證) and filing of bio-safety laboratory. For details, see “Regulatory Overview – Regulation of Medical Devices – Production Permit and GMP for Medical Devices” and “Regulatory Overview – Regulation of Laboratories” in this Document. Such permits, licenses and certificates are subject to periodic reviews and renewals by the government authorities, and the standards of such reviews and renewals may change from time to time or become more stringent. There can be no assurance that the government authorities will approve our applications or renewal applications in the future. Any failure by us to obtain the necessary permits, licenses and certificates, or procure such renewals and otherwise maintain all the licenses, permits and

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certificates required for our business at any time could disrupt our business, which could have a material adverse effect on our business, financial condition and results of operation. If, as a result of any change in the interpretation or implementation of existing laws and regulations or the implementation of new laws and regulations, we are required to obtain additional licenses, permits or certificates for our production of products and product candidates, we cannot assure you that we will be successful in obtaining such licenses, permits or certificates in a timely manner, or at all.

**The regulatory approval processes are lengthy, expensive and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.**

We currently market and intend to continue to market a substantial portion of our products in China in the foreseeable future. We are required to obtain regulatory approvals before we can market our products in China. As the PRC government has been increasing the level of regulatory control over the medical device industry in recent years, the regulatory approval process tends to take a longer time to complete than before. Significant time, effort and expense are required to bring our products to market in compliance with the regulatory process, and we cannot assure you that any of our products will be approved for sale. Before obtaining regulatory approvals for the commercial sale of any products for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. We are also required to report any serious or potentially serious incidents involving our products to the NMPA or its local counterparts. We cannot be certain that any submissions will be accepted for filing 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. Even if regulatory approval or clearance of our products is granted, the approval or clearance could limit the uses for which our products may be labeled and promoted, which may in turn limit the market for our products. Any failure to obtain, or delay in obtaining, regulatory approvals or clearances or to renew registrations for our products could prevent us from successfully marketing our products, which could materially and adversely affect our business, financial condition and results of operation.

Furthermore, results of the regulatory approval process are unpredictable. We could fail to receive regulatory approval for product candidates for many reasons, including: (i) failure to begin or complete preclinical studies or clinical trials; (ii) failure to demonstrate that a product candidate is safe and effective; (iii) failure to deliver clinical trial results to meet the level of statistical significance required for approval; (iv) data integrity issues related to our clinical trials; (v) government authority’s disagreement with our interpretation of data from pre-clinical studies or clinical trials; (vi) 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; (vii) 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; (viii) clinical sites, investigators or other participants in our clinical trials deviating from a trial



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protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial; and/or (ix) rejection by the regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension, revocation or withdrawal of approvals. All these factors, among others, may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we are unable to obtain regulatory approval for our product candidates, 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.

In addition, changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to the regulatory authorities to reflect these changes, which may impact the costs, timing or successful completion of a clinical trial. 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.

**Our products, services and any future products and services will be subject to ongoing regulatory obligations and continued regulatory review and any failure to comply with such obligations may result in withdrawal of approvals for our products or subject us to penalties.**

Our testing services, products and any additional product candidates that are approved by the regulators are and will be subject to ongoing or additional regulatory requirements with respect to manufacturing, testing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China and/or other jurisdictions. Our testing and 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 products and any approvals that we receive for our product candidates are and may be subject to limitations on the uses for which our product may be marketed. The approvals we obtain may also be subject to other conditions which may require precautions, contraindications or warnings on the product labeling, or potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of our products or product candidates. Such limitations and conditions could adversely affect the commercial potential of our products.



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Following an approval for commercialization of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA and/or comparable regulatory authorities. 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 marketing approval if we fail to maintain compliance with these ongoing or additional regulatory requirements or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our products or 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, (i) restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or voluntary or mandatory product recalls; (ii) fines, untitled or warning letters, or holds on clinical trials; (iii) 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; (iv) product seizure or detention, or refusal to permit the import or export of our products and product candidates; (v) injunctions or the imposition of civil, administrative or criminal penalties; and/or (vi) confiscation of illegal income, fines and/or industry entrance prohibition on the legal representative, person in charge and/or other persons responsible.

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 may be subject, directly or indirectly, to applicable anti-kickback, false claims laws, doctors 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, doctors and others play a primary role in the recommendation and prescription of our testing services and any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China, including, without limitation, criminal law of the PRC, Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and the Administrative Measures for the Registration of Medical Devices (《醫療器械註冊管理辦法》). These laws may impact, among other things, our proposed sales, marketing and

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education programs. In addition, we may be subject to personal privacy regulation. 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 the PRC government. Furthermore, there are ambiguities as to what is required to comply with certain requirements, and if we fail to comply with an applicable law requirement, we could be subject to penalties.

If any of the doctors or other providers or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

### **Risks Relating to the Commercialization of our Products and Services**

**Our success depends on our ability to provide reliable, high-quality data and analysis and to rapidly evolve to meet our customers’ needs. If our products and services, or services and products similar to ours that are available in the market in general, do not meet the expectations of customers due to inaccurate results, misunderstanding or inappropriate reliance on the information we provided, our operating results, reputation and business could suffer.**

Our success depends on our ability to provide reliable, high-quality data and analysis and to rapidly evolve to meet our customers’ and end-users’ needs. However, there is no assurance that our products and services will perform as expected at all times. If our tests fail to accurately detect gene variants or other cancer indicators, or fail to, or incompletely or incorrectly, identify the significance of gene variants or other cancer indicators or make other errors, our operating results, reputation and business could be materially and adversely affected. We classify variants in accordance with guidelines that are subject to change and subject to our interpretation. There can be flaws in the databases, third-party tools, algorithms we use, and in the software that handle automated parts of our classification protocol. If we receive poor quality or degraded samples, our tests may be unable to accurately detect or we may fail to or incompletely or incorrectly identify the significance of gene variants or other cancer indicators, which could have a significant adverse impact on our business. In addition, end-users also rely on the interpretations by doctors or physicians of our testing reports and we are not able to ensure the interpretations will be correct and complete. Inaccurate results or misunderstanding of, or inappropriate reliance on, the information we provide to our customers could lead to termination of our services or claims against us. A product liability or professional liability claim could result in substantial damages and be costly and time consuming for us to defend, and our liability insurance, if any, may not cover at all, or have sufficient coverage on, such liability claims or damages.

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Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could also increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend sales of our tests or cause a suspension of our license to operate. The occurrence of any of these events could have an adverse effect on our business, reputation and results of operations.

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

The commercial success of our existing and future products and services depends upon their market acceptance. Our products may fail to receive broad acceptance from hospitals and other target customers as anticipated. If our existing or future products and services fail to gain sufficient market acceptance, the sales of our products will be adversely affected. In addition, hospitals and other target customers may prefer other products and services to ours. Failure to achieve an adequate level of acceptance or to improve market awareness of our products and services may have an adverse impact to our financial conditions, business and results from operations. The degree of market acceptance of our products and services, if approved for commercial sale, will depend on a number of factors, including:

- doctors, end-users and hospitals considering our products and services as safe and effective;
- the potential and perceived advantages of our products and services over alternatives;
- 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 NMPA for our IVD products;
- the willingness of end-users to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- our ability to maintain our laboratory certification, accreditation and regulatory approvals, and complete required inspections;
- the impact of negative publicity regarding our or our competitors’ tests and technologies resulting from defects or errors;
- changes of governmental policies or guidelines in respect of medical testing;

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- accelerated research and development progress of our competitors; and
- the effectiveness of our sales and marketing efforts.

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

We believe that maintaining and enhancing our brand identity and increasing market awareness of our company and offerings is critical to achieving widespread acceptance of our services and products, strengthening our relationships with our existing clients and our ability to attract new clients. 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.

**We rely on our in-house marketing force and distributors to promote our services and products. If we will fail to maintain or expand our sales network, our business and sales of the relevant products and services could be adversely affected.**

We rely on our in-house marketing force and distributors to promote our services and products. If we will fail to maintain or expand our sales network, our business and sales of the relevant products and services could be adversely affected.

We rely on both of our in-house marketing team and distributors to market and promote our services and products. We incurred selling and distribution costs of RMB107.8 million, RMB127.0 million and RMB102.6 million for the years ended December 31, 2020 and 2021 and the nine months ended September 30, 2022, respectively. The success of our marketing efforts depends on our ability to attract, motivate and retain qualified and professional employees in our marketing, promotion and sales teams who have, among other things, the sufficient expertise in the molecular testing areas and are able to communicate effectively with medical professionals. If we are unable to attract, motivate and retain a sufficient number of highly-trained sales personnel to support our marketing model, sales volumes or margin of our existing and future products may be adversely affected.

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In addition, we also rely on qualified distributors to ensure timely distribution of our products and services. As of December 31, 2020, 2021 and September 30, 2022, we had a total of 116, 111 and 88 distributors, respectively. With regards to our distributorship model, however, we have limited control to manage the activities of our distributors. We cannot assure that our distributors will fully comply with or satisfy the terms set forth in the distribution agreements, which may include, among other things, (i) failing to meet certain target sales amounts; (ii) selling our products outside their designated distribution territories or to hospitals without further authorization, possibly in violation of the exclusive distribution rights of our other distributors; (iii) failing to comply with regulatory requirements when marketing and selling our products; (iv) failing to provide proper training and other services to our end customers; or (v) violating applicable laws, including the anti-corruption laws of China or other countries, including improper payments to hospitals and physicians, in the marketing and sale of our products. Failure to adequately manage our network of distributors, or noncompliance by distributors with our distribution agreements could harm our corporate reputation and disrupt our sales. In such cases, our financial condition and results of operations could be materially adversely affected.

Our distributors may also terminate their relationships with us. We may not be able to identify or engage a sufficient number of distributors with an extensive sales network. If our distributors fail to expand or maintain their sales network, or otherwise encounter any difficulties in selling our products and services, our sales will decline and our business, results of operations and prospects may be materially and adversely affected.

**The sizes of the markets for our current and future products have not been established with precision, and may be smaller than we estimate, and we may not be able to fully capture the target populations of our products.**

Our estimates of the total addressable markets and target population for our current services and products and candidate services and products are based on a number of internal and third-party estimates, including, without limitation, the size of target populations and the assumed prices at which we can sell the relevant product or service 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 current or future products may be proved to be incorrect. If the target population who would benefit from our products, the price at which we can sell our products or the total addressable markets for our products is smaller than we have estimated, our sales growth may be impaired and there may be an adverse impact on our business.

In addition, we may not be able to fully capture the target populations of our products or services. For example, Gongmeian endometrial cancer screening test kit targets a high-risk endometrial cancer population in China of 195.1 million in 2023 as estimated by Frost & Sullivan. As of the Latest Practicable Date, we had not commercialized our Gongmeian endometrial cancer screening test kit, and the extent to which it can capture the 195.1 million

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target population in China depends on various factors, such as the successful commercialization of Gongmeian endometrial cancer screening test kit as a standalone medical device, inclusion of this test kit under national public medical insurance program and continuous policy support from the PRC government.

**Fluctuation, in particular downward change, in pricing and profit margin of our products and services may have a material adverse effect on our business and results of operations.**

We may face downward change in pricing of our products and services due to increasing market competition, launch of competitive product or evolving regulatory regime which may impose pricing control or other restrictive measures. In line with market practice, we also sell a portion of our services and products through distributors. For our direct sales to customers, we negotiate the price directly with them on a case-by-case basis. With respect to sales through distributors, our distributors negotiate and set retail prices directly with its customers. For details, see “Business – Sales and Marketing – Pricing”. Our direct customers may gain more bargaining power depending on the availability of alternative products, demands of end-users and the preference of physicians. If our direct customers lower order prices of our services or products and therefore reduce our profitability, it will have significant negative impact on our results of operations. For our distributors, if the resell price of our services or products is having downward pressure and therefore lowers the profitability of our distributors, our distributors may have less incentive to purchase and promote our products, and our distributors may gain more bargaining power due to other reasons. In these cases, we may need to lower the order price we set for our distributors, which in turn will have a material and adverse impact on our business, financial performance and results of operations.

The gross profit margin of our LDT services provided is highly correlated with test volumes we can provide to customers and utilization of our laboratories, as most of the costs for such services are fixed in nature, such as staff costs, rental costs, and depreciation and amortization. There is no assurance that future gross profit margin of the IVD test kits will be higher than the gross profit margin of their corresponding LDT services.

Additionally, more competing services and products may become available, which will offer alternatives for hospitals and end-users. If the PRC government issues price guidance for molecular testing products and services, it may negatively affect the price of our products and services. We may also face downward pricing pressure if our products and services are included in the medical insurance reimbursement list. Any downward change in pricing of our products may have a material adverse effect on our business and results of operations.

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**Our sales may be affected by the level of medical insurance reimbursement patients receive for using our services and products.**

Our ability to sell our services and products may be affected by the availability of governmental and private health insurance in China. China has a complex medical insurance system that is undergoing reform. The governmental insurance coverage or reimbursement level in China for new medical device is subject to significant uncertainty and varies from region to region, as local government approvals for such coverage must be obtained in each geographic region in China. In addition, the PRC government may change, reduce or eliminate the governmental insurance coverage currently available for treatments based on a number of factors, including price and efficacy.

