
RISK FACTORS

An investment in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before deciding to invest in our Shares. Our operations involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all or part of your investments in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any such an event, the market price of our Shares could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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

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 related to our business and industry; (ii) risks relating to our products and services, comprising (a) risks relating to the development of our product candidates and services, (b) risks relating to extensive government regulations, (c) risks relating to 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 property rights; (iii) risks relating to our financial position and need for additional capital; (iv) risks relating to our operations; (v) risks relating to our corporate structure and contractual arrangements; (vi) risks relating to doing business in China; 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.

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KEY RISKS RELATING TO OUR BUSINESS AND INDUSTRY

We may be adversely affected by the uncertainties and changes in the laws and regulations in the PRC with respect to the oncology molecular diagnostics and testing industry, particularly those in relation to the Laboratory Developed Test (“LDT”) business model. 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.

Due to the relatively short history of the oncology molecular diagnostics and testing 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 our industry, such as the provision of LDT services using unregistered testing reagents, which we also adopt might be viewed as not being in full compliance with the existing PRC laws and regulations.

According to the applicable PRC laws and regulations, genetic diagnostic devices which meet the definition of medical devices shall be treated and registered as medical devices with the NMPA or its local counterparts. 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 the NMPA or its local counterparts. Due to the short history of LDTs and the early-stage of the oncology molecular diagnostics and testing industry in China, PRC laws and regulations in relation to such LDT services are still evolving. We have provided LDT services during the Track Record Period, and our revenue generated from the provision of LDT services amounted to RMB267.9 million, RMB331.0 million and RMB337.5 million in 2020, 2021 and 2022, respectively. As of the Latest Practicable Date, we had obtained the Class III medical device registration certificate for Genecast IVD – KNBP from the NMPA in February 2021. According to Frost & Sullivan, it is consistent with market practices that other medical companies conducting similar LDTs in the PRC do not make registrations or filings with governmental authorities for the use of LDTs, the technologies involved, or the provision of LDT services.

If the competent PRC governmental authorities take a rigid view and apply the related laws and regulations on medical devices fully to LDTs, we could be subject to administrative penalties for providing LDT services without product registrations with the NMPA or its local counterparts. Such penalties include suspension of use of LDTs, confiscation of LDTs, monetary penalties and suspension of overall operations. Further, the NMPA or its local counterparts may refuse to accept the application for registration of medical devices from the violating laboratories for the following ten years.

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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 legislations, 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. Based on government consultations with the NHC and the NMPA and as advised by our PRC Legal Adviser, our provision of LDT services is in compliance with PRC laws and regulations currently in effect in all material respects, but there are risks and uncertainties brought by the evolving laws and regulations and possible different interpretations. For details, see “Business — Legal Proceedings and Regulatory Compliance — Regulatory Compliance” in this document. If the PRC government promulgates clear requirement for approval or regulation of LDT services, we will take necessary actions to meet such requirements. We have not received penalties or been investigated for offering LDT services as of the date of this document, however, 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 under our in-hospital business model and our MRD detection services. There can be no assurance that we will be able to successfully commercialize our products and services.

Our ability to successfully market our products and services may involve more inherent risks, take longer time and cost 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 one IVD product, 16 LDT services and three IVD equipment and software products. We started marketing our Genecast IVD – KNBP under our in-hospital business model since we obtained NMPA approval in February 2021. We launched Genecast MRD – Lung, our LDT service for MRD detection, in November 2020. 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.

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.

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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 similar oncology molecular diagnostics and testing services and products available in the market in general, do not meet the expectations of customers, 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 patients’ 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, patients also rely on the interpretations by 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.

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.

In addition, our success depends on the market’s confidence in oncology molecular diagnostics and testing products and services in general. If other oncology molecular diagnostics and testing products and services do not perform to expectations, it may result in lower confidence in our industry in general and will then adversely affect our business.

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

Our business substantially depends on our ability to complete the development of our product candidates and services under development, obtain the requisite regulatory approvals of our product candidates and successfully commercialize our services and approved products in a timely manner. We have invested significant efforts and financial resources in the development of our product candidates and services under development. The successful development and commercialization of our product candidates and services will depend on several factors, including but not limited to:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals;
- enhancing commercial manufacturing capabilities, either by enlarging our existing facilities or building new facilities ourselves or making arrangements with third-party manufacturers;
- expanding our testing capabilities including expanding our laboratories;
- expanding our research and development capabilities including attracting and retaining talents with extensive scientific experience;
- the ability of third parties, such as CROs and SMOs, we may retain to conduct or assist in conducting our clinical trials safely and efficiently and in accordance with our specified trial protocols;
- the performance by any other third parties we may retain in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- obtaining required marketing authorizations and launching commercial sales in China, the United States and other targeted markets, if and when approved;
- obtaining favorable government reimbursement policy or commercial insurance coverage for our products, if and when approved, and services;
- appropriately pricing our product candidates and services under development and timely collecting payments;

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- efficiently and cost-effectively enhancing our marketing and distribution capabilities;
- competition with other oncology molecular diagnostics and testing products and services; and
- continued acceptable safety profile following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to obtain approval for our product candidates, and/or to successfully commercialize our services and approved products, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in a timely manner or at all, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

During the clinical trial process, failure can occur at any time. The results of preclinical studies of our product candidates may not be predictive of the results of clinical trials. Product candidates in clinical trials may fail to show the desired safety and efficacy traits, such as sensitivity and specificity, despite having progressed through preclinical studies. Clinical trials or procedures may experience significant setbacks even after preclinical studies have shown promising results. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the physical conditions of the subject populations and the rate of dropout among clinical trial participants. Clinical trials of our product candidates may produce negative or inconclusive results. Even if our future clinical trial results show favorable efficacy, not all subjects may benefit. If we decide or are required by regulators to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, or if we are unable to successfully complete clinical trials of our product candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be forced to abandon the relevant product development programs, (ii) be subject to substantial liabilities, (iii) be delayed in or even prevented from obtaining regulatory approval for our product candidates, (iv) obtain approval for indications that are not as broad as intended, (v) have the product removed from the market after obtaining regulatory approval, (vi) be subject to additional post-marketing testing requirements, (vii) be subject to restrictions on how the product is distributed or used; or (viii) be unable to obtain reimbursement for use of the product. Any of such events could materially and adversely affect our ability to commercialize the subject products and generate sales revenues.

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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 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.

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Comparably, we are also required to obtain various governmental approvals in the relevant jurisdictions before we sell our products in the international markets. Regulatory authorities outside of China, such as the FDA, also have requirements for approval of medical devices for commercial sale with which we must comply prior to the marketing in those areas. Foreign regulations may vary from jurisdiction to jurisdiction and may be different from PRC regulations and the NMPA requirements, and therefore could delay or prevent the introduction of our product candidates in those areas. Additional time, efforts and expenses may be required to bring our products to the international markets in compliance with different regulatory processes. We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our products will be approved for sale in those jurisdictions. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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.