Currently only our prenatal tests are not covered by the public medical insurance in China and we may plan to obtain public medical insurance coverage in China if the terms are favorable to us. We cannot assure you that our products once approved in the future will be covered by the PRC public medical insurance reimbursement list in the near future. As of the Latest Practicable Date, we had not yet initiated any formal discussion with the regulatory authorities in China for inclusion of our LDT or IVD product candidates on the public medical insurance reimbursement list. In addition, currently certain private insurance companies in China tend to reimburse patients for a higher percentage of the product cost if they use a medical device manufactured by a Chinese domestic company as opposed to an imported device. We cannot be certain that insurers will continue to adopt this favorable policy in the future.

On the other hand, PRC regulations and medical insurance plans may exert significant influence over our pricing policies, which could affect our profitability. We may need to lower the prices of our products in order to have them included in the medical insurance reimbursement list, and such price cut and reimbursement may not necessarily lead to increase in our sales and our results of operations may be adversely affected.

### **Risks Relating to Manufacture and Supply of our Products and Services**

**Failure to meet the quality standards required under applicable laws in our testing and manufacturing processes may adversely affect our operating results, business and reputation.**

Our testing and manufacturing processes are required to meet certain quality standards. We have a quality control and assurance system and adopted standardized operating procedures in order to prevent quality issues with respect to our testing and manufacturing processes. For further details of our quality control and assurance system, see “Business – Quality Control.” Despite our quality control and assurance system and procedures, we cannot eliminate the risk of failure. Quality defects may fail to be detected or remediated as a result of a number of factors, many of which are outside of our control, including:

- inherent inability of molecular testing to be 100% accurate;



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- poor quality or degraded samples;
- operational or manufacturing errors;
- technical or mechanical malfunctions in the operation or manufacture process;
- human error or malfeasance by our quality control personnel;
- tampering by third parties; and/or
- quality issues with the equipment, medical devices, reagents, third party tools, software or raw materials we purchase or use.

Our success depends on the market confidence that we and our products can provide accurate, reliable and high-quality tests that will provide end-users or physicians with valuable clinical or diagnostic information. However, there is no assurance that we or our products will perform as expected at all times. Our tests or our products may fail to accurately, completely or correctly identify the relevant diseases, or may contain other misleading testing results due to a variety of reasons (such as malfunction of our laboratory equipment, manufacturing defects and degraded samples provided by our delivery service providers), which may result in negative perception of our tests and significant damage to our reputation. In addition, failure to detect shortcomings in our services or products or to prevent such misleading results from being delivered to our end-users could result in injury or death, license revocation, regulatory fines, professional liabilities or other problems that could seriously harm our reputation and business, expose us to liability, and materially and adversely affect our revenue and profitability. For example, we could face medical liability claims if anyone alleges that our services or products identified inaccurate or incomplete information regarding a targeted testing item, or otherwise failed to perform as designed. An end-user could allege that our test results caused unnecessary treatment or other costs or resulted in him or her missing the best opportunity or timing for treatment. An end-user could also allege other mental or physical injury because we or our products provided inaccurate or misleading information concerning the diagnosis, prognosis or recurrence of, or available therapies for a disease. We may also be subject to medical liability for errors in, a misunderstanding of or inappropriate reliance upon the diagnostic information we or our products provided. Any medical liability or professional liability lawsuit could damage our reputation, or cause our business partners to terminate existing agreements with us and seek other business partners, or cause us to lose our current or potential end-users.

Insurance companies in China generally only offer a limited selection of medical liability and professional liability insurance policies and it is often difficult to secure suitable medical liability and professional liability insurance coverage at reasonable rates in China. In line with the market practice and in accordance with our business needs, we purchase group insurance policies for our end users who purchase and use certain of our prenatal and precision oncology services. The end users would be eligible for claim if a false negative result is produced. We currently do not maintain product liability insurance. Any medical liability or professional liability claim related to our services and products brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage. Any of these developments could adversely impact our results of operations and business prospects.

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**If our laboratory facilities fail to comply with applicable laboratory license requirements, or become contaminated, damaged, destroyed or inoperable, or we are required to vacate the facility, our ability to sell and provide our services, pursue our research and development efforts and operate our business may be jeopardized.**

Our existing laboratories in Beijing and our laboratories that may be built in the future are subject to extensive regulations in China. To operate these testing laboratories, we need to obtain approvals and accreditation from the NHC or their respective local offices. We currently have the primary approvals and accreditations from the NHC or their respective local offices that are required for our existing laboratory. See “Business – Licenses, Approvals and Permits” for details. However, if we increase the number of our laboratories to meet increasing demand for our molecular testing services, we will be required to obtain NHC approvals and accreditation for such additional laboratories, and there is no guarantee that we would obtain such approvals and accreditation in a timely manner, or at all, as the NHC approval and accreditation process is costly, lengthy and uncertain. If we fail to maintain or renew any major license, permit, certificate, approval or accreditations for all or any of our laboratories, or if the testing professionals at our laboratories become unlicensed at any time during their practices, or if we or our laboratories are found to be non-compliant with any applicable PRC laws or regulations, we may face penalties, suspension of operations or even revocation of operating licenses, depending on the nature of the findings, any of which could materially and adversely affect our business, financial condition and results of operations.

Although our Beijing laboratory has implemented back-up measures, the data and samples stored in our laboratory facilities are still subject to various risks beyond our control. Our Beijing laboratory could also 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 for us to sell or perform our services for some period of time. The inability to sell or to perform our services, or the backlog of samples that could develop if our facility is inoperable for even a short period of time, may 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 facilities and the equipment used to perform our services and 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 using biological samples as the basis for the development of our services. In some cases, these samples are difficult to obtain. If the parts of our laboratory 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 jeopardized.

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**The manufacturing and testing processes of our products are highly complex and subject to strict quality controls. If we or any of our suppliers or logistics partners encounters manufacturing, logistics, or quality problems, including as a result of natural disasters, our business could suffer.**

The manufacturing and testing processes 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 or testing failure. Problems can arise during the manufacturing and testing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, raw material problems, software problems, sample contamination, or human error. Furthermore, if contaminants are discovered in the supply of our products or product candidates or in the manufacturing and testing facilities, such manufacturing and testing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Stability failures and other issues relating to the manufacturing and testing of our products or product candidates 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. We may also face unanticipated surges in demands for our products which could strain our production or testing capacity once our IVD test kits are commercialized. If these problems arise or if we otherwise fail to meet our internal quality standards or those of 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 our business could otherwise be adversely affected.

In addition, our manufacturing, testing 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.

**We may experience supply interruptions or shortages that could harm our ability to manufacture products.**

We purchase certain of the materials and components used in the manufacture of our products from external suppliers, and we purchase certain supplies from fixed sources or single sources for reasons of quality assurance, cost effectiveness, availability, or constraints resulting from regulatory requirements.

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. 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. In addition, due to the rigorous regulations and requirements of 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

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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 amount 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. A reduction in, or lack of availability of, raw materials or interruptions in the supply chain may also impact our profitability to the extent that we are required to pay higher prices for, or are unable to secure adequate supplies of, the necessary raw materials.

Moreover, as our businesses grow, our existing suppliers may not be able to meet our increasing demand, and we may need to find additional suppliers. There is no assurance that we will be able to secure suppliers who provide products at reasonable and acceptable prices, and the failure to do so will adversely affect our business performance and results of operations.

**We depend on third-party suppliers to supply raw materials to be used in performing our testing services and manufacture our products and products candidates. If these suppliers can no longer provide satisfactory products to us on commercially reasonable terms, our business and results of operations could be adversely affected.**

Our raw materials primarily include reagents and consumables. We mainly rely on third-party suppliers to supply such raw materials with consistently high quality and in sufficient volumes. Selecting, managing and supervising these third-party suppliers requires significant resources and expertise. Any disruption in production or inability of our suppliers to produce adequate quantities to meet our needs could impair our ability to manufacture products as scheduled and to operate our business on a day-to-day basis. Moreover, we expect our demand for such raw materials to increase as we expand our business scale and commercialize our products, and we cannot guarantee that current suppliers have the capacity to meet our 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 such materials 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 raw materials supplied to us. If they are unable to do so and the quality of our products suffers as a result, 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 issue, which may have a material and adverse effect on our business, financial condition and results of operations.

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Although we take precautions to detect and prevent misconduct by our suppliers, it is difficult to identify and deter such misconduct, and we may not be able to effectively control unknown or unmanaged risks or losses, or protect us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Our suppliers or service providers who are responsible for the claims, disputes or legal proceedings against us due to defective supplies or services sold to us may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

**We rely on a limited number of suppliers for our products and may not be able to find replacements or immediately transition to alternative suppliers.**

We source raw materials used in our production and procure manufacturing machinery and equipment from a limited number of suppliers. For the years ended December 31, 2020 and 2021, and the nine months ended September 30, 2022, purchases from our five largest suppliers in aggregate accounted for 29.3%, 31.6% and 25.8% of our total purchases, respectively, and purchases from our largest supplier accounted for 9.0%, 9.1% and 8.1% of our total purchases for the same periods, respectively. Our production may be interrupted if we encounter delays or difficulties in securing these supplies, or if we become unable to procure supplies from any of these suppliers due to their lack of required licenses, permits or certifications. If we cannot timely obtain an acceptable substitute, our business, financial condition, results of operations and reputation could be adversely affected.

We believe that a number of replacement suppliers are capable of supplying all of the raw materials necessary for our production and machinery and equipment. However, transitioning to a new supplier may be time consuming and expensive, and may result in interruptions in our production. In addition, there can be no assurance that replacement suppliers will meet our quality control and performance requirements. If we encounter delays or difficulties in procuring equipment and supplies we require, our business, financial condition, results of operations and reputation could be adversely affected.

**We face risks in the transportation of test samples, which may result in additional costs for re-sampling to us and reputational damage due to inaccurate test results.**

For some of our direct sales orders of our testing services, we are primarily responsible for testing sample quality during transportation of testing samples from our customers to our laboratory. We contract with a logistics service provider to transport these testing samples. After sample collection is completed, the testing sample is handed to the logistics service provider to be delivered to our testing facility. For other testing service orders, our distributors or direct sales customers are responsible for the delivery of the test samples. The quality of our clinical molecular testing services largely depends on the delivery of well-preserved samples quickly and reliably to our laboratory. Accurate testing results require the samples to be preserved at a high standard, which could be difficult as testing samples are sensitive to various external conditions, such as heat or light. During the transportation process, our third-party logistics service provider, distributor or customers may cause the testing samples to be exposed

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to inappropriate temperatures, contamination or other improper storage conditions and lose activity or effectiveness. In addition, disruptions in delivery, whether due to factors beyond our control such as distance, natural disasters, terrorist threats, political instability, governmental policies, failures by physicians to properly label or package the samples, labor disruptions, bad weather or other factors could adversely affect our receipt of samples or specimen integrity, and could impact our ability to process samples in a timely manner and to provide our services effectively to our customers. In such event, the testing results may become inaccurate and we may have to conduct re-sampling, which may incur additional costs and resources. Accordingly, our reputation, business and financial performance may be materially and adversely affected if inaccurate testing reports are issued based on any undiscovered unqualified testing samples. As a result, our business, results of operations and financial condition could be adversely affected, and our reputation and ability to provide our molecular testing services on a timely basis could be harmed.

In addition, disputes with or a termination of our contractual relationship with our third-party logistics service provider could result in delayed delivery of the testing samples or increased costs. There can be no assurance that we will continue or extend the relationship with our third-party logistics service provider on terms acceptable to us, or that we will be able to establish relationships with new third-party logistics service providers or enhance the relationship with our existing third-party logistics service provider to ensure accurate, timely and cost-efficient logistics services. Failure to do so may inhibit our ability to provide our testing services, on a timely basis or at prices acceptable to our end-users. As we do not have any direct control over any third-party logistics service provider, we cannot guarantee their quality of services. If there is any delay in delivery or any other issue, our service offering may be affected.

**If we are unable to support the demand for our services or products in the future, including ensuring that we have adequate capacity to meet increased demand, or maintain the operation of our laboratory facilities, our business could suffer.**

As the market demand for our services or, once approved, our products grows in the future, we will need additional laboratory scientists, and technicians and other scientific and technical personnel to process higher volumes of our services and product manufacturing orders. The expansion of our operations or hiring of additional personnel may lead to significant costs and divert our management attentions and development resources. We will also need to purchase additional equipment, some of which can take several months or more to procure, set up, and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory or manufacturing facilities to accommodate such required expansion.



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As we commercialize additional services and our products, we will need to incorporate new equipment, implement new technology systems and laboratory and manufacturing processes, and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher service and production costs, declining service and product quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our services, and could damage our reputation and the prospects for our business.

**We mainly rely on our manufacturing facilities in Beijing and Hangzhou for the manufacturing of our products and product candidates; any disruptions to the operation of our manufacturing facilities could materially adversely affect our business, financial condition and results of operations.**

We manufacture, assemble and test our products at our manufacturing facilities which are located in our leased property in Beijing and Hangzhou, China. For details, see “Business – Testing and Manufacturing Facilities” in this Document. The operation of our manufacturing facilities may be substantially interrupted due to a number of factors, many of which are outside of our control, including but not limited to fires, floods, earthquakes, power outages, fuel shortages, epidemic, mechanical breakdowns, termination of lease by lessor, loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities, and regulatory changes.

If the operation of our manufacturing facilities are substantially disrupted, we may not be able to replace the equipment or inventories at such facilities, or use different facilities or a third-party contractor to continue production in a timely and cost-effective manner or at all. Although we maintain property insurance for our manufacturing facilities and material equipment, the amount of our insurance coverage may not be sufficient to cover our losses in the event of a significant disruption to our production facility. Problems may also arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, the expansion of our existing manufacturing site, implementing changes in manufacturing site and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. As a result of disruption to our manufacturing facilities or any problems in manufacturing our products, we may fail to fulfill contract obligations or meet market demand for our products, and our business, revenue and profitability could be materially adversely affected.



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**Delays in completing and receiving regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.**

Our manufacturing facilities will be subject to ongoing, periodic inspection by the NMPA or other comparable regulatory agencies to ensure compliance with GMP. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of products or product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

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 facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any 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 products or product candidates in a timely manner could materially harm our business, financial condition and operating results.

Currently, we maintain insurance coverage against damage to our property and equipment in amounts we believe are reasonable. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our products and product candidates if there were a catastrophic event or failure of our manufacturing facilities or processes.

### **Risks Relating to Our Intellectual Properties**

**We may be subject to intellectual property infringement or misappropriation claims by third parties, which may force us to incur substantial legal expenses and, if determined adversely against us, could disrupt our business.**

The validity, enforceability and scope of intellectual property rights protection in China are uncertain and still evolving. We cannot be certain that our tests, technologies and services do not or will not infringe patents, software copyrights, trademarks or other intellectual property rights held by third parties. From time to time, we may be subject to legal proceedings and claims alleging infringement of patents, trademarks or copyrights, or misappropriation of

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creative ideas or formats, or other infringement of proprietary intellectual property rights. Any such proceedings and claims could result in significant costs to us and divert the time and attention of our management and technical personnel from the operation of our business. These types of claims could also potentially adversely impact our reputation and our ability to conduct business and raise capital, even if we are ultimately absolved of all liability. Moreover, third parties making claims against us may be able to obtain injunctive relief against us, which could block our ability to offer one or more devices or tests and could result in a substantial award of damages against us. In addition, since we sometimes indemnify our customers, we may have additional liability in connection with any infringement or alleged infringement of third-party intellectual property. Intellectual property litigation can be very expensive, and we may not have the financial means to defend ourselves or our customers.

Because patent applications can take many years to issue, there may be pending applications, some of which are unknown to us, that may result in issued patents upon which our services, tests or proprietary technologies may infringe. Moreover, we may fail to identify issued patents of relevance or incorrectly conclude that an issued patent is invalid or not infringed by our technology or any of our devices or tests. There is a substantial amount of litigation involving patents and other intellectual property rights in our industry. If a third-party claims that we infringe upon a third-party’s intellectual property rights, we may have to, among others:

- seek to obtain licenses that may not be available on commercially reasonable terms, if at all;
- abandon any services alleged or held to infringe, or redesign our services or processes to avoid potential assertion of infringement, resulting in a delayed process of developing or commercializing our product candidates;
- pay substantial damages if a court decides that our services, products or technology infringes upon or violates the third party’s rights;
- pay substantial royalties or fees or grant cross-licenses to our technology; and
- defend litigation or administrative proceedings that may be costly whether we win or lose, which could result in a substantial diversion of our financial and management resources.

**If we are unable to maintain the confidentiality of our trade secrets or know-hows, our reputation, business and competitive position may be harmed.**

Our commercial success will depend, in large part, on our ability to obtain, maintain and defend know-hows and other intellectual property protection with respect to our services. We seek to protect our trade secrets or know-hows, in part, by entering into agreements, including confidentiality agreements and non-disclosure agreements or containing such provisions, with parties that have access to them, such as our employees, consultants, corporate partners and,

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other third-party service providers. Nevertheless, there can be no guarantee that an employee or a third party will not make an unauthorized disclosure of such proprietary confidential information. This might happen intentionally or inadvertently. It is possible that a competitor will make use of such information, and that our competitive position will be compromised, despite any legal action we might take against persons making such unauthorized disclosure. In addition, to the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related work completed or the resulting know-how and inventions. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets or know-hows is expensive and time-consuming, and the outcome is unpredictable. If any of the trade secrets or know-hows 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.

We sometimes collaborate with third parties, such as research institutions to conduct research relevant to our business. The ability of these third parties to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our confidential information, then our ability to obtain patent protection or to protect our trade secrets or know-hows may be jeopardized. Failure to protect our intellectual property may severely disrupt our business operations, reduce or eliminate any competitive advantage we have developed and materially harm our business, financial condition results of operations and prospects and any remediation may significantly divert management’s attention and resources from other activities.

### **Patent terms may not be sufficient to effectively protect our services and 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 services and products 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.

As of the Latest Practicable Date, we had a total of 54 patents and 69 patent applications. 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 and results of operation may be adversely affected.

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

Periodic maintenance fees 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 procedural, 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.

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

We currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. 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, 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.

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### **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. The following examples are illustrative:

- others may be able to independently develop similar or alternative technologies or designs that are similar to our services and products but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patent applications not issuing or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could result in the patent applications not issuing or being invalidated after issuing;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive services and products for commercialization in our major markets;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our services and products candidates for one or more cancer types.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

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### RISKS RELATING TO OUR OPERATIONS

**Failure to maintain and predict inventory levels in line with the level of demand for our services and products could cause us to lose sales or face excess inventory risks and holding costs, either of which could adversely affect our business, financial condition and results of operations.**

To operate our business successfully and meet our customers’ and end-users’ demands and expectations, we must maintain a certain level of inventory for our services and products to ensure molecular testing can be carried out promptly. Furthermore, we are required to maintain an appropriate level of inventory of our raw materials for our services and products, such as reagents and consumables. We maintain our inventory levels based on our internal forecasts, which are inherently uncertain. If our forecast demand is lower than actual demand, we may not be able to maintain an adequate inventory level of our medical devices and reagents, and may lose sales and market share to our competitors. On the other hand, we may be exposed to increased inventory risks due to accumulated excess inventory of medical devices and reagents. Excess inventory levels may increase our inventory holding costs, risk of inventory obsolescence or write-offs.

In addition, we actively monitor our inventory level. However, there is no guarantee that the inventory information we collect is complete and accurate or that such information would allow us to effectively manage our inventory level. If we fail to maintain and predict inventory levels in line with the level of demand for our services and products, our business, financial condition and results of operations will be adversely affected.

**Failure to attract and retain our senior management, key personnel in research and development team, sales and marketing team, and other valuable employees could adversely affect our business.**

Our future success is significantly dependent upon the continued service of our senior executives. If we lose their services, we may not be able to locate suitable or qualified replacements, and we may incur additional expenses to recruit new senior executives, which could severely disrupt our business and growth. In addition, if these personnel join our competitors or form a competing business, our business and prospects could be adversely affected. Furthermore, if the relationship between any of these personnel and any of our substantial shareholders deteriorates, our operations could be disrupted, which may materially and adversely affect our business and prospects.

Our laboratory operations and research and development activities depend on our ability to attract and retain highly skilled scientists and researchers. We are also in strong need of sales and marketing personnel with the relevant technology background and industry expertise in order to effectively conduct our sales and marketing activities and increase network of health checkup centers and hospitals. We face intense competition for qualified individuals from healthcare companies, universities, governmental entities and other research institutions. We may be unable to attract and retain suitably qualified individuals, and our failure to do so could adversely affect our business.

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### **Our past performance may not be indicative of our future results.**

Our historical financial and operating results are not necessarily indicative of future performance. In addition, our financial and operating results may not meet the expectations of public market analysts or investors, which could cause the future price of our shares to decline. The effects of changing regulatory, economic, public health, environmental, competitive conditions and future expansion of our testing facility, and many other factors cannot be fully predicted and may have a material adverse effect on our business, financial condition, results of operations and prospects. For example, for the nine months ended September 30, 2022, our revenue from pathogenic detection accounted for more than half of our total revenue. With the relaxation of the COVID-19 prevention measures by the PRC government and that COVID-19 testing accounted for the vast majority of our pathogenic detection business, we expect the percentage of revenue contribution from pathogenic detection to decrease. For more details, please see “Our business operations and financial performance have been materially affected by the COVID-19 pandemic, may in the future continue to be affected by the COVID-19 pandemic, and may be affected by other force majeure events, natural disasters, pandemic, outbreak of epidemics, and other unforeseeable catastrophes.” As we continue our business integration and expansion, we cannot assure you that we will achieve the expected results or maintain the same levels of revenue growth and profitability as we have achieved historically. We believe that period-to-period comparisons of our operating results during the Track Record Period may not be indicative of our future performance and you should not rely on them to predict the future performance of our operating results.

### **Intense competition we face with existing and potential competitors could adversely affect our results of operations.**

The development and commercialization of clinical molecular testing services is highly competitive. We face competition from other companies engaging in the clinical molecular testing business. We anticipate that we will continue to face increased competition as existing companies develop new or improved services and as new companies enter the market with new technologies. Extensive competition may render one or more of our technologies obsolete or uneconomical. Some of our competitors have greater financial and personnel resources, broader product lines, more focused product lines, a more established customer base, or more experience in research and development than we do. In addition, as a result of mergers and acquisitions in the industry, even more resources are being concentrated in our competitors and our upstream and downstream business partners. Competition may increase further due to the progress and improvements made in the commercial applicability of technologies and the increased capital investment in our industries. Our competitors may operate and develop services and products in a more cost effective manner than ours, or obtain patent protection, regulatory approval, product commercialization, and market penetration more rapidly than we do.



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**Significant fluctuations in the price of medical devices, reagents and medical consumables may have an adverse effect on our margins and results of operations.**

We procure medical devices, reagents, medical consumables and other goods and services necessary for our operations. The prices may increase in the future or there may be a reduction in the availability of raw materials due to various factors beyond our control. The prices of the raw materials may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, natural disasters and economic conditions in China and around the world. In the event of significant price increases for such supplies, we may have to pass the increased costs to our customers. However, we cannot assure you that we will be able to raise the prices of our services sufficiently to cover such increased costs. As a result, any significant price increase for or reduction in the availability of our raw materials may have an adverse effect on our profitability and results of operations.

**If we, or our shareholders, Directors, senior management, employees, customers, suppliers or partners, become subject to litigation, legal or contractual disputes, governmental investigations, administrative proceedings or negative publicity, our reputation may be harmed and we may incur substantial cost.**

From time to time, we, or our shareholders, Directors, senior management, employees, customers, suppliers or partners, may be involved in claims, disputes, government investigations, court orders, or other administrative or legal proceedings, or they may issue profit warnings or negative earnings releases. These may concern issues relating to, among others, shareholders litigations, insolvency or bankruptcy litigations, consumer liability, environmental matters, breach of contract, employment or labor disputes, infringement of intellectual property rights or financial performance. Any resulting claims, disputes or legal proceedings initiated by or brought against us, or any resulting negative media coverage on us, our Directors, senior management, employees, customers, suppliers or partners, with or without merit, may result in significant reputational harm to us, or result in substantial costs or diversion of our resources. Furthermore, claims, disputes, government investigations, court orders, or administrative or legal proceedings against us may be related to defective supplies sold to us by our suppliers, who may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings. During the Track Record Period and up to the Latest Practicable Date, to our knowledge, we have not been, and none of our shareholders, Directors, senior management, employees, customers, suppliers or partners were, involved in any claims, disputes, government investigations, court orders or other administrative or legal proceedings that could have a material adverse effect on our business.

In addition, any negative publicity concerning us, our affiliates or subsidiaries, shareholders, Directors, senior management, employees, customers, suppliers or partners, even if untrue, could adversely affect our reputation and business prospects, which could damage our brand image or have a material adverse effect on our business, results of operations and

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financial condition. Damage to our reputation could be difficult, expensive and time-consuming to restore and could make potential or existing customers reluctant to use our services or products, resulting in a loss of business, and could adversely affect our recruitment and retention efforts. Damage to our reputation could also reduce the value and effectiveness of our brand name and could reduce investor confidence in us, adversely affecting the price of our Shares.

**Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.**

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected personal health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our Company and our vendors. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Despite the implementation of security measures including cybersecurity classified protection policies, our internal computer systems are vulnerable to damage from computer viruses and unauthorized access. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices.

We depend on our information technology for significant portion of our operations. We have also installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling financial reporting and controls, customer relationship management, laboratory information management system, and other infrastructure operations.

Our information and other technology systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious or inadvertent human acts and natural disasters. Our servers are potentially vulnerable to physical or electronic break-ins, employee errors, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party

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service providers could prevent us from conducting tests, preparing and providing reports to our customers, billing customers, collecting revenue, handling inquiries from our customers, conducting research and development activities, and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

To ensure compliance with relevant laws and regulations, such as the Administrative Measures for Hierarchical Protection of Information Security (《信息安全等級保護管理辦法》), we adopted various internal protocols and management procedures to regulate confidentiality and privacy issues related to testing samples and data. Our data protection system has obtained the certification of the Grade III of Hierarchical Protection of Information Security approved by the Ministry of Public Security of the People’s Republic of China in 2021. In addition, we also conduct regular training to raise data security awareness among our employees. For more information, see “Business – Data and Privacy Protection” in this Document.

Although we develop and maintain systems and controls designed to prevent these events from occurring, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

**If we are unable to manage our growth, our business and prospects may be materially and adversely affected.**

Our business has grown substantially in recent years, and we expect to continue growing our business in the future. In addition, as we continue to diversify our service and product offerings and enhance our presence, we will need to continuously enhance and upgrade our services and technology, optimize our branding, sales and marketing efforts, and expand, train and manage our employees. All these efforts will require significant managerial, financial and human resources. We cannot assure you that we will be able to effectively manage our growth, that our current technology, infrastructure and operational capabilities will be adequate to support our expanding operations, or that our strategies and new business initiatives will be executed successfully. If we are not able to manage our growth, our expansion may not be successful and our business, financial condition and results of operations may be materially and adversely affected.