We face substantial competition and rapid market changes, which may result in others discovering, developing or commercializing competing products and services before or more successfully than we do, or respond and adapt to the market changes more quickly and effectively.

The development and commercialization of new oncology molecular diagnostics and testing products and services is highly competitive. We face competition from other companies engaging in oncology molecular diagnostics and testing. For details, see “Industry Overview” and “Business — Competition” in this document. Potential competitors include diagnostics and testing service providers, medical device companies as well as academic institutions, government agencies and other public and private research organizations or healthcare service providers that could conduct research, development, manufacturing and commercialization and seek patent protection for similar oncology molecular diagnostics and testing products and services.

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Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products and services that are more effective, convenient or affordable than the products and services that we commercialize or develop. Our competitors may also be applying for marketing approvals in China or other jurisdictions for products with the same intended use as our products and product candidates. The ability of the relevant authorities, such as the NMPA, to concurrently review multiple marketing applications for the same type of innovative medical device may be limited. When our product and its competing products are subject to the NMPA's concurrent review, the NMPA's schedule may be affected, and the registration process of our product may be prolonged. Moreover, our competitors may obtain approval from the NMPA or other comparable regulatory authorities for their products more rapidly than we obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and/or slow our regulatory approval.

Many of the companies against which we are competing have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and commercialization than we do. Mergers and acquisitions in the medical device industries may result in even more resources being concentrated among a small number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and marketing personnel, establishing clinical trial sites and subject enrollment for clinical trials, acquiring technologies complementary to, or necessary for, our development programs, selling and promoting products and services to the target customers, among others. Our business and results of operations will suffer if we fail to compete effectively.

Our operations and business plans may be adversely affected by natural disasters, epidemics and pandemics, civil and social disruption and other outbreaks, in particular the COVID-19 outbreak.

An outbreak of a respiratory disease COVID-19 was first reported in December 2019 and continues to expand globally. In March 2020, the World Health Organization characterized the COVID-19 outbreak as a global pandemic. Significant rises in COVID-19 cases have been reported since then, causing governments around the world to implement unprecedented measures such as city lockdowns, travel restrictions, quarantines and business shutdowns. The COVID-19 outbreak is expected to have an unprecedented impact on the global economy.

The COVID-19 outbreak has caused and may continue to cause a long-term adverse impact on the economy and social conditions in China and other affected countries, which may have an impact on our industry and cause temporary suspension of projects and shortage of labor and raw materials, which would severely disrupt our operations and have a material adverse effect on our business, financial condition and results of operations. We are uncertain as to when the COVID-19 outbreak will be contained globally, and we also cannot predict

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whether COVID-19 will have long-term impact on our business operations. Our operations could also be disrupted if any of our employees or employees of our suppliers and other business partners were suspected of contracting or contracted COVID-19, since this could require us and our suppliers and other business partners to quarantine some or all of these employees and disinfect facilities used for operations. In addition, the commencement of new clinical trials for other product candidates in our development pipeline could also be delayed or prevented by any delay or failure in subject recruitment or enrollment. Our commercialization plan for commercial-ready or near commercial-ready assets could also be disrupted. For example, in 2022, the COVID-19 resurgences in major cities in China, such as Shanghai, Xi'an and Changchun, and the stringent disease control measures taken by the PRC government, had a negative impact on our business, as some of our major hospital customers are located in those affected cities. If we are not able to effectively and efficiently develop and commercialize our product candidates and services under development as planned, we may not be able to grow our business and generate revenue from sales of our product candidates and services under development as anticipated, our business operations, financial condition and prospects may subsequently be materially and adversely affected.

In addition, any future occurrence of force majeure events, natural disasters or outbreaks of other epidemics and contagious diseases, including avian influenza, severe acute respiratory syndrome, swine influenza caused by the H1N1 virus, or H1N1 influenza or the Ebola virus, may materially and adversely affect our business, financial condition and results of operations. Moreover, the PRC has experienced natural disasters such as earthquakes, floods and droughts in the past few years. Any future of such events may materially and adversely affect our business, financial condition and results of operations.

RISKS RELATING TO OUR PRODUCTS AND SERVICES

Risks Relating to the Development of Our Product Candidates 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 oncology 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 2022, our R&D expenses amounted to RMB137.4 million, RMB176.2 million and RMB250.2 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

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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.

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

The timely completion of clinical trials in line with their protocols depends on, among other things, our ability to enroll a sufficient number of subjects who remain in the trial until its conclusion. We may experience difficulties or delays 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 one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of 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 projected clinical trials. If we experience delays in the completion of, or even termination of, any clinical trial of our product candidates, our ability to obtain requisite regulatory approvals, commercialize our products, commence product sales and generate revenues will be jeopardized. Any of these occurrences may have a material adverse effect our business, financial condition 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 products and product candidates are classified as medical devices in the catalog issued by the NMPA. To obtain product registrations for medical devices, we 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 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.

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Before obtaining regulatory approval for the sale of our products, we must conduct clinical trials to demonstrate the safety and effectiveness of our products. 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;
- 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;
- the cost of clinical trials of our products may be greater than we anticipate; and
- the supply or quality of our products or other materials necessary to conduct clinical trials of our products may be insufficient or inadequate.

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

The markets for oncology molecular diagnostics and testing products and services are characterized by technological changes, frequent new product introductions, and evolving industry standards. Our products and services could become technologically obsolete or more susceptible to competition without timely introduction of new and improved technologies. For details, see “— Key Risks Relating to Our Business and Industry — We face substantial competition and rapid market changes, which may result in others discovering, developing or commercializing competing products and services before or more successfully than we do, or respond and adapt to the market changes more quickly and effectively” in this section. Our success therefore depends on our ability to develop and market more advanced products and services in a timely manner. Because product and service designs can change with market conditions and hospitals’ and physicians’ preferences, identifying and developing new or improved products in a timely manner can be difficult. We may not be able to successfully market our new or improved products and services.

The success of our new or improved product and service offerings will depend on several factors, including our ability to (i) properly identify and predict industry trends and market demand; (ii) complete product and service development process successfully in a timely manner; (iii) minimize the time and costs required to obtain regulatory approvals; (iv) optimize our procurement and manufacturing processes to predict and control costs; (v) manufacture and deliver new products in a timely manner; (vi) efficiently and cost-effectively enhance our marketing and distribution capabilities; (vii) price our products and services at both competitive and commercially justifiable levels; (viii) increase end-customer awareness and acceptance of our new or improved products and services; and (ix) compete effectively with other medical device developers, manufacturers and marketers. If we are not successful in manufacturing or selling our new or improved products and services to meet market demand, or if there is insufficient demand for our new or improved products and services in the market, our business, financial condition, results of operations and prospects could be materially adversely affected.

Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, vendors, CROs and SMOs and commercial partners may engage in misconduct or other improper activities, including noncompliance 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, CROs and SMOs and commercial partners may engage in fraudulent or other illegal activities with respect to our business. Misconduct by these individuals and institutions could include intentional, reckless or negligent conduct or unauthorized activity that violates the regulations of the NMPA and other regulatory authorities.

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Misconduct by these parties could involve the creation of fraudulent data in our preclinical studies or clinical trials. Their improper activities could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of medical devices.

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. In addition, our employees and third parties who are responsible for the claims, disputes or legal proceedings against us due to their misconduct 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 may not be able to maintain or renew all the permits, licenses and certificates required for our production.

Companies manufacturing medical devices in China are required to obtain permits and licenses issued by various government authorities, including but not limited to the medical device production permit (醫療器械生產許可證), and if such manufacturing companies store and sell medical devices in places other than their domiciles and the places of production of medical devices, they are also required to obtain the medical device operation permit (醫療器械經營許可證). For details, see “Regulatory Overview — Regulations Relating to Medical Devices — Production Permit of Medical Devices” and “Regulatory Overview — Regulations Relating to Medical Devices — Permit for Medical Devices Operation” 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 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.

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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.

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.

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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.

If our current and new products and services do not meet the quality standards required under applicable laws, our business and reputation could be harmed, and our revenue and profitability could be materially and adversely affected.

Our production and manufacturing processes are required to meet certain quality standards. We have established a quality control management system and standard operating procedures to help prevent quality issues in respect of our products and services. For further details of our quality control management system and standard operating procedures, please see “Business — Quality Control” in this document. Despite our quality control system and procedures, we cannot eliminate the risk of errors, defects or failure. We may fail to detect or cure quality defects as a result of a number of factors, many of which are outside our control, including manufacturing errors, technical or mechanical malfunctions in the manufacture process, human error or malfeasance by our quality control personnel, tampering by third parties and/or quality issues with the raw materials we purchase or produce.

In addition, when we expand our manufacturing capacity in the future, we may not be able to ensure consistent quality between products manufactured in the existing and new facilities, or need to incur substantial costs for doing so. Furthermore, if we acquire other companies, we may not be able to immediately ensure that their manufacturing facilities and processes will meet our own quality standards.

Any quality defect in our oncology molecular diagnostics and testing products and services may result in misdiagnosis and product liability claims. Product liability claims against us may include allegations of defects in design and manufacturing, improper handling or transportation of products, negligence, strict liability and a breach of warranties. We may be subject to product liability claims if our products have latent quality issues that were undetected during our inspections and quality control. Even if our products do not have latent defects, other factors that are out of our control, such as the quality and skill of physicians using our products, may affect the outcome of the testing. Patients may still initiate legal proceedings against hospitals and us, and the hospitals may claim, with or without merit, that our products have latent defects. Failure to detect quality defects in our products or to prevent such defective products from being delivered to customers could result in product recalls or withdrawals, license revocation or regulatory fines, or other problems that could seriously harm our reputation and business, expose us to liability, and adversely affect our revenues and profitability.

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We face risks associated with uncertainties relating to the interpretation and implementation of the Regulation for the Administration of Human Genetic Resources and other applicable laws and regulations.

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, or HGR Regulation, except for activities relating to human genetic resources conducted for some specific purposes including clinical diagnosis and treatment. As advised by our PRC Legal Adviser, given our oncology molecular diagnostics and testing business is for the purpose of clinical diagnosis and treatment, such activities relating to human genetic resources in our oncology molecular diagnostics and testing business would not be governed by HGR Regulation. However, we cannot assure you that our oncology molecular diagnostics and testing business will be continuously deemed as conducted for the purpose of clinical diagnosis and treatment 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 collection, preservation and usage of human genetic resources, including human tissues and specimen in our research and development activities, including those conducted in collaboration with external institutions for scientific research are governed by HGR Regulation.

Pursuant to HGR Regulation, there are some limitations for foreign entities, individuals and such entities established or actually controlled thereby (“**Restricted Entities**”, and each, a “**Restricted Entity**”) to engage in activities relating to human genetic resources. For example, a Restricted Entity is not allowed to collect or preserve human genetic resources of Chinese, while it is prohibited from using human genetic resources of the Chinese unless such Restricted Entity has filed with relevant government authority for international cooperation with a domestic entity. Although an entity controlled, directly or indirectly, by foreign persons through shareholding ownership would be deemed as a Restricted Entity, HGR Regulation remains unclear as to whether a variable interest entity controlled by a wholly foreign owned enterprise through contractual arrangements would be deemed as a Restricted Entity. We cannot assure you that our Consolidated Affiliated Entities will not be deemed as Restricted Entities in the future, given the lack of clear statutory interpretation regarding HGR Regulation. If our Consolidated Affiliated Entities are deemed as the Restricted Entities by relevant government authority, our business would be adversely affected and we may have to obtain approval for our current business from the relevant government authority, which may be difficult or even impracticable and/or cooperate with domestic entities that are not Restricted Entities for purposes of the HGR Regulation 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.

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Any change in the regulations governing the use of personal data in China, which are still under development, and any failure to comply with such current or future regulations, could adversely affect our business and reputation.

In the ordinary course of our business, we collect and store sensitive data, including protected health information, personally identifiable information, financial information, intellectual property, and proprietary business information owned or controlled by ourselves or our customers, payors, and other parties in China. Any such 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. For example, pursuant to the Administrative Measures for Population Health Information (On Trial) (《人口健康信息管理办法(试行)》), the medical institutions including our medical laboratories are responsible for collection, management, utilization, safety and privacy protection of personal healthcare data.

We have established internal systems to safeguard relevant personal healthcare data. 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.

Risks Relating to the Commercialization of Our Products and Services

If physicians, KOLs and hospitals are not receptive to our products and services, our results of operations may be negatively affected.

Physicians, KOLs and hospitals play important roles in recommending and deciding what products and services to be used. If our products and services are not widely accepted by physician, KOLs and hospital communities, sales of our currently commercialized products and services may decline, and we may not be able to effectively market our other product candidates and services under development upon commercialization.