**Any litigation, legal and contractual disputes, claims, investigations, or legal and administrative proceedings against us could be costly and time-consuming to defend or settle.**

We may from time to time be involved in litigation, legal and contractual disputes, claims, investigations, or legal and administrative proceedings arising out of the ordinary course of business or pursuant to governmental or regulatory enforcement activity.

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While we do not believe that any existing legal proceeding against us will have a material adverse effect on our business, financial condition and results of operations, any existing or future legal proceeding might result in substantial costs and divert management’s attention and resources. Furthermore, any litigation, legal disputes, claims or administrative proceedings that are initially not material may escalate and become material to us due to a variety of factors, such as changes in the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. If any verdict or award is rendered against us or if we settle with any third parties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business projects. In addition, negative publicity arising from litigation, legal or contractual disputes, investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. Laws, regulations and legal actions could also have significant regulatory consequences and result in regulatory enforcement actions. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

Our insurance might not cover claims brought against us, might not provide sufficient payments to cover all of the costs to resolve one or more such claims and might not continue to be available on terms acceptable to us. In particular, any claim could result in unanticipated liability to us if such claim is outside the scope of any indemnification arrangement we may have with our customers, our customers do not abide by the indemnification arrangement as required or the liability exceeds the amount of any applicable indemnification limits or available insurance coverage. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our business, financial condition and results of operations.

### **Product and professional liability claims or lawsuits could cause us to incur substantial liabilities.**

We face an inherent risk of product and professional liability as a result of the commercialization of our products, the provision of our services, the clinical testing and any future commercialization of our product candidates in China. For example, we may be sued if our products or product candidates cause or are perceived to cause injury, fail to deliver required testing results or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product and professional liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the medical device product, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product and professional liability claims, we may incur substantial liabilities or be required to limit commercialization of our products and product candidates and provision of our services. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products and services;
- injury to our reputation;

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- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or subjects, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and/or
- a decline in our Share price.

If we are unable to obtain sufficient product and professional liability insurance at an acceptable cost, potential product and professional liability claims could prevent or inhibit the commercialization of our products and product candidates. Our insurance policies may also have various exclusions, and we may be subject to a product and professional liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

**We rely on our employees, third-party suppliers, consultants and commercial partners to not engage in misconduct or other improper activities, and their misconduct or other improper activities may have a material adverse effect on our business, financial condition and results of operations.**

We are exposed to the risk of fraud or other misconduct by our employees, third-party suppliers, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of NMPA and other regulators that have jurisdictions over us, comply with healthcare fraud and abuse laws and regulations in China and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information, including sensitive information such as personal data and other

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## RISK FACTORS

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privacy, obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We provide training to our employees on a regular basis, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, which could have a significant impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and divert the attention of management in defending ourselves against any of these claims or investigations.

In addition, we may have disputes with our employees, third-party suppliers, consultants and commercial partners due to such misconduct or for other reasons, such as quality of products or services provided by these third-parties, which may result in suspension or termination of supply of products or services to us, suspension or termination of certain of our production or research and development activities, litigation or arbitrations, contractual damages and other payments by us, other liabilities of ours, write off of amounts paid or receivables, and other negative impacts on our business operations, and such results may have a material adverse effect on our business, financial condition and results of operations.

**The lease and sublease agreements of our leased and subleased properties have not been registered with the relevant PRC government authorities as required by PRC law, which may expose us to potential fines. Challenges from third parties or government authorities relating to title defects of our leased properties in China may force us to relocate and thus incur additional cost.**

As of the Latest Practicable Date, we had 8 leases in the PRC for our business operations, and 2 of our leases was registered and filed with the relevant PRC government authorities. The agreements with respect to the remaining 6 leases had not been registered and filed with the relevant PRC government authorities, primarily due to the difficulty of obtaining relevant landlords’ cooperation to register such lease and sublease agreements. As advised by our PRC Legal Advisor, failure to register such lease and sublease agreements with the relevant PRC government authorities does not affect the validity of the relevant lease and sublease agreements but the relevant PRC government authorities may order us or the lessors to, within a prescribed time limit, register the lease agreements. Failure to do so with the time limit may subject us to a fine ranging from RMB1,000 to RMB10,000 for each non-registered lease. During the Track Record Period and as of the Latest Practicable Date, we had not received any such request or suffered any such fine from the relevant PRC government authorities. We



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## RISK FACTORS

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intend to continue to communicate with landlords and lessors of our leased and subleased properties in order to obtain their assistance in the filing and registration of our lease and sublease agreements. As of the Latest Practicable Date, one of our leased properties may have title defect as the lessor does not provide the title certificate. We cannot assure you that the landlords of this property have the right to lease the relevant property to us or has complied with relevant laws and regulations in relation to the usage, plan as well as the construction of the property. We may not be able to continue to use such property if the ownership of the property we have leased and/or the validity of such lease is challenged by third parties or government authorities. In such a scenario we will have to relocate to other premise, which could result in additional costs. As of the Latest Practicable Date, we were not aware of any challenge made by any third party or government authority on the title of this leased property that might affect our current occupation. We cannot assure you that in the future, we may not encounter such challenges. In addition, in the event of relocation, we may incur additional costs, which could adversely affect our daily operation and cause an impact on our financial condition.

**If we or parties on whom we rely fail to maintain the necessary licenses for the development, production, sales and distribution of our products and services, our ability to conduct our business could be materially impaired.**

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products and services. Third parties, such as research institutions and suppliers on whom we may rely to develop, produce, promote, our products and services, may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the third parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates.

**We may be subject to penalties under relevant PRC laws and regulations due to failure to be in full compliance with social insurance and housing provident fund regulation.**

Pursuant to 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,

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unemployment insurance and housing provident fund. During the Track Record Period, we engaged a third-party human resources agency to pay social insurance premium and housing provident funds for certain of our employees. However, pursuant to PRC laws and regulations, we are required to pay social insurance premium and housing provident funds for our employees under our own accounts instead of making payments under third-party accounts. The contributions to social insurance premium and housing provident funds made through third-party accounts may not be viewed as contributions made by us, and as a result, we may be required by government authorities to pay the outstanding amount, and could be subject to late payment penalties or enforcement application made to the court. Pursuant to the agreements entered into between us and such third-party human resources agency, the third-party human resources agency has the obligation to pay social insurance premium and housing provident funds for our relevant employees. These third-party human resources agency has confirmed in writing that it paid such contributions in compliance with applicable laws and regulations. As of the Latest Practicable Date, we did not receive any administrative penalty or labor arbitration application from employees for its arrangement with third-party human resources agency. In addition, if such human resources agency fails to pay the social insurance premium or housing provident funds for and on behalf of our employees as required by applicable PRC laws and regulations, we may also be subject to additional contribution, late payment fee and/or penalties imposed by the relevant PRC authorities for failing to discharge our obligations in relation to payment of social insurance and housing provident funds as an employer or be ordered to rectify. This in turn may adversely affect our financial condition and results of operations.

As the interpretation and implementation of labor laws and regulations are still evolving, we cannot assure you that our employment practice policy is and will at all times be deemed to be in full compliance with labor-related laws and regulations in China, which may subject us to labor disputes or government investigations. If we are deemed to have violated relevant labor laws and regulations, we could be required to provide additional compensation to our employees and our business, financial condition and results of operations could be materially and adversely affected. For more details, please see “Business – Employees.”

**We are subject to environmental protection and health and safety laws and regulations and may be exposed to potential costs for compliance and liabilities, including consequences of accidental contamination, biological or chemical hazards, or personal injury.**

Our operations involve the use of hazardous and flammable materials, including chemicals, in the development and delivery of our products and services. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, project constructions, work safety and prevention of occupational diseases, and the handling, use, storage, treatment and disposal of hazardous materials and wastes. We cannot assure you that we will be able to obtain all environmental related approval or licenses (including without limitation, sewage discharge permit) on a timely basis, or at all. Although we have engaged qualified third parties to collect and process waste water to lower the risks may cause to the environment, we cannot eliminate the risks of accidental contamination, biological hazards or personal injury brought by our operations. In the event of

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any accident, we could be held liable for damages and clean-up costs that, to the extent not covered by existing insurance or indemnification, could be burdensome to our business. We could also incur significant costs associated with civil or criminal fines and penalties. Moreover, we may also be forced to close or suspend operations at our affected facility temporarily or permanently. As a result, any accidental contamination or personal injury could have adverse impact on our reputation, business, financial condition and results of operations.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

**Our insurance coverage may not completely cover the risks related to our business and operations.**

Our operations are subject to hazards and risks associated with our research and manufacturing operations, which may cause significant harm to persons or damage to properties. We maintain different types of insurance policies, including social welfare insurance for our employees in accordance with relevant PRC laws and regulations, and we also maintain commercial insurance for our employees. We purchase group insurance policies for our end users who purchase and use certain of our prenatal and precision oncology products and services. The end users would be eligible for claim if a false negative result is produced. For details, see “Business – Insurance”. However, there is no assurance that our insurance policies will be adequate to cover all losses incurred. Losses incurred and associated liabilities may have a material adverse effect on our results of operation if such losses or liabilities are not covered by our insurance policies.

**If we fail to maintain or implement an effective internal control system, our financial reporting accuracy and our stock price may be adversely affected.**

If we fail to maintain or implement an effective internal control system over financial reporting, we could suffer material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could, in turn, limit our access to capital markets, harm our results of operations and lead to a decline in the [REDACTED] price of our Shares. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential penalties, regulatory investigations and civil or criminal sanctions.

**Ethical, legal and social concerns related to the use of genetic information in China could adversely affect the demand for our products and services.**

Negative sentiment and distrust from consumers regarding the use of genetic testing may lead to lower demand for our services and products. For example, genetic testing has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Government authorities could, for social or other purposes, limit or regulate the

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use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead consumers to refuse to use, or health checkup centers and hospitals to be reluctant to order, genetic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our services and products or reduce demand for such services and products, either of which could have a material adverse effect on the business, financial condition and results of operations.

**We do not own any real property and may incur substantial relocation expenses and face disruption of operations if any lease for our offices or facilities is not renewed upon its expiration or is terminated or if we are forced to relocate. Our leased properties are regulated by various laws and regulations in relation to use of properties and construction requirements from different government authorities. Failure to comply with such laws and regulations may cause us to pay fines, be ordered to suspend use of our leased properties.**

We do not own any real property for our operations. As of the Latest Practicable Date, we lease an aggregate area of around 12,600 sq.m. in Hangzhou and Beijing. Upon expiration of the leases, we will need to negotiate for renewal of the leases and may have to pay increased rent. Also, pursuant to PRC laws, construction, expansion or renovation of construction projects is subject to various permits, approvals and filings from different government authorities. We may not be able to obtain such approvals, permits and filings or follow the requisite requirements in a timely manner or at all. We cannot assure you that we will be able to renew our leases on terms which are favorable or otherwise acceptable to us, or at all. If we cannot continue to use any of our leased property due to failure to renew our leases, or termination of our leases, or if we fail to comply with applicable laws and regulations in relation to use of properties and construction requirements from different government authorities, we may have to pay fines or need to seek an alternative location and incur expenses related to such relocation, and our operation and businesses may also be disrupted or even suspended if we are not able to complete the relocation, including the reconstruction of relevant facilities in the new location, in a timely manner.

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

As of December 31, 2020 and 2021 and September 30, 2022, we recorded trade receivables of RMB56.8 million, RMB83.6 million and RMB208.5 million, respectively, of which trade receivables due in 12 months represented 81.0%, 92.0% and 96.1%, respectively, of the total amount of our trade receivables recorded for the same periods. The impairment of our trade receivables amounted RMB3.0 million, RMB4.6 million and RMB5.7 million, respectively, for the same periods. For the years ended December 31, 2020 and 2021 and September 30, 2022, our average trade receivables turnover days were 82 days, 102 days and 103 days, respectively. Any substantial defaults or delays could materially and adversely affect our cash flows, and we could be required to terminate our relationships with customers in a manner that will impair our sales, which in turn would adversely impact our financial condition and operations. See “Financial Information” for a discussion of our receivables.

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**If we determine our other intangible assets to be impaired, our results of operations and financial condition may be adversely affected.**

As of September 30, 2022, we had other intangible assets of RMB88.8 million, which comprised software, trademarks and patents. Our determination on whether other intangible assets are impaired requires an estimation on recoverable amount of other intangible assets, which is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, the carrying amount of other intangible assets may exceed its recoverable amount, our other intangible assets may be impaired. Any significant impairment of other intangible assets could have a material adverse effect on our business, financial condition and results of operations. For more details of our impairment policy in relation to intangible assets, see Note 18 to the Accountant’s Report in Appendix I to this Document.

**Goodwill impairment could negatively affect our results of operations.**

Hangzhou Shenyi became a wholly-owned subsidiary of our Group in 2022. During the Track Record Period, our goodwill amounted to RMB2.9 million, RMB2.9 million and RMB166.2 million as of December 31, 2020, 2021 and September 2022, respectively, accounting for 0.9%, 0.9% and 20.2% of our total assets for the same periods.