In addition, many of our products, product candidates, services and services under development represent innovative therapies in China or even globally. Physicians and KOLs face a learning process to become proficient in the use of some of our products, product candidates, services and services under development, which may take a longer time than we expected. Encouraging physicians and KOLs to dedicate their time and energy necessary for adequate training remains challenging, and we may not be successful in these efforts. If physicians and KOLs are not properly trained, they may misuse or ineffectively use our products and services, which may also result in misdiagnosis of patients, negative publicity or lawsuits against us, any of which could have a significant adverse effect on our reputation,

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business, financial condition, results of operations and prospects. Following completion of training, we also rely on trained physicians and KOLs to advocate the benefits of our products and services in the marketplace. If we are not able to enhance our products and services awareness and receive recognition from these physicians and KOLs, other physicians and hospitals may not be inclined to use our products and services, and our results of operations may be adversely affected.

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

The commercial success of our products and services depends upon the degree of market acceptance they can achieve, particularly among customers, physicians and hospitals. As diagnosis methods recently developed and introduced to the China market, our products and services may fail to receive broad acceptance from target customers, physicians or patients as anticipated.

In addition, customers, patients, physicians and third-party payors may prefer other innovative products to ours. If our products and services do not achieve an adequate level of acceptance, we may not be able to generate significant products and services sales revenues and to achieve profitability. Failure to achieve an adequate level of acceptance or to improve market awareness of our products, product candidates, services and services under development may have an adverse impact to our financial conditions, business and results from operations. The degree of market acceptance of our products, product candidates, if approved for commercial sale, services and services under development will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- patients, physicians and hospitals considering our products, product candidates (upon commercialization), services and services under development (upon commercialization) as a safe and effective treatment;
- the potential and perceived advantages and disadvantages of our products, product candidates (upon commercialization), services, services under development (upon commercialization) and relevant treatments compared to alternative products, services and treatments;
- our ability to further validate our products and services through clinical research and accompanying publications;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing and scope of approval by the NMPA for our products and market introduction of our products, product candidates (upon commercialization) as well as competitive products;
- the cost of treatment in relation to alternative treatments;

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- the availability of adequate coverage, pricing and reimbursement by third-party payors and government authorities;
- the willingness of patients 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 oncology molecular diagnostics and testing;
- developments in cancer treatments that may undermine or reduce the necessity of oncology molecular diagnostics and testing;
- accelerated research and development progress of our competitors; and/or
- the effectiveness of our sales and marketing efforts.

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 introduced are more favorably accepted by the market and more cost effective than our products and services, which may render our products and services obsolete.

The successful promotion of our brand will depend largely on our ability to continue to offer high-quality products and services 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.

If we fail to maintain an effective sales channel for our products and services, our business and sales of the relevant products and services could be adversely affected.

We provide our products and services to patients through direct sales channels to hospitals. Our ability to maintain and grow our business will depend on our ability to maintain an effective sales network that ensure timely distribution of our products and services. As of the Latest Practicable Date, our sales network covered 836 hospitals in China. The success of our commercialization primarily depends on our ability to maintain and expand our relationships with our sales channels and customers. If we are unable to maintain and expand our relationships with our sales channels and customers, sales volumes or margin of our existing and future products and services may be adversely affected.

Our highly trained sales team works with our sales channels and customers to help them become more effective. We provide our channels and customers with technical support, such as training in the basic technologies of our products and services and participating in presentations to physicians and hospitals. Our customers face a learning process with respect to our products, product candidates, services and services under development, particularly for those newly introduced to the market.

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We mainly rely on our in-house marketing team to promote our products and services. There is no guarantee that we will succeed in expanding our sales network to cover new sales and distribution channels.

We rely on our in-house marketing team to market and promote our products and services. The success of our 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 areas and are able to communicate effectively with medical professionals. Furthermore, since we expect to launch new products and services targeting various types of cancers, we expect to hire more employees with relevant oncology molecular diagnostics and testing experience and knowledge to strengthen our marketing and sales workforce. We face intense competition for experienced personnel. There can be no assurance that we will be able to develop and successfully maintain our in-house sales and commercial distribution capabilities or establish or maintain relationships with physicians, hospitals and other third parties to successfully commercialize our products and services. If we are unable to attract, motivate and retain a sufficient number of qualified sales personnel to support our marketing model, sales volumes or margin of our existing and future products may be adversely affected.

In addition, we plan to continue strengthening our cooperative relationship with hospitals, physicians and research institutions for enhancing our products and services awareness in the market. For example, we may offer education programs to hospitals and physicians to introduce our products and services. However, such promotional activities may not be as effective as we expected, or may be impeded by unanticipated events such as outbreaks of COVID-19, which may cause a decline of our sales revenue, and have a material adverse effect on our business, financial condition and results of operations.

The sizes of the markets for our current or future products and services 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 and services.

Our estimates of the total addressable markets and target population for our current products and services 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 candidates and services under development 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 and services may be proved to be incorrect. If the target population who would benefit from our products and services, the price at which we can sell our products and services or the total addressable markets for our products and services is smaller than we have estimated, our sales growth may be impaired and there may be an adverse impact on our business.

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In addition, we may not be able to fully capture the target populations of our products and services. For example, Genecast IVD – KNBP targets the colorectal cancer population in China. According to Frost & Sullivan, 467.6 thousand patients in China were diagnosed with colorectal cancer in 2021 and the number of patients in China diagnosed with colorectal cancer is expected to grow to 606.3 thousand in 2030. Whether Genecast IVD – KNBP can capture a substantial portion of the target population in China depends on various factors, such as the inclusion of Genecast IVD – KNBP under the 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 products and services or evolving regulatory regime which may impose pricing control or other restrictive measures. We provide our products and services to patients through direct sales channels to hospitals. In terms of pricing strategy, we combine multi-factor joint analysis to formulate the price of new products and services, and negotiate the price directly with hospitals on a case-by-case basis. Our hospital customers may gain more bargaining power depending on the availability of alternative products and services, demands of patients and the preference of physicians. If our hospital customers lower order prices of our products and services and therefore reduce our profitability, it will have significant negative impact on our results of operations.

We sell Genecast IVD – KNBP to hospitals and medical institutions. Pricing of Genecast IVD – KNBP sold to hospitals or other medical institutions is based on arm’s length business negotiations on a case by case basis between us and hospitals or medical institutions. The pricing of Genecast IVD – KNBP we ultimately agree with hospitals or other medical institutions may be lower than our expected price and such downward price may have a material adverse impact on our financial conditions and results of operations. Given the uncertainty of the pricing level or gross profit margin of Genecast IVD – KNBP, there is no assurance that the future sales of Genecast IVD – KNBP will have a positive impact on our overall profit margin. The gross profit margin of Genecast CRC test provided as a LDT service is highly correlated with test volumes we can provide to customers and utilization of our laboratories, as most of the costs for Genecast CRC are fixed in nature, such as staff costs, rental costs, and depreciation and amortization.

More competing oncology molecular diagnostics and testing products and services may become available, which will offer alternatives for hospitals and patients. If the PRC government issues price guidance for oncology molecular diagnostics and 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 that patients can receive for using our products and services.