Goodwill is initially measured at cost. After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is tested for impairment annually or more frequently if events or changes in circumstances indicate that the carrying value may be impaired. Testing for impairment requires an estimation of the value in use of the cash-generating units to which the goodwill is allocated. Estimating the value in use requires us to make an estimate of the expected future cash flows from the cash-generating units and also to choose a suitable discount rate in order to calculate the present value of those cash flows. There are inherent uncertainties related to these factors and to our judgment in applying these factors to the assessment of goodwill recoverability. We could be required to evaluate the recoverability of goodwill, including the one created by the acquisition of Hangzhou Shenyi, if there are any potential impairment indicators. Impairment charges could substantially affect our results of operations in the periods of such charges. In addition, impairment charges would negatively impact our financial ratios and could limit our ability to obtain financing in the future.

**If we experience delays in collecting payments from our customers, our cash flows and operations could be adversely affected.**

Although we actively manages our trade receivables, our ability to collect from customers depends on supply and demand dynamics, budgetary cycles, shifting availability of funds and other factors that may not be within our control. If our customers’ cash flows, working capital, financial condition or results of operations deteriorate, they may be unable, or they may otherwise be unwilling, to make payments owed to us promptly or at all. Hospitals and government agencies are the main types of our targeted customer.

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## RISK FACTORS

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### **We incurred net liabilities during the Track Record Period.**

We were in a net current asset position during the Track Record Period, but had net liabilities of RMB262.5 million as of September 30, 2022, primarily attributable to the increase in our convertible redeemable preferred shares which we recorded as non-current liabilities, by RMB526.5 million from RMB63.7 million as of December 31, 2021 to RMB590.2 million as of September 30, 2022. Although we expect our net liability position to be reversed after the automatic conversion of the convertible redeemable preferred shares into Shares upon the [REDACTED], a net liabilities position can expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all. Any difficulty or failure to meet our liquidity needs as and when needed can have a material adverse effect on our prospects.

### **We recorded net current liabilities.**

We recorded net current liabilities of RMB604.3 million as of January 31, 2023, being the latest practicable date for the purpose of liquidity disclosure in the Document, as compared to net current assets of RMB13.1 million as of September 30, 2022. The change from a net current asset position to a net current liabilities position was primarily attributable to the reclassification of our convertible redeemable preferred shares from non-current liability to current liability as the redemption rights of our preferred shareholders shall resume to be exercisable on December 31, 2023 if we fail to complete the [REDACTED] in time. For more details, see “History, Reorganization and Corporate Structure – [REDACTED] Investments – II. Special Rights” and “Financial Information – Discussion of Certain Selected Items from the Combined Statements of Financial Position.” We cannot assure you that we will not have net current liabilities positions in the future, which would expose us to liquidity risk. Our future liquidity and ability to make additional capital investments necessary for our operations and business expansion will depend primarily on our ability to maintain sufficient cash generated from operating activities. We may not have sufficient cash from operating activities or may need to obtain additional financing, which may not be available on commercially acceptable terms, or at all.

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

Historically, we have issued to investors series of convertible redeemable preferred shares, consisting of Series A, Series A+, Series B and Series C Preferred Shares (the “Convertible Redeemable Preferred Shares”), upon the completion of certain specified events, respectively. For more information about the terms of such convertible redeemable preferred shares, including their conversion and redemption features, see Note 28 to the Accountant’s Report set out in Appendix I to this Document. Upon the completion of this [REDACTED], all of such Convertible Redeemable Preferred Shares will be automatically converted into ordinary shares. Additionally, the foregoing investors have the right to require us to redeem



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such Convertible Redeemable Preferred Shares if this [REDACTED] is not consummated on or prior to certain date or upon the occurrence of some specified events. For the identity and background of the foregoing investors, see the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments” in this Document.

Upon conversion, the Convertible Redeemable Preferred Shares will be recorded on a fair value basis based on market valuation. We use significant unobservable inputs, such as expected volatility, discount for lack of marketability, risk-free interest rate, expected rate of return and discount rate, in valuing certain of our assets and liabilities, including the Convertible Redeemable Preferred Shares and financial assets at fair value through profit or loss. The fair value change of Convertible Redeemable Preferred Shares and financial assets at fair value through profit or loss may significantly affect our financial position and results of operations. Accordingly, such determination requires us to make significant estimates, which may be subject to material changes, and therefore inherently involves a certain degree of uncertainty.

We recorded fair value changes in financial liabilities at fair value through profit or loss of RMB1.5 million, RMB12.2 million, RMB12.1 million and RMB183.0 million for the year ended December 31, 2020, 2021 and the nine months ended September 30, 2021 and 2022, respectively. Factors beyond our control can significantly influence and cause adverse changes to the estimates we use and thereby affect the fair value of such assets and liabilities. These factors include, but are not limited to, general economic condition, changes in market interest rates and stability of the capital markets. Any of these factors, as well as others, could cause our estimates to vary from actual results, which could materially and adversely affect our results of operation and financial condition. In addition, the process for determining whether an impairment of financial asset is other-than-temporary usually requires complex and subjective judgments, which could subsequently prove to have been wrong. After the automatic conversion of the Convertible Redeemable Preferred Shares into Shares upon the completion of the [REDACTED], we do not expect to recognize any further gains or losses on fair value changes from these Convertible Redeemable Preferred Shares in the future.

If the Company were to be required to redeem all such Convertible Redeemable Preferred Shares if the [REDACTED] is not consummated on or prior to December 31, 2023 or upon the occurrence of certain specified events, the aggregate redemption price shall be the sum of the aggregate consideration for the issuance of such Convertible Redeemable Preferred Shares, plus applicable interest accrued thereon. As of September 30, 2022, our cash and cash equivalents was RMB178.0 million. The redemption of the Convertible Redeemable Preferred Shares, if triggered, could have a negative impact on our cash and liquidity position and financial condition.

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**As we increase or expand our testing capability and capacity through upgrades to our existing laboratory and establishment of new laboratories, depreciation and amortization expenses could negatively impact our results of operations.**

As of the Latest Practicable Date, we have one advanced medical testing laboratory in Beijing and two GMP-compliant manufacturing facilities in Beijing and Hanzhou for IVD testing kits and microfluidic biochips. We plan to use the net [REDACTED] from the [REDACTED] for the expansion of our testing and manufacturing capacity. Such upgrades and establishment will also require the procurement of a significant number of testing equipment. See “Future Plans and Use of [REDACTED]” for our expected use of [REDACTED]. The depreciation and amortization of fixed assets is typically done on a straight-line basis to write off the cost of such fixed asset to its residual value over its estimated useful life. Given the significant amount of fixed assets involved in our planned upgrades and expansion, the depreciation and amortization of such fixed assets could negatively impact our results of operations.

**We require substantial capital for our operations. If we cannot satisfy such requirement with cash from operations or raise sufficient additional capital on acceptable terms, our business, financial condition and prospects may be adversely affected.**

In order to further expand our business, develop new services and remain competitive, we may require additional capital to be expended in our operations. We expect to satisfy such capital commitments using cash from operations and various channels and instruments available to us. Financing may be unavailable in amounts or on terms acceptable to us. Our ability to use cash from operations and to obtain additional capital is subject to a variety of uncertainties, including our future financial condition, results of operations and cash flows, general market conditions for capital-raising activities and economic, political and other conditions in China. The future incurrence of indebtedness may result in debt service obligations and could result in operating and financing covenants restricting our operations or our ability to make acquisitions or pay dividends. Any failure to meet our capital requirements may materially and adversely affect our business, financial condition and results of operations.

**Raising additional capital may lead to dilution of shareholdings by our existing shareholders, restrict our operations, and may further result in fair value loss adversely affecting our financial results.**

We may seek additional funding through a combination of equity and debt financings and collaborations. To the extent that we raise additional capital through the issue of equity or convertible debt securities, the ownership interest of existing holders of our shares may be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our existing shareholders. 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 our business.

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## RISK FACTORS

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**Future grants of share-based awards may have an adverse effect on our financial condition and results of operations and have dilutive impact on your [REDACTED].**

In 2020, 2021 and the nine months ended September 30, 2022, we incurred share-based payments of RMB1.8 million, RMB6.0 million and RMB2.7 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

**The discontinuation of any government grants and other favorable policies currently available to us could adversely affect our financial condition, results of operations and prospects.**

We have historically received government grants in the form of subsidies for certain of our product development projects. For the years ended December 31, 2020 and 2021 and the nine months ended September 30, 2022, we recognized government grants as other income and gains of RMB2.1 million, RMB1.0 million and RMB3.1 million, respectively. For further details of our government grants, see “Financial Information”. Moreover, our growth has also been supported by favorable government policies, including preferential tax treatment. The timing, amount and criteria of government grants and other favorable policies are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate such grants or policies at any time. Our eligibility for government grants and other favorable policies is dependent on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, the availability of funding at different granting authorities and the research and development progress made by other peer companies. In addition, some of the government grants and policies are on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. In addition, the policies under which we historically received government grants may be halted by the relevant government entities at their sole discretion. We cannot assure you of the continued availability of the government grants and other favorable policies currently enjoyed by us. Any reduction or elimination of such government grants and other policies would materially adversely affect our business, financial condition, results of operations and prospects.

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

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

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

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

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### RISKS RELATING TO CONDUCTING BUSINESS IN CHINA AND RELATED REGULATIONS

**Uncertainties in the interpretation and enforcement of PRC laws and regulations could limit the legal protections available to you and us.**

We conduct our businesses in China primarily through our PRC Consolidated Entities. Our operations in China are governed by PRC laws and regulations. Our PRC subsidiaries are subject to laws and regulations applicable to foreign investment in China. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. The PRC legal system is evolving rapidly, and the interpretation of many laws, regulations and rules may contain inconsistencies, and the enforcement of these laws, regulations and rules involves uncertainties.

From time to time, we may have to resort to administrative and court proceedings to enforce our legal rights. Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business and results of operations. Furthermore, the PRC legal system is based, in part, on government policies and internal rules, some of which are not published in a timely manner, or at all, and which may have retroactive effect. As a result, we may not always be aware of any potential violation of these policies and rules until after the occurrence of violation. Such unpredictability towards our contractual, property and procedural rights could adversely affect our business and impede our ability to continue our operations.

**It may be difficult to effect service of process, enforce foreign judgments and arbitral awards against us or our Directors and senior management.**

We are incorporated under the laws of the Cayman Islands, but substantially all of our assets are located in the PRC. In addition, a majority of our Directors and senior management personnel reside within the PRC. As a result, it may not be possible to effect service of process outside the PRC upon our Directors and senior management personnel.

On July 3, 2008, the Supreme People’s Court of the PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned\* (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “Arrangement”). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final

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judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. On January 18, 2019, the Supreme People’s Court and the government of Hong Kong Special Administrative Region signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “**New Arrangement**”), which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the PRC. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court and the completion of the relevant legislative procedures in the Hong Kong. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

**Changes in China’s economic, political, and social conditions could adversely affect our business, financial condition, results of operations, cash flows, and prospects.**

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources.

While the PRC economy has experienced significant growth over the past four decades, growth has been uneven both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. Our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.



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

The Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors, or the M&A Rules, adopted by six PRC regulatory agencies in 2006 and amended in 2009, and certain other regulations and rules concerning mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex, including requirements in some instances that the MOFCOM be notified for approval in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise. Moreover, the Anti-Monopoly Law requires that approval from the Anti-Monopoly Bureau of SAMR shall be obtained in advance of any concentration of undertaking if certain thresholds are triggered. In addition, the security review rules issued by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review, including by structuring the transaction through a proxy or contractual control arrangement. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain our market share.

**We may be classified as a “PRC resident enterprise” for PRC enterprise income tax purposes, which could result in unfavorable tax consequences to us and our Shareholders and have a material adverse effect on our results of operations and the value of your Shares.**

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside of the PRC with a “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 over and overall management of the business, productions, personnel, accounts and properties of an enterprise. In April 2009, the State Administration of Taxation, or STA, issued a circular, known as Circular 82, which provides certain specific criteria for determining whether the “de facto management body” of a PRC-controlled enterprise that is incorporated offshore 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 like us, the criteria set forth in the circular may reflect the STA’s general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. According to Circular 82, an offshore incorporate 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

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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 resources 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 none of our entities outside of China is 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.” As substantially all of our management members are based in China, it remains unclear how the tax residency rule will apply to our case. If the PRC tax authorities determine that we or any of our subsidiaries outside of China is a PRC resident enterprise for PRC enterprise income tax purposes, then we or such subsidiary could be subject to PRC tax at a rate of 25% on our or the subsidiary’s worldwide income, which could materially reduce our net income. In addition, we will also be subject to PRC enterprise income tax reporting obligations. Furthermore, if the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, dividends paid by us (including any dividends held via [REDACTED]) will, and gains realized on the sale or other disposition of our ordinary shares may, be subject to PRC tax, at a rate of 10% in the case of non-PRC enterprises or 20% in the case of non-PRC individuals (in each case, subject to the provisions of any applicable tax treaty), and in the case of dividends, the PRC tax will be withheld at source if such dividends or gains are deemed to be from PRC sources. It is unclear whether non-PRC Shareholders of our company would be able to claim 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.

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

The value of RMB against the Hong Kong dollar, the U.S. dollar and other currencies fluctuates, is subject to changes resulting from the PRC government’s policies and depends a large extent on domestic and international economic and political developments as well as supply and demand in the local market. It is difficult to predict how market forces or government policies may impact the exchange rate between the RMB and the Hong Kong dollar, the U.S. dollar or other currencies in the future. In addition, the People’s Bank of China regularly intervenes in the foreign exchange market to limit fluctuations in RMB exchange rates and achieve policy goals.