Currently, oncology molecular diagnostics and testing products and services are not covered by governmental medical insurance in China, except in Beijing. The availability of governmental and private health insurance in China for treatments using our products and services will influence our ability to sell our products and services. China has a complex medical insurance system that is currently undergoing reform. The governmental insurance coverage or reimbursement level in China for oncology molecular diagnostics and testing and the medical device used in such diagnostics and testing 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 addition, the PRC government may change, reduce or eliminate the governmental insurance coverage then available for treatments using our products and services. We cannot assure you that our products and services will be included in the medical insurance reimbursement list at all times, or at all. To the extent that our products and services are not included in the medical insurance reimbursement list or if any such insurance schemes are changed or canceled which result in any removal of our products and services from medical insurance catalog, patients may choose, and hospitals may recommend alternative treatment methods, which will reduce demand for our products and services, and our sales may be adversely impacted or not able to achieve our expected levels, which may lead to a material and adverse effect on our business, results of operations and financial condition.

Currently, a majority of commercial insurance companies do not cover NGS-based oncology molecular diagnostics and testing products and services. Commercial insurance companies in China tend to reimburse patients for a higher percentage of the products and services cost if they use a medical device manufactured by a Chinese domestic company as opposed to an imported device. We cannot guarantee that commercial insurance companies will continue to adopt this favorable policy in the future.

Moreover, we may need to lower the prices of our products and services in order to have them included in the medical insurance reimbursement list, while such price cut and reimbursement may not necessarily cause our sales to increase and our results of operations may be adversely affected.

Our financial performance is subject to seasonal fluctuations.

Sales of our products and services are subject to seasonality. Some hospitals in China prefer to place more procurement orders for oncology diagnostics and testing medical devices towards the end of the year to replenish inventory and meet patients’ needs, according to Frost & Sullivan. Based on historical data, demand for our products and services from partner hospitals have generally been higher in the fourth quarter of the calendar year. On the other hand, some components of our costs and expenses such as rental expenses and staff costs are relatively fixed in nature and not affected by the seasonality impact. As a result of the foregoing, our financial performance is subject to seasonal fluctuations.

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Risks Relating to Manufacture and Supply of Our Products and Services

We mainly rely on our manufacturing facilities in Taizhou 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 Taizhou, China. For details, see “Business — Manufacturing Capacity” 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.

We depend on third-party suppliers to supply raw materials to 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 for our products and product candidates primarily include chemical and biochemical materials, and packaging materials. 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

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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.

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. 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.

The manufacturing and testing processes of our products and services 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 and services are 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.

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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. As we increase our market penetration of Genecast IVD – KNBP and LDT services, we may face unanticipated surges in demands for our products and services which could strain our manufacturing or testing capacity. If these problems arise or if we otherwise fail to meet our internal quality standards or those of the NMPA or other applicable regulatory body, which include detailed record-keeping requirements, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product and professional liability and other costs, product approvals could be delayed, and 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.

If our logistics service providers encounter any performance issues, our business, results of operations and financial condition could be adversely affected, and our reputation and ability to provide our oncology molecular diagnostics and testing products and services on a timely basis could be harmed.

The quality of our oncology molecular diagnostics and testing products and services largely depends on our ability to deliver well-preserved samples quickly and reliably from hospitals to our laboratory. To render an accurate testing results requires us to preserve the samples at a high standard, which could be difficult as testing samples are sensitive to various external conditions, such as biological materials, low-temperature, heat or light. Our third-party logistics service providers may encounter performance issues that cause the testing samples to be exposed to inappropriate temperatures 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. As a result, our business, results of operations and financial condition could be adversely affected, and our reputation and ability to provide our services on a timely basis could be harmed.

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In addition, disputes with or a termination of our contractual relationship with our third-party logistics service providers 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 providers 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 customers. 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.

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.

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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.

As of the Latest Practicable Date, we had four laboratories in operation located in Beijing, Wuhan and Wuxi in China. Our laboratory facilities are subject to various regulatory requirements, and failure to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, operating restrictions and criminal prosecutions, any of which could harm our business.

Although all of our laboratory facilities have back-up measures, the data and samples stored in our laboratory facilities are still subject to various risks beyond our control. While our multi-location laboratories help us weather operational breakdowns at any one location, our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including pandemic, pollution, fires, earthquakes, flooding, power outages and other defects, which may render it difficult or impossible 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.

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

We may be subject to product liability claims if our products have quality issues. For example, we may be sued if our product candidates are perceived to cause injury or are found to be otherwise unsuitable during clinical testing and manufacturing. Any serious failures or defects could cause us to withdraw or recall products, and subject us to product liabilities, which may damage our brand name and may have a material adverse effect on our business, financial condition, results of operations and prospects. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material customer complaint or product return from customers.

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The coverage of our insurance policies may not be broad enough or the indemnifiable amount may not be sufficient to cover all of our losses incurred. Furthermore, we may be unable to acquire such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. In this regard, if we cannot successfully defend ourselves against, obtain indemnification from our collaborators, or acquire sufficient insurance at an acceptable cost, we may incur substantial liabilities or be required to limit commercialization of our product candidates, and our business, financial condition, results of operations and prospects may be materially and adversely affected.

If we are unable to support demand for our existing or future products and services, including ensuring that we have adequate capacity to meet increasing demand, our business could suffer.

To meet anticipated market demand for our tests and products, we may need to increase, or scale up, the testing and production capacity and the utilization rate in the future. In 2020, 2021 and 2022, our testing capacity was 72,000 tests, 96,000 tests and 96,000 tests, respectively, and our utilization rate was 74.4%, 71.5% and 72.0%, respectively. In addition, we had a production capacity of 4,950 kits, 4,950 kits and 4,950 kits, respectively, and utilization rate of 19.0%, 48.0% and 45.2%, respectively, in 2020, 2021 and 2022. Advances in testing and manufacturing technologies may render our facilities and equipment inadequate or obsolete, and therefore we may also need to develop advanced manufacturing technologies and process controls in order to fully utilize our facilities. To enhance our testing and production capacity, we also need to expand our testing and production facilities, further upgrade our automated production lines and employ more workers. If we are unable to do so, or if the process to do so is delayed, or if the cost of the planned scale up or upgrade is not economically feasible for us or we cannot find a third-party supplier, we may not be able to supply our products in a sufficient quantity to meet future demand, which would limit our development and commercialization activities and our opportunities for growth.

Our ability to successfully implement our expansion plan is subject to a number of risks, including our ability to obtain the requisite permits, licenses and approvals for the construction and operation of the new testing facilities and production lines, the risk of construction delays, as well as our ability to timely recruit sufficient qualified staff to support the increase in testing and production capacity. The expansion process may be lengthy and costly and may divert our management attentions and development resources. Consequently, there can be no assurance that we will be able to increase our overall testing or production capacity or develop advanced technologies and process controls in the manner we contemplate, or at all. In the event we fail to increase our testing or production capacity or develop advanced technologies and process controls, we may not capture the expected growth in demand for our products, or to successfully commercialize new products, each of which could materially and adversely affect our business prospects. Moreover, our plans to increase our production capacity require significant capital investment, and the actual costs of our expansion plan may exceed our original estimates, which could materially and adversely affect the realization of expected return on our expenditures. In addition, as our sales volume grows, we will need to continue to expand our internal quality assurance program, and extend our products to support comprehensive data analysis at a larger scale within expected turnaround times.

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There can be no assurance that our existing and future testing and production facilities will be sufficient in the event of any significant change in market demand. In such event, we may have to engage third parties to meet such demand. Consequently, we are exposed to the risks of increased pricing for our sub-contracted testing and production and that the third parties may not comply with our specifications or meet market demand. As a result, our sales volumes and margins for the relevant products could be materially and adversely affected.

Failure in our information technology infrastructure, storage systems or equipment may cause significant disruptions to our operations and our research and development efforts.

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 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.

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

We rely on our suppliers for our business, which exposes us to risks associated with fluctuations in prices of raw materials, and reductions in the availability of raw materials may disrupt our operations. 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 such as fires, outbreak of epidemics or diseases such as COVID-19, the PRC and global economic conditions. A significant increase in the costs of raw materials may increase our cost of sales and negatively affect our profit margins and, more generally, our business, financial conditions, results of operation and prospects.

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We have limited control over our third-party suppliers. Illegal actions, misconduct or any failure by our suppliers to provide satisfactory services could materially and adversely affect our business, reputation, financial condition, and results of operations. In addition, we may be unable to receive sufficient compensation from our suppliers for the losses caused by them.

Since we rely on third-party suppliers to conduct certain aspects of our business, such as providing the testing equipment, reagents, materials and courier delivery services, including cold-chain delivery services, we are exposed to the risk of illegal actions, misconduct or any failure by our third-party suppliers to provide satisfactory services. For instance, certain of our suppliers are subject to various regulations and are required to obtain and maintain various qualifications, government licenses and approvals. If any of these suppliers loses its qualification or eligibility because of its failure to comply with regulatory requirements, we may not be able to find alternative suppliers in a timely manner or at all. Some of our suppliers import certain equipment and materials from manufacturers located outside China and resell to us. As a result, trade or regulatory embargoes imposed by foreign countries or China could also result in delays or shortages that could harm our business. Moreover, general economic conditions could also adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and services used in our operations. In addition, suppliers may fail to supply products that meet our quality standards. If we are unable to identify alternative materials or suppliers and secure approval for their use in a timely manner, our business, operations and the development of our product candidates could be materially harmed. Any change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to service performance or incorporate unique technology, and the loss of existing supply contract may have a material adverse effect on us. Any material misconduct or disputes against our suppliers could potentially harm our business and reputation.

Failure to maintain and predict inventory levels in line with the level of demand for our products could cause us to lose sales or face excess inventory risks and holding costs, either of which could have a material adverse effect on our business, financial condition and results of operations.

To operate our business successfully and meet our customers’ demands and expectations, we must maintain a certain level of inventory for our products to ensure timely delivery when requested. Furthermore, we are required to maintain an appropriate level of inventory of our raw materials for our commercial production. In 2020, 2021 and 2022, our average inventory turnover days were 116 days, 100 days and 102 days, respectively. However, 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 products or produce our products in a timely manner, 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 our products or raw materials. Excess inventory levels may increase our inventory holding costs, risk of inventory obsolescence or write-offs.

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We actively monitor our inventory level and track the flow of our products through an online distribution platform where we can monitor the flow of our products to hospitals on a real-time basis. 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 market demand, it could cause us to lose sales or face excess inventory risks and holding costs, either of which could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Our Intellectual Property Rights

If we are unable to obtain and maintain patent protection for our products, product candidates, services and services under development through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends in a large part on our ability to protect our proprietary technology, products, product candidates, services and services under development from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technology, products, product candidates, services and services under development that we consider commercially important by filing patent applications in the PRC and other countries, relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or at all. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Although we enter into non-disclosure and confidentiality agreements with our employees, consultants, contractors and other third parties who have access to confidential or patentable aspects of our research and development output, any of these parties may breach such agreements and disclose such output before a patent application is filed, jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries. Patent applications in China and other jurisdictions are typically not published until 18 months after application, or in some cases, not at all.

Furthermore, the PRC and the United States have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, even after reasonable investigation, we may still be unable to determine with certainty whether any of our products, services, processes, technologies, inventions, improvement and other related matters have infringed upon the intellectual property rights of others, because such third party may have

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filed a patent application without our knowledge while we are still developing that product or service, and the term of patent protection starts from the date the patent was filed, instead of the date it was issued. Therefore, the validity of issued patents, patentability of pending patent applications and applicability of any of them to our programs may be lower in priority than third-party patents issued on a later date if the application for such patents was filed prior to ours and the technologies underlying such patents are the same or substantially similar to ours. In addition, we may be involved in claims and disputes of intellectual property infringement in other jurisdictions, and the defense of these claims or disputes, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Moreover, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the China National Intellectual Property Administration (the “CNIPA”), for confidentiality examination. Otherwise, such patent application for an invention or utility model will not be granted if it is later filed in China. In addition, changes in patent law by the Standing Committee of the National People’s Congress (the “SCNPC”) may diminish the value of our patents.

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

Given the amount of time required for the development, testing and regulatory review of new product candidates or services under development, patents protecting such product candidates or services under development might expire before or shortly after such product candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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Failure to adequately protect our intellectual property rights may adversely affect our reputation and disrupt our business.

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

Our success depends, in part, on our ability to protect our proprietary technologies. We have built a comprehensive intellectual property portfolio in China and other overseas jurisdictions to protect our technologies, inventions and know-how and ensure our future success with commercializing our products and services. As of the Latest Practicable Date, we owned 72 granted patents in China, 28 pending patent applications in China, seven pending patent applications in the U.S. and five active PCT patent applications. For details, see “Business — Intellectual Property Rights” in this document. Due to the different regulatory bodies and varying requirements in these jurisdictions, we cannot assure you that we will be able to obtain patent protection for all or any aspects of our products and services in all or any of these jurisdictions. The process of seeking patent protection can be lengthy and expensive, and we cannot assure you that our patent applications will result in patents being issued, or that our existing or future issued patents will be sufficient to provide us with meaningful protection or commercial advantage. Since many of our current or potential competitors have substantial resources and have made substantial investments in competing technologies, we cannot assure you that they do not have, and will not obtain, patents that will prevent, limit or interfere with our ability to make, use or sell our products in either China or abroad. In addition, if we are unsuccessful in obtaining trademark protection for our primary brands, our business may be adversely affected. See “— 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” in this section.