The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any appreciation of the RMB against the Hong Kong dollar may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the RMB may adversely affect the value of, and any dividends payable on, the 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 required to obtain the SAFE’s approval before converting significant sums of foreign currencies into RMB if we want

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to use such [REDACTED] in the PRC. 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, the Shares in foreign currency terms.

**The PRC government’s control of foreign currency conversion and future fluctuation of Renminbi exchange rates may reduce the value of our Shares in foreign currency terms and may limit our foreign exchange transactions, including dividend payments on our Shares.**

The PRC government imposes controls on the convertibility of the RMB into foreign currencies and, in certain cases, the remittance of currency out of China. We receive substantially all of our net revenues in RMB. Under our current corporate structure, our Company relies on dividend payments from our PRC subsidiaries to fund any cash and financing requirements we may have. Under existing PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. Therefore, our PRC subsidiaries are able to pay dividends in foreign currencies to us without prior approval from SAFE, subject to the condition that the remittance of such dividends outside of the PRC complies with certain procedures under PRC regulations, among other things, such as tax clearance, reservation of capital reserve, the overseas investment registrations by the beneficial owners of our company who are PRC residents. However, approval from or registration with appropriate governmental authorities or their designated agencies like commercial banks is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies.

The PRC government has imposed more restrictive foreign exchange policies and stepped up scrutiny of major outbound capital movement. More restrictions and substantial vetting process are put in place by SAFE to regulate cross-border transactions falling under the capital account. The PRC government may at its discretion further restrict access to foreign currencies in the future for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders.

**Heightened scrutiny over acquisition transactions by the PRC tax authorities may have a negative impact on our business operations, our acquisition, or restructuring strategy or the value of your [REDACTED].**

On February 3, 2015, the State Administration of Tax issued a Public Notice Regarding Certain Corporate Income Tax Matters on Indirect Transfer of Properties by Non-Tax Resident Enterprises (the “**Public Notice 7**”, 《國家稅務總局關於非居民企業間接轉讓財產企業所得稅若干問題的公告》). Public Notice 7 extends its tax jurisdiction to not only indirect transfers of equity interests in a PRC resident enterprise by way of disposing of equity interests in an overseas holding company but also transactions involving transfer of other PRC taxable assets through the offshore transfer of a foreign intermediate holding company. In addition, Public Notice 7 provides clear criteria on how to assess reasonable commercial purposes and has introduced safe harbors for internal group restructurings and the purchase and sale of equity

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through a public securities market. Public Notice 7 also brings challenges to both the foreign transferor and transferee (or other person who is obligated to pay for the transfer) of the taxable assets. Where a non-resident enterprise conducts an “indirect transfer” by transferring the taxable assets indirectly by disposing of the equity interests of an overseas holding company, the non-resident enterprise being the transferor, or the transferee, or the PRC entity which directly owned the taxable assets may report to the relevant tax authority such indirect transfer. Using a “substance over form” principle, the PRC tax authority may re-characterize such indirect transfer as a direct transfer of the equity interests in the PRC tax resident enterprise and other properties in China. As a result, gains derived from such indirect transfers may be subject to PRC enterprise income tax, and the transferee or other person who is obligated to pay for the transfer is obligated to withhold the applicable taxes, currently at a rate of up to 10% for the transfer of equity interests in a PRC resident enterprise. Both the transferor and the transferee may be subject to late payment fees and penalties under PRC tax laws if the transferee fails to withhold the taxes and the transferor fails to pay the taxes on a timely manner.

We face uncertainties with respect to the reporting and consequences of private equity financing transactions, share exchange or other transactions involving the transfer of shares in our company by investors that are non-PRC resident enterprises, or sale or purchase of shares in other non-PRC resident companies, or other taxable assets, by us. Our company and other non-resident enterprises of ours may be subject to filing or tax obligations if our company and other non-resident enterprises of ours are transferors in such transactions, and we may be subject to withholding obligations if our company and other non-resident enterprises of ours are transferees in such transactions, under Public Notice 7. For the transfer of shares in our company by investors that are non-PRC resident enterprises, our PRC subsidiaries may be requested to assist in the filing under Public Notice 7. As a result, we may be required to expend valuable resources to comply with Public Notice 7 or to request the relevant transferors from whom we purchase taxable assets to comply with these circulars, or to establish that our company and other non-resident enterprises of ours should not be taxed under these circulars. The PRC tax authorities have the discretion under Public Notice 7 to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under Public Notice 7, our income tax costs associated with such transactions may be increased, which may have an adverse effect on our financial condition and results of operations. We have made investments in the past and may conduct additional investments or acquisitions in the future. We cannot assure you that the PRC tax authorities will not, at their discretion, adjust any capital gains and impose tax return filing obligations on us or require us to provide assistance to them for the investigation of any transactions we were involved in. Heightened scrutiny over acquisition transactions by the PRC tax authorities may have a negative impact on potential acquisitions we may pursue in the future.

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**We may be subject to penalties, including restriction on our ability to inject capital into our PRC subsidiaries and our PRC subsidiaries’ ability to distribute profits to us, if our PRC resident Shareholders or beneficial owners fail to comply with relevant PRC foreign exchange regulations.**

The SAFE has promulgated several regulations that require PRC residents to register with, and obtain approval from, local branches of the SAFE and/or their designated commercial banks in connection with their direct or indirect offshore investment activities. The Circular on Relevant Issues Relating to Domestic Resident’s Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, (the “SAFE Circular 37”, 《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程外匯管理有關問題的通知》), was promulgated by the SAFE in July 2014 that requires PRC residents to register with the SAFE or its local branch or designated commercial banks in connection with their establishment or control of an offshore entity established for the purpose of overseas investment or financing. These regulations apply to our Shareholders who are PRC residents. In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or SAFE Circular 7, replacing the previous rules issued by the SAFE in March 2007. Under SAFE Circular 7 and other relevant rules and regulations, PRC residents who participate in a stock incentive plan in an overseas publicly [REDACTED] company are required to register with the SAFE or its local branches and complete certain other procedures. Participants of a stock incentive plan who are PRC residents must retain a qualified PRC agent, which could be a PRC subsidiary of the overseas publicly listed company or another qualified institution selected by the PRC subsidiary, to conduct the SAFE registration and other procedures with respect to the stock incentive plan on behalf of its participants. The participants must also retain an overseas entrusted institution to handle matters in connection with their exercise of stock options, the purchase and sale of corresponding stocks or interests and fund transfers. In addition, the PRC agent is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan, the PRC agent or the overseas entrusted institution or other material changes.

Under these foreign exchange regulations, PRC residents who make, or have previously made, prior to the implementation of these foreign exchange regulations, direct or indirect investments in offshore companies are required to register those investments. In addition, any PRC resident who is a direct or indirect shareholder of an offshore company is required to update the previously filed registration with the local branch or commercial banks of the SAFE, with respect to that offshore company, to reflect any material change involving its round-trip investment, capital variation, such as an increase or decrease in capital, transfer or swap of shares, merger or division. If any PRC shareholder fails to make the required registration or update the previously filed registration, the PRC subsidiary of that offshore parent company may be restricted from distributing their profits and the proceeds from any reduction in capital, share transfer or liquidation to their offshore parent company, and the offshore parent company may also be restricted from injecting additional capital into its PRC subsidiary. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC laws for evasion of applicable foreign exchange restrictions, including (i) the requirement by the SAFE to return the foreign exchange remitted overseas or into PRC within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas or into PRC and deemed to have been evasive



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or illegal and (ii) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive or illegal. Failure of our PRC share option holders or restricted shareholders to complete their SAFE registrations may subject these PRC residents to fines of up to RMB300,000 for entities and up to RMB50,000 for individuals and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiary, limit our PRC subsidiary’s ability to distribute dividends to us, or otherwise materially adversely affect our business.

We have requested PRC residents holding direct or indirect interest in our Company to our knowledge to make the necessary applications, filings and amendments as required by applicable foreign exchange regulations. In addition, we may not always be able to compel them to comply with SAFE Circular 37 or other related regulations. Failure by any such Shareholders to comply with SAFE Circular 37 or other related regulations could subject us to fines or legal sanctions, restrict our investment activities in the PRC and overseas or cross-border investment activities, limit our subsidiaries’ ability to make distributions, pay dividends or other payments to us or affect our ownership structure, which could adversely affect our business and prospects.

As there is uncertainty concerning the reconciliation of these foreign exchange regulations with other approval requirements, it is unclear how these regulations, and any future regulation concerning offshore or cross-border transactions, will be interpreted, amended and implemented by the relevant governmental authorities. We cannot predict how these regulations will affect our business operations or future strategy. For example, we may be subject to a more stringent review and approval process with respect to our foreign exchange activities, such as remittance of dividends and foreign currency-denominated borrowings, which may adversely affect our results of operations and financial condition. In addition, if we decide to acquire a PRC domestic company, we cannot assure you that we or the owners of such company, as the case may be, will be able to obtain the necessary approvals or complete the necessary filings and registrations required by the foreign exchange regulations. This may restrict our ability to implement our acquisition strategy and could adversely affect our business and prospects.

### **Certain judgments obtained against us by our Shareholders may not be enforceable.**

We are an exempted company incorporated in the Cayman Islands and substantially all of our assets are located in China and substantially all of our current operations are conducted in China as well. As of the Latest Practicable Date, most of our current directors and officers are nationals and residents of China and substantially all of the assets of these persons are located in China. As a result, it may be difficult or impossible for you to effect service of process within Hong Kong upon us or these persons, or to bring an action in Hong Kong against us or against these individuals in the event that you believe that your rights have been infringed under the applicable securities laws or otherwise. In addition, because there are no specific statutory and judicial interpretations or guidance on a PRC court’s jurisdiction over cases brought under foreign securities laws other than those specified in the Securities Law of the People’s Republic of China, the PRC Criminal Code and its corresponding procedural laws or conflicts of laws, it may be difficult for you to bring an original action against us or our PRC resident officers and directors in a PRC court based on the liability provisions of non-PRC



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securities laws. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands and of China may render you unable to enforce a judgment against our assets or the assets of our directors and officers.

*The permit, filing or other requirements of the CSRC or other PRC government authorities in relation to our proposed [REDACTED] or further capital raise activities may be required under PRC laws.*

On July 6, 2021, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued the Opinions on Strictly Cracking Down on Illegal Securities Activities (《關於依法從嚴打擊證券違法活動的意見》), which emphasized the need to strengthen the administration over illegal [REDACTED], and the supervision over overseas [REDACTED] by domestic companies. Stringent measures aimed at establishing a robust regulatory system are expected to be taken to deal with the risks associated with overseas [REDACTED] companies based in or having significant operations in China, and to tackle any related cybersecurity and data security, cross-border data transmission, and confidential information management, among other matters.

Further, on February 17, 2023, the CSRC released the Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) and five ancillary interpretive guidelines (collectively, the “Overseas Listing Trial Measures”), which apply to overseas offerings and listing by domestic companies of equity shares, depository receipts, corporate bonds convertible to equity shares, and other equity securities, and will come into effect on March 31, 2023. According to the Overseas Listing Trial Measures, overseas offering and listing by domestic companies shall be made in strict compliance with relevant laws, administrative regulations and rules concerning national security in spheres of foreign investment, cybersecurity, data security and etc., and duly fulfill their obligations to protect national security, and the domestic companies may be required to rectify, make certain commitment, divest business or assets, or take any other measures as per the competent authorities’ requirements, so as to eliminate or avert any impact of national security resulting from such overseas offering and listing. No overseas offering and listing shall be made under any of the following circumstances: (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law, among other scenarios. The Overseas Listing Trial Measures provide that if an issuer meets both of the following conditions, the overseas securities offering and listing conducted by such issuer will be determined as an indirect overseas offering and listing subject to the filing procedure set forth under the Overseas Listing Trial Measures: (i) 50% or more of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements over the same period for the most recent accounting year is accounted for by domestic companies; and (ii) the main parts of the issuer’s business activities are conducted in the Chinese Mainland, or its main places of business are located in the Chinese Mainland, or the senior managers in charge of its business operation and management are mostly Chinese citizens or domiciled in the Chinese Mainland. For an initial public offering and listing in an overseas market, the issuer shall designate a major domestic operating entity to file with the CSRC within 3 working days after

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the relevant application is submitted overseas. For details, please refer to “Regulatory Overview – Regulations of M&A Rules and Overseas Listings” in this Document. Based on the foregoing, we will be required to complete the filing procedures with the CSRC in connection with the [REDACTED] pursuant to the Overseas Listing Trial Measures.

On the same date, the CSRC further published one notice clarifying that from the effective date of the Overseas Listing Trial Measures, the issuer that have already submitted valid application of the initial public offering and listing but have not obtained the overseas regulatory authorities or security stock exchange may reasonably arrange the time of filing their applications and shall complete the filing procedures with the CSRC before the overseas offering and listing. In addition, in the process of filing, where the issuer may be under any of the forbidden circumstances provided under the Overseas Listing Trial Measures, the CSRC may solicit the opinions of the competent government authorities under the State Council. With respect to the issuer with Contractual Arrangements, at a press conference held for these new regulations, officials from the CSRC clarified that the CSRC will seek opinions from relevant government authorities on the Contractual Arrangements and agree those issuers with Contractual Arrangements as well as in compliance with relevant requirements to file for its overseas offering and listing.