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

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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.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our products and product candidates could be found invalid or unenforceable if being challenged in court or before the CNIPA or courts or related intellectual property agencies in other jurisdictions.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and

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potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

Defendant counterclaims alleging invalidity or unenforceability are commonplace, a third party can assert invalidity or unenforceability of a patent on numerous grounds. Third parties may also raise similar claims before administrative bodies in China or abroad, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we, our patent counsel, and the patent examiner could be unaware of invalidating prior art during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and financial penalties and may have to redesign or discontinue selling the affected products.

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves an analysis of complex legal and factual issues, the determination of which is often uncertain. We may be unaware of third-party patents or patent applications, and given the dynamic nature of the area in which we operate, additional patents are likely to be issued that relate to our business. We face the risk of claims that we have infringed on third parties' intellectual property rights in the countries where we operate, principally China. In addition, a number of our employees have previously worked for one or more of our competitors. There can be no assurance that such employees have not used, or will not use in the future, their previous employers' proprietary know-how or trade secrets in their work for us, which could result in litigation against us. Prior to developing major new products, we evaluate existing intellectual property rights. However, our competitors may also have filed for patent protection which is not as yet a matter of public knowledge or claim trademark rights that have not been revealed through our searches of relevant public records. Our efforts to identify and avoid infringing on third parties' intellectual

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property rights may not always be successful. Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Any claims of patent or other intellectual property infringement, even those without merit, could:

- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;
- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, if feasible;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management;
- result in hospitals and physicians terminating, deferring or limiting their purchase of the affected products until resolution of the litigation;
- reduce the resources available for our development activities or any future sales, marketing or distribution activities; or
- result in securities analysts or investors perceive these results to be negative, which could have a substantial adverse effect on the market price of our Shares.

In addition, new patents obtained by our competitors could threaten a product's continued life in the market even after it has already been introduced.

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, the USPTO and other patent agencies in several stages over the lifetime of the patent. The CNIPA, the USPTO 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.

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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. 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.

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

Depending on decisions by the SCNPC and the State Council, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The United States has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any.

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

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our products and product candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisers and other third parties. We also enter into employment agreements or consulting agreements with our employees and consultants that include undertakings regarding assignment of inventions and discoveries. However, non-disclosure agreements with employees, consultants, contractors and other parties may not adequately prevent disclosures of our trade secrets and other proprietary information. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party

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illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, some of our employees, including our senior management, were previously employed at other oncology molecular diagnostics and testing companies, including our competitors or potential competitors. Some of these employees may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any material threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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;

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- 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.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

Our revenues mainly rely on the provision of oncology molecular diagnostics and testing products and services. If we are unable to maintain the sales volumes, pricing levels or profit margins of our products and services, our business, financial condition and results of operations may be materially and adversely affected.

During the Track Record Period, a substantial amount of our revenue was derived from the provision of oncology molecular diagnostics and testing products and services, which include the provision of LDT services and the sale of IVD products. Our revenue generated from the provision of LDT services and the sale of IVD products accounted for 95.6%, 97.0% and 96.6% of our total revenue in 2020, 2021 and 2022, respectively.

However, we cannot assure you that demand for our oncology molecular diagnostics and testing products and services will achieve the anticipated levels. There is also no assurance that we will be able to achieve the expected sales and profit margin for our oncology molecular diagnostics and testing products and services, which may be adversely affected by many factors outside of our control, including downward pricing pressure caused by changes in market competition, expiration of patent protection, introduction of substitute products marketed by our competitors, disruptions in manufacturing or sales, issues with respect to product quality, coverage of medical insurance and disputes over intellectual property or other matters with third parties. In addition, the percentage of our revenue derived from each of our central laboratory business model and in-hospital model may vary from time to time, which, coupled

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with the uncertainty to the gross profit margin of each business model, may negatively affect our overall profitability. If we are unable to achieve the expected sales volumes, pricing levels or profit margins of our oncology molecular diagnostics and testing products and services, our business, financial condition and results of operations may be materially and adversely affected. Moreover, there is no guarantee that we may be able to develop or acquire new products and services that would diversify our product and service portfolio, or to do so in a timely or competitive manner.

We have consistently incurred net losses since our inception, and may continue to incur losses for the foreseeable future, and you may lose substantially all your investments in us given the high risks involved in the medical device business.

We are a commercial stage biotech company. Investment in medical device development entails substantial upfront capital expenditures and significant risk that a product candidate may fail to gain regulatory approval or become commercially viable, or a service under development may fail to become commercially viable. You may lose substantially all of your investments in our Company given the nature of the biotechnology industry. During the Track Record Period, we generated revenue from our commercialized IVD product, 16 LDT services and three IVD equipment and software products while at the meantime consistently incurred expenses related to our operations. As a result, in 2020, 2021 and 2022, we recorded net losses of RMB580.9 million, RMB406.9 million and RMB428.6 million, respectively, and operating losses of RMB210.8 million, RMB286.1 million and RMB416.7 million, respectively. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs, from costs of sales and from selling and marketing, and administrative expenses associated with our operations.

We expect that our financial performance will fluctuate from period to period due to the development status and the regulatory approval timeline of our product candidates, and the development status of our services under development. We may continue to incur losses for the foreseeable future. The size of our future net losses will depend, in part, on the number, scope and complexity of our product and service development programs and the associated costs of those programs, the cost of commercializing any service or approved products, our ability to generate revenues and other payments we make or receive with arrangements with third parties.

We are unable to predict when, or whether, we will be able to achieve or maintain profitability. In addition, we may not be able to generate revenues that are significant or sufficient enough to achieve profitability. 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 may impact investors’ perception of the potential value of our Group and could impair our ability to maintain and enhance our research and development efforts, continue our operations, raise capital or expand our business. You may lose all or part of your investment due to any decline in the value of our Group.

RISK FACTORS

We may need to obtain additional financing to fund our operations and we had net cash outflows from our operating activities during the Track Record Period. If we are unable to obtain that financing, we may be unable to complete the development and commercialization of our product candidates and services under development.

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

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

- revenue and cash generated from our commercialized products and services;
- selling and marketing costs associated with our products and services;
- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll subjects in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our product candidates;
- the number and characteristics of product candidates and services;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other product candidates and services under development;
- the cost and timing of development and completion of commercial-scale internal or outsourced, if any, manufacturing activities; and/or
- our headcount growth and associated costs.