We cannot assure you that we could meet such requirements, obtain such permit from the relevant government authorities, or complete such filing in a timely manner or at all. Any failure may restrict our ability to complete [REDACTED] or any future capital raising activities, which would have a material adverse effect on our business and financial positions. However, as the Overseas Listing Trial Measures was recently promulgated, there remains substantial uncertainties as to its interpretation and implementation and how it may impact our ability to raise or utilize fund and business operation.

**We are subject to complex and evolving laws, regulations and governmental policies regarding privacy and data protection. Actual or alleged failure to comply with privacy and data protection laws, regulations and governmental policies could subject us to significant legal, financial and operational consequences.**

In the ordinary course of our business, we may collect and store data, including protected genetic information and personally identifiable information. Any unauthorized access, loss, or dissemination of information could result in legal claims, proceedings or liability under PRC laws and regulations that protect the privacy of personal information. In recent years, privacy and data protection has become an increasing regulatory focus of government authorities across the world. The PRC government has enacted a series of laws, regulations and governmental policies for the protection of personal data in the past few years and we are subject to such laws, regulations and governmental policies regarding data privacy and protection. For example, the Administrative Measures for Population Health Information (for Trial Implementation) (《人口健康信息管理辦法》(試行)), provides that certain medical institutions are responsible for collection, management, utilization, safety and privacy protection of personal healthcare data. The Data Security Law (《數據安全法》), which was promulgated by the SCNPC on June 10, 2021 and took effect on September 1, 2021, provides for data security and privacy obligations on entities and individuals carrying out data activities. The Personal Information Protection Law (《個人信息保護法》), which was promulgated by

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the SCNPC on August 20, 2021 and took effect on November 1, 2021, integrates multiple rules with respect to personal information rights and privacy protection. We have taken measures to maintain the confidentiality of the test takers’ personal and medical information, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization and setting internal rules requiring our employees to maintain the confidentiality of test takers’ personal and medical information. However, the laws and regulations regarding privacy and data protection in China, as well as other jurisdictions, are generally complex and evolving, with uncertainty as to the interpretation and application thereof. As such, we cannot assure you that our privacy and data protection measures are, and will be, always considered sufficient under applicable laws and regulations. If we are unable to comply with the applicable laws and regulations, or to address any data privacy and protection concerns, such actual or alleged failure could damage our reputation, deter current and potential customers from using our tests and could subject us to significant legal, financial and operational consequences.

For example, on December 28, 2021, the Cyberspace Administration of China, or the CAC, and other twelve PRC regulatory authorities jointly revised and promulgated the Cybersecurity Review Measures (《網絡安全審查辦法》), which stipulates the applicable scope of the cybersecurity review and came into effect on February 15, 2022. Pursuant to the Cybersecurity Review Measures, critical information infrastructure operators (the “**CIIOs**,” which refer to operators of important network facilities and information systems of important industries and sectors, such as public communications and information services, energy, transport, water conservation, finance, public services, e-government, and science and technology industry for national defense as well as other important network facilities and information systems that may significantly endanger national security, national economy and the people’s livelihood and public interests if they are damaged or suffer from malfunctions, or if any leakage of data in relation thereto occurs) that intend to purchase internet products and services and network platform operators (“**Network Platform Operators**”) engaging in data processing activities that affect or may affect national security must be subject to the cybersecurity review. The Cybersecurity Review Measures further stipulates that network platform operators with personal information data of more than one million users that seek for listing in a foreign country are obliged to apply for a cybersecurity review by the Cybersecurity Review Office. In addition, on November 14, 2021, the CAC published the Administration Regulations on Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》) (“**Draft Regulations on Cyber Data Security Management**”), which reiterates the circumstances under which data processors shall apply for cybersecurity review, including, among others, (i) the data processors who process personal information of at least one million users apply for “foreign” listing; and (ii) the data processors’ listing in Hong Kong affects or may possibly affect national security. However, the Cybersecurity Review Measures and the Draft Regulations on Cyber Data Security Management provide no further explanation or interpretation for “foreign” listing or “affect or may affect national security”.

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We are of the view that we do not need to proactively apply for cybersecurity review for the following reasons: (i) as of the Latest Practicable Date, the Group has not received any notice or determination from applicable PRC governmental authorities identifying it as a critical information infrastructure operator (“CIIO”); (ii) our business of providing clinical molecular testing services does not fall within the scope of “Network Platform Operators” or “Internet Platform Operators,” although the Cybersecurity Review Measures provide no further explanation or interpretation on “Network Platform Operators,” the Draft Regulations on Cyber Data Security Management define “Internet Platform Operators” as data processors that provide users with Internet platform services such as information release, social networking, transactions, payments and audio-visual services, which usually refer to services provided by e-commerce platform and social networks; (iii) the Group is applying for [REDACTED] in Hong Kong, and Hong Kong does not fall within the scope of “foreign country”; and (iv) we do not commit any act that threatens or endangers national security, and have not received any investigation, notice, warning or sanction from any governmental authority with respect to national security issues arising in the operation of our business and the [REDACTED] as of the Latest Practicable Date.

However, we cannot rule out the possibility that relevant governmental authorities may find us subject to security review due to the uncertainty of the terms “Network Platform Operators” and “national security,” and we cannot guarantee whether future regulatory changes would impose additional restrictions on companies like us. If we are found to be subjected to security review for a clearance in terms of our proposed [REDACTED] in Hong Kong, or future capital raising activities, we may face uncertainties as to whether such clearance can be timely obtained, or at all. Pursuant to the Cybersecurity Review Measures, any violation could be punished in accordance with the Cybersecurity Law and the Data Security Law of the PRC, the punishment measures under which includes, among others, government enforcement actions and investigations, fines, penalties and suspension of our non-compliant operations.

**We may be directly or indirectly subject to anti-bribery, anti-corruption, anti-money laundering, financial or economic sanctions, export restrictions and control measures, or other similar laws, and non-compliance with such laws can subject us to administrative, civil and criminal fines and penalties, remedial measures and legal expenses, which could adversely affect our business, results of operations, financial condition and reputation.**

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws and regulations of the jurisdictions we operation, including for example, the Anti-Unfair Competition Law and provisions of the Criminal Code, prohibit giving and receiving money or property (which includes cash, proprietary interests and items of value) to obtain an undue benefit. Further, the Anti-Money Laundering Law of the People’s Republic of China (《中華人民共和國反洗錢法》), promulgated by the Standing Committee of the National People’s Congress prohibits money laundering. In addition, many of our customers require us to follow strict anti-bribery as part of doing business with us.

Our operations are also affected by financial and economic sanctions, export restrictions and control measures laws of different jurisdictions in which we operate, including China and the United States, in which our wholly owned subsidiary, DCH Molecular Diagnostics Inc., is based. For example, being added to the Entity List administered by the U.S. Department of Commerce, Bureau of Industry and Security (“BIS”), would restrict its ability to purchase or otherwise access items that are subject to the Export Administration Regulations (“EAR”), without a license from the BIS. Non-compliance could result in fines, penalties, or revocation of export.

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## RISK FACTORS

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Despite our internal control measures, there is no assurance that our procedures and controls to monitor anti-bribery, anti-money laundering and financial, economic and export compliance would be adequately followed, and may be insufficient to address concerns associated with any applicable anti-bribery, anti-money laundering, economic sanctions or export control law. Failure of compliance on any of the above could have a material adverse effect on our business, financial condition and results of operations.

### **RISKS RELATING TO OUR CORPORATE STRUCTURE AND CONTRACTUAL ARRANGEMENTS**

**If the PRC government finds that the agreements that establish the structure for operating our businesses in China do not comply with applicable PRC laws and regulations, or if these regulations or their interpretations change in the future, we could be subject to severe consequences, including the nullification of Contractual Arrangements and the relinquishment of our interest in PRC Consolidated Entities.**

Current PRC laws and regulations impose certain restrictions or prohibitions on foreign ownership of companies that engage in the development and application of technologies for diagnosis and treatment of human stem cells and genes, to which our Relevant Business are relevant. Pursuant to the Special Administrative Measures (Negative List) for Foreign Investment Access (《外商投資准入特別管理措施(負面清單)》), the latest amended version of which is jointly promulgated by the MOFCOM and the NDRC on December 27, 2021 and takes effect from January 1, 2022, or the Negative List, certain industries are specifically prohibited for foreign investment, including the development and application of technologies for diagnosis and treatment of human stem cells and genes.

We are an exempted company incorporated under the laws of the Cayman Islands. Youxu Borui (the “WFOE”) is considered a foreign-invested enterprise. To comply with PRC laws and regulations, we provide clinical molecular testing services through our PRC Consolidated Entities based on the Contractual Arrangements which enable us to (i) have the power to direct the activities that most significantly affect the economic performance of PRC Consolidated Entities; (ii) receive substantially all of the economic benefits from PRC Consolidated Entities in consideration for the services provided by Youxu Borui (the “WFOE”); and (iii) have an exclusive option to purchase all or part of the equity interests in PRC Consolidated Entities when and to the extent permitted by PRC law, or request that any existing shareholder of PRC Consolidated Entities to transfer any or part of the equity interest in PRC Consolidated Entities to another PRC person or entity designated by us at any time at our discretion according to the relevant law. Because of the Contractual Arrangements, we are the primary beneficiary of PRC Consolidated Entities and hence consolidate its results of operations into ours. PRC Consolidated Entities hold certain licenses, approvals and key assets that are essential for our business operations. See the section headed “Contractual Arrangements” in this Document for detailed terms of the Contractual Arrangements.



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## RISK FACTORS

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If the PRC government finds that the Contractual Arrangements do not comply with its restrictions on foreign investment in businesses, or if the PRC government otherwise finds that we or PRC Consolidated Entities are in violation of PRC laws or regulations or lack the necessary permits or licenses to operate our business, the relevant PRC regulatory authorities, including the MOFCOM, NHC and NMPA, would have broad discretion in dealing with such violations or failures, including, without limitation:

- revoking our business and operating licenses;
- discontinuing or restricting our operations;
- imposing fines or confiscating any of our income that they deem to have been obtained through illegal operations;
- imposing conditions or requirements with which we or our PRC subsidiaries and PRC Consolidated Entities may not be able to comply;
- requiring us or our PRC subsidiaries and PRC Consolidated Entities to restructure the relevant ownership structure or operations;
- restricting or prohibiting our use of the [REDACTED] from the [REDACTED] or other of our financing activities to finance the business and operations of PRC Consolidated Entities; or
- taking other regulatory or enforcement actions that could be harmful to our business.

Any of these actions could cause significant disruption to our business operations and may materially and adversely affect our business, financial condition and results of operations. In addition, it is unclear what impact the PRC government actions would have on us and on our ability to consolidate the financial results of PRC Consolidated Entities in our consolidated financial statements, if the PRC governmental authorities find our legal structure and the Contractual Arrangements to be in violation of PRC laws, rules and regulations. If any of these penalties results in our inability to direct the activities of PRC Consolidated Entities that most significantly impact their economic performance and/or our failure to receive the economic benefits from PRC Consolidated Entities, we may not be able to consolidate PRC Consolidated Entities into our consolidated financial statements.

On February 17, 2023, the CSRC released the Overseas [REDACTED] Trial Measures, according to which, we will be required to complete the filing procedures with the CSRC in connection with the proposed [REDACTED] or any future capital raising activities. We may fail to complete the filing with the CSRC in a timely manner or at all, due to our Contractual Arrangements, and we may even need to unwind our Contractual Arrangements or restructure our business operations to rectify the failure to complete the filings. Under the possible trend of tightened state supervision of Chinese companies [REDACTED] overseas represented by the Overseas [REDACTED] Trial Measures, we cannot assure you that we would not be



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## RISK FACTORS

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subject to a closer review by relevant government authorities and that we would be able to comply with relevant laws, regulations and regulatory requirements in all respects, which may have a material adverse effect on our business, operations and financial condition. However, given that the Overseas [REDACTED] Trial Measures were recently promulgated, substantial uncertainties exist with respect to their interpretation, application, and enforcement and how they will affect our operations, the legality of our corporate structure.

**The Contractual Arrangements may not be as effective in providing operational control as direct ownership. PRC Consolidated Entities or its Registered Shareholders may fail to perform their obligations under the Contractual Arrangements.**

Due to PRC restrictions or prohibitions on foreign ownership of companies that engage in the development and application of technologies for diagnosis and treatment of human stem cells and genes, we provide genetic testing services through PRC Consolidated Entities in China, in which we have no ownership interest. We rely on the Contractual Arrangements with PRC Consolidated Entities and their Registered Shareholders to control and operate its business. The Contractual Arrangements are intended to provide us with effective control over PRC Consolidated Entities and allow us to obtain economic benefits from it. See “Contractual Arrangements” for more details about these contractual arrangements.

Although we have been advised by our PRC Legal Advisor that the Contractual Arrangements with PRC Consolidated Entities constitute valid and binding obligations against each party of such agreements in accordance with their terms, the Contractual Arrangements may not be as effective in providing control over PRC Consolidated Entities as direct ownership. If our PRC Consolidated Entities or their Registered Shareholders fail or refuse to perform their respective obligations under the contractual arrangements, we may incur substantial costs and expend substantial resources to enforce our rights. The Contractual Arrangements are governed by, and interpreted in accordance with, PRC laws and disputes arising from the Contractual Arrangements will be resolved through arbitration or litigation in China. However, the legal system in China is still evolving and not as developed as in other jurisdictions. There are very few precedents and little official guidance as to how contractual arrangements in the context of a variable interest entity should be interpreted or enforced under PRC law. There remain significant uncertainties regarding the outcome of arbitration or litigation. These uncertainties could limit our ability to enforce the Contractual Arrangements. In the event we are unable to enforce the Contractual Arrangements or we experience significant delays or other obstacles in the process of enforcing the Contractual Arrangements, we may not be able to exert effective control over our affiliated entities and may lose control over the assets owned by PRC Consolidated Entities. As a result, we may be unable to consolidate PRC Consolidated Entities in our consolidated financial statements and our ability to conduct our business may be negatively affected.

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## RISK FACTORS

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**We may lose the ability to use licenses, approvals and assets held by PRC Consolidated Entities that are material to our business operations if PRC Consolidated Entities declare bankruptcy or become subject to a dissolution or liquidation proceeding.**

We do not have priority pledges and liens against the assets of our PRC Consolidated Entities. If any of our PRC Consolidated Entities undergoes an involuntary liquidation proceeding, third-party creditors may claim rights to some or all of its assets and we may not have priority over such third-party creditors on the assets of our PRC Consolidated Entities. If any of our PRC Consolidated Entities liquidates, we may take part in the liquidation procedures as a general creditor under the PRC Enterprise Bankruptcy Law and claim any outstanding liabilities owed by such PRC Consolidated Entity to Youxu Borui (the “WFOE”) under the exclusive business cooperation agreement, along with other general creditors.

If the Registered Shareholders of our PRC Consolidated Entities attempt to voluntarily liquidate our PRC Consolidated Entities without obtaining our prior consent, we may not be able to prevent such unauthorized voluntary liquidation by exercising our right to request the Registered Shareholders of our PRC Consolidated Entities to transfer all of their respective equity ownership interests to a PRC entity or individual designated by us in accordance with the exclusive call option agreement with the Registered Shareholders of our PRC Consolidated Entities. In the event that the Registered Shareholders initiate a voluntary liquidation proceeding without our authorization or attempts to distribute the retained earnings or assets of our PRC Consolidated Entities without our prior consent, we may need to resort to legal proceedings to enforce the terms of the Contractual Arrangements. Any such legal proceeding may be costly and may divert our management’s time and attention away from the operation of our business, and the outcome of such legal proceeding will be uncertain.

**The Registered Shareholders of PRC Consolidated Entities may have conflicts of interest with us, which may materially and adversely affect our business.**

The Registered Shareholders of PRC Consolidated Entities may potentially have a conflict of interest with us, and they may breach the Contractual Arrangements, if they believe it would further their own interest or if they otherwise act in bad faith. We cannot assure you that when conflicts of interest arise between us and PRC Consolidated Entities, the Registered Shareholders of PRC Consolidated Entities will act in our interests or that the conflicts of interest will be resolved in our favor.

In addition, the Registered Shareholders of PRC Consolidated Entities may breach or cause PRC Consolidated Entities to breach the Contractual Arrangements. If PRC Consolidated Entities or its Registered Shareholders breach the Contractual Arrangements or otherwise have disputes with us, we may have to initiate legal proceedings, which involve significant uncertainty. Such disputes and proceedings may significantly disrupt our business operations, adversely affect our ability to control PRC Consolidated Entities and otherwise result in negative publicity. We cannot assure you that the outcome of any such dispute or proceeding will be in our favor.

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## RISK FACTORS

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**If we exercise the option to acquire equity ownership and assets of PRC Consolidated Entities, the ownership or asset transfer may subject us to certain limitations and substantial costs.**

Pursuant to the Contractual Arrangements, Youxu Borui (the “WFOE”) or its designated person(s) has the exclusive right to purchase all or any part of the equity interests in PRC Consolidated Entities from their Registered Shareholders for the lowest price.

The equity transfer may be subject to the approvals from and filings with the SAMR and other competent governmental authorities and/or their local competent branches. In addition, the equity transfer price may be subject to review and tax adjustment by the relevant tax or commerce authority. The Registered Shareholders of PRC Consolidated Entities will pay the equity transfer price they receive to PRC Consolidated Entities under the Contractual Arrangements. The amount to be received by PRC Consolidated Entities may also be subject to enterprise income tax. Such tax amounts could be substantial.

**Substantial uncertainties exist with respect to the interpretation and implementation of the Foreign Investment Law and how it may impact the viability of our current corporate structure, corporate governance and business operations.**

On January 1, 2020, the Foreign Investment Law came into effect. The Foreign Investment Law (《外商投資法》) replaced the Sino-Foreign Equity Joint Venture Enterprise Law (《中外合資經營企業法》), the Sino-Foreign Cooperative Joint Venture Enterprise Law (《中外合作經營企業法》) and the Wholly Foreign-Invested Enterprise Law (《外資企業法》) to become the legal foundation for foreign investment in the PRC. The Foreign Investment Law defines foreign investment as any investment activity directly or indirectly carried out in the PRC by one or more foreign natural persons, enterprises or other organizations (“**Foreign Investor(s)**”) and specifically stipulates four forms of investment activities as foreign investment, namely, (a) establishment of a foreign invested enterprise in the PRC by a Foreign Investor, either individually or collectively with any other investor, (b) obtaining shares, equities, assets interests or any other similar rights or interests of an enterprise in the PRC by a Foreign Investor; (c) investment in any new construction project in the PRC by a Foreign Investor, either individually or collectively with any other investor and (d) investment in any other manners stipulated under laws, administrative regulations or provisions prescribed by the State Council.

Conducting operations through contractual arrangements has been adopted by many PRC-based companies, including us, to obtain and maintain necessary licenses and permits in the industries that are currently subject to foreign investment restrictions or prohibitions in China. The Foreign Investment Law stipulates four forms of investment activity as foreign investment. However, the Foreign Investment Law does not explicitly stipulate the contractual arrangements as a form of foreign investment.

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## RISK FACTORS

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Notwithstanding the above, the Foreign Investment Law stipulates that “investment in any other manners stipulated under laws, administrative regulations or provisions prescribed by the State Council.” Therefore, there is the possibility that future laws, administrative regulations or provisions of the State Council may stipulate certain contractual arrangements to be a means of foreign investment, which may affect whether our contractual arrangements will be recognized as foreign investment, whether our contractual arrangements will be deemed to be in violation of the foreign investment access requirements, and therefore how our contractual arrangements will be handled are uncertain.

In an extreme scenario, we may be required to unwind the Contractual Arrangements and/or dispose of PRC Consolidated Entities, which could have a material and adverse effect on our business, financial condition and result of operations. In the event that we no longer have a sustainable business after the aforementioned unwinding of the Contractual Arrangements or disposal or in the event such measures are not complied with, the Stock Exchange may take enforcement actions against us which may have a material adverse effect on the [REDACTED] of our Shares or even result in the [REDACTED] of our Company. For details of the Foreign Investment Law and its potential impact on our Company, see “Regulatory Overview – Regulation of Foreign Investment.”

Therefore, there is no guarantee that the Contractual Arrangements and the business of PRC Consolidated Entities will not be materially and adversely affected in the future.

**The Contractual Arrangements may be subject to scrutiny by the PRC tax authorities, and a finding that we owe additional taxes could substantially reduce our consolidated net income and the value of your [REDACTED].**

Under PRC laws and regulations, arrangements and transactions among related parties may be subject to audit or challenge by the PRC tax authorities. We could face material and adverse tax consequences if the PRC tax authorities determine that the Contractual Arrangements do not represent an arm’s-length price and adjust PRC Consolidated Entities’ income in the form of a transfer pricing adjustment. A transfer pricing adjustment could, among other things, result in a reduction for PRC tax purposes, of expense deductions recorded by PRC Consolidated Entities, which could in turn increase their tax liabilities. In addition, the PRC tax authorities may impose late payment fees and other penalties to our PRC variable interest entities for under-paid taxes. Our results of operations may be materially and adversely affected if our tax liabilities increase or if we are found to be subject to late payment fees or other penalties.

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## RISK FACTORS

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### RISKS RELATING TO THE [REDACTED]

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

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

**The [REDACTED] price of the Shares may be volatile, which could result in substantial losses to you.**

The [REDACTED] price of our Shares may be volatile and could fluctuate widely in response to factors beyond our control, including general market conditions of the securities markets in Hong Kong, China, the United States and elsewhere in the world. In particular, the performance and fluctuation of the [REDACTED] of other companies with business operations located mainly in China that have listed their securities in Hong Kong may affect the volatility in the [REDACTED] of and [REDACTED] for our Shares. A number of PRC-based companies have listed their securities and some are in the process of preparing for listing their securities, in Hong Kong. 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 towards PRC-based companies listed in Hong Kong and consequently may impact the trading performance of our Shares. These broad market and industry factors may significantly affect the [REDACTED] and volatility of our Shares, regardless of our actual operating performance.

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

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

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## RISK FACTORS

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**You will incur immediate and substantial dilution and may experience further dilution in the future.**

As the [REDACTED] of our Shares is higher than the net tangible book value per Share of our Shares immediately prior to the [REDACTED], purchasers of our Shares in the [REDACTED] will experience an immediate dilution. If we issue additional Shares in the future, purchasers of our Shares in the [REDACTED] may experience further dilution in their shareholding percentage.

**The actual or perceived sale or availability for sale of substantial amounts of our Shares, especially by our Directors, executive officers and our existing shareholders, could adversely affect the [REDACTED] of our Shares.**

Future sales of a substantial number of our Shares, especially by our Directors, executive officers and our existing shareholders, or the perception or anticipation of such sales, could negatively impact the [REDACTED] of our Shares in Hong Kong and our ability to raise equity capital in the future at a time and price that we deem appropriate.

The Shares held by our certain existing shareholders are subject to certain [REDACTED] periods. We cannot assure you that our existing shareholders will not dispose of any Shares after the expiration of such [REDACTED] periods. A disposal of a significant amount of our Shares in the future may cause a decline in our [REDACTED].

**We are an exempted company incorporated under the laws of the Cayman Islands with limited liability and, because protection to minority shareholders under the laws of the Cayman Islands may be different from that under the laws of Hong Kong or other jurisdictions, you may have difficulties in enforcing your shareholder’s rights.**

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



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## RISK FACTORS

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

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

PRC regulations on investments and loans by offshore holding companies to PRC entities may delay or prevent us from using the [REDACTED] of the [REDACTED] to make additional capital contributions or loans to members of our Group. Any capital contribution or loan that we, as an offshore entity, make to any current or future PRC members of our Group, including from the [REDACTED] of the [REDACTED], are subject to PRC regulations. For example, the total of any offshore loan to the PRC members of our Group cannot exceed the difference between the registered capital and total investment of the relevant PRC member of our Group, which must comply with certain regulatory limits prescribed by the MOFCOM and such loans must be registered with SAFE. In addition, our capital contributions to the PRC members of our Group must be approved by MOFCOM and SAFE. We cannot assure you that we will be able to obtain these approvals on a timely basis, or at all. If we fail to obtain such approvals, our ability to capitalize the relevant PRC members of our Group or fund our operations or to utilize the [REDACTED] of the [REDACTED] in the manner described in “Future Plans and Use of [REDACTED]” section of this Document may be adversely affected, which could adversely affect the liquidity of the relevant PRC members of our Group, our ability to grow our business and our financial condition and results of operations.

**You must rely on the judgment of our management as to the use of the [REDACTED] of the [REDACTED], and such use may not produce income or increase the price of our Shares.**

Our management will have considerable discretion in the application of the net [REDACTED] received by us. You will not have the opportunity, as part of your [REDACTED] decision, to assess whether [REDACTED] are being used appropriately. The net [REDACTED] may be used for corporate purposes that do not improve our efforts to achieve or maintain profitability or increase the price of our Shares. The net [REDACTED] may be placed in [REDACTED] that do not produce income or that lose value.

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## RISK FACTORS

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**We cannot assure you that our Shares will remain [REDACTED] on the Stock Exchange.**

Although we currently intend to retain the [REDACTED] of our Shares on the Stock Exchange, there is no guarantee of the continued [REDACTED] of the Shares. Among other factors, our Shares may also fail to satisfy the [REDACTED] requirements of the Stock Exchange. Accordingly, Shareholders will not be able to sell their Shares through trading on the Stock Exchange if the Shares are no longer [REDACTED] on the Stock Exchange.

**There can be no assurance of the accuracy or completeness of certain facts, forecasts and other statistics obtained from various independent third-party sources, including the industry expert reports, contained in this Document.**

This Document, particularly the sections headed “Business” and “Industry Overview,” contains information and statistics relating to the molecular testing market. Such information and statistics have been derived from a third-party report commissioned by us, official government publications, available sources from public market research and other sources from third parties. We believe that the sources of the information are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. However, the information from official government sources has not been independently verified by us, the Sole Sponsor, [REDACTED], [REDACTED], [REDACTED], any of their respective directors and advisors, or any other persons or parties involved in the [REDACTED], save for Frost & Sullivan, and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics included in this Document being inaccurate or not comparable to statistics produced for other economies. You should therefore not place undue reliance on such information. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. You should consider carefully the importance placed on such information or statistics.

**You should read this Document carefully and should not rely on any information contained in press articles or other media regarding us or the [REDACTED]**

We strongly caution you not to rely on any information contained in press articles or other media regarding us and the [REDACTED]. Prior to the publication of this Document, there has been press and media coverage regarding us and the [REDACTED]. Such press and media coverage may include references to certain information that does not appear in this Document, including certain operating and financial information and projections, valuations and other information. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for any such press or media coverage or the accuracy or completeness of any such information or publication. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information or publication. To the extent that any such information is inconsistent or conflicts with the information contained in this Document, we disclaim responsibility for it and you should not rely on such information.