RISK FACTORS

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

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 2022, the aggregate revenue generated from our five largest customers were RMB34.9 million, RMB61.4 million and RMB74.4 million, respectively, representing 11.4%, 15.7% and 17.1% of our revenue, respectively. Our five largest customers during the Track Record Period included hospitals, biotechnology companies and medical service centers. 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.

We had net current liabilities and net liabilities during the Track Record Period, which may expose us to liquidity risk.

We had net current liabilities of RMB1,365.8 million, RMB1,772.4 million and net current assets of RMB611.8 million as of December 31, 2020, 2021 and 2022, respectively, and may have net current liabilities in the future. We had net liabilities of RMB1,290.8 million, RMB1,640.6 million and RMB2,045.4 million as of December 31, 2020, 2021 and 2022, respectively, and may have net liabilities in the future. Our net liabilities position as of December 31, 2020, 2021 and 2022 was primarily attributable to the issuance of Series Angel, A, B, C-1, C-2, D and E redeemable preferred shares, which were classified as financial liabilities at FVTPL in an amount of RMB2,562.9 million, RMB2,722.1 million and RMB2,787.4 million as of December 31, 2020, 2021 and 2022, respectively. For details, see “Financial Information — Indebtedness — Financial Liabilities at Fair Value Through Profit or Loss” and Note 28 to the Accountants’ Report in Appendix I to this document. A net current liabilities position may expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources including the [REDACTED], and/or other sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all. Any difficulty or failure to meet our liquidity needs as and when needed may have a material adverse effect on our business, financial condition, results of operations and prospects.

RISK FACTORS

We are subject to credit risk in collecting trade and bills receivables from our customers and recover prepayments, other receivables and other assets.

Our cash flow and profitability would be affected by the timely settlement of payments by our customers. Our trading terms with customers are mainly on credit, except for individual customers, where payment in advance is normally required. The credit period is generally from one month to six months. On a very selected basis, credit terms for certain major customers may be extended, if such customers specifically request for longer credit terms on reasonable grounds such as internal approval requirements for public hospitals, and if we determine that they are creditworthy customers. As of December 31, 2020, 2021 and 2022, our trade and bills receivables were RMB34.2 million, RMB72.3 million and RMB102.5 million, respectively. The average turnover days of our trade and bills receivables (eliminating the impact of revenue from the central laboratory business received in advance) for the same periods were 131 days, 205 days and 231 days, respectively. 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. 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 the effective distribution of our products. Therefore, we may be exposed to credit risk in relation to our customers.

In addition, there are uncertainties about the recoverability of our prepayments, other receivables and other assets which primarily included prepayments, [REDACTED], other receivables and value-added tax recoverable. As of December 31, 2020, 2021 and 2022, our prepayments, other receivables and other assets were RMB36.2 million, RMB52.8 million and RMB74.1 million, respectively. However, there is no guarantee that the suppliers and service providers will perform their obligations in a timely manner and we are subject to credit risk in relation to prepayments, other receivables and other assets. We conduct assessments on the recoverability of prepayments, other receivables and other assets based on, among others, our historical settlement records, our relationship with relevant counterparties, payment terms, current economic trends and to a certain extent, the larger economic and regulatory environment, which involve the use of various judgments, assumptions and estimates by our management. However, there is no assurance that our expectations or estimates will be entirely accurate for the future, as we are not in control of all the underlying factors affecting such prepayments, other receivables and other assets. Therefore, if we are not able to recover the prepayments, other receivables and other assets as scheduled, our financial position and results of operations may be adversely affected.

Fair value changes for our financial assets measured at fair value through profit or loss may materially affect our financial condition and results of operations.

During the Track Record Period, we purchased short-term and low-risk structured deposits and wealth management products issued by banks in China, which were recorded as financial assets at FVTPL. As of December 31, 2020, 2021 and 2022, we had financial assets at FVTPL of RMB1,173.1 million, RMB894.5 million and RMB95.3 million, respectively. The fair value of such financial assets is estimated by discounting the future contractual cash flows

RISK FACTORS

at the market interest rate available to us for similar financial instruments. The estimation of our financial assets at FVTPL primarily uses unobservable inputs, such as the expected rate of return of the structured deposits and wealth management products. This requires our management to make estimates about expected future cash flows, credit risk, volatility and discount rates, and hence they are subject to uncertainty. As a result, such treatment of carrying amounts of our financial assets measured at FVTPL may cause significant volatility in or materially and adversely affect our period-to-period earnings, financial condition and results of operations.

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

As of December 31, 2022, we had intangible assets of RMB7.4 million, which comprised software, licenses and patents. Our determination on whether intangible assets are impaired requires an estimation on recoverable amount of the 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 the intangible assets may exceed its recoverable amount, our intangible assets may be impaired. Any significant impairment of 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 Notes 2.4 and 16 to the Accountants’ Report in Appendix I to this document.

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 new medical equipment development and funds for talents received from the local governments. In 2020, 2021 and 2022, we recognized government grants as other income of RMB4.3 million, RMB6.9 million and RMB5.7 million, respectively. For further details of our government grants, see “Financial Information — Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income — Other Operating Income” in this document. Moreover, our growth has also been supported by favorable government policies. 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. 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. 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.

RISK FACTORS

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

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

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

We adopted the Share Award Plan on March 11, 2022 to attract and retain talents and to promote the success of our business. For details, see “D. Share Award Plan” in Appendix IV to this document. In 2020, 2021 and 2022, we incurred share-based payments expenses of RMB60.3 million, RMB57.8 million and RMB112.4 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional restricted share units or restricted shares in the future. Issuance of additional Shares with respect to such restricted share units or restricted shares may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such restricted share units or restricted shares may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

RISKS RELATING TO OUR OPERATIONS

Our future success depends on our ability to retain executives, key personnel in research and development, sales and marketing team and other consultants and to attract, hire, retain and motivate qualified personnel.

Our business and growth depend on the continued service of our senior management and personnel in our research and development team to develop product candidates and our sales and marketing team to promote our products. Although we have formal employment agreements with each of our employees, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

RISK FACTORS

In addition, we rely on consultants and advisers, including scientific and clinical advisers, to assist us in formulating our discovery, clinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

To induce valuable employees to remain at our Company, in addition to salary and cash incentives, we have provided share awards to our employees. The value to employees of these equity grants may be significantly affected by movements in the Share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, any of our employees could leave our employment at any time, with or without notice.

Furthermore, replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous medical device companies for similar personnel.

We also experience competition for the hiring of research and development and clinical personnel from universities, research institutions, government entities and other organizations. Our consultants and advisers may be engaged by our competitors and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

We were founded in 2014. Our operations to date have focused on business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials of our product candidates and the commercialization of our products and services. For our IVD reagent business, other than Genecast IVD – KNBP, we have not yet obtained regulatory approvals for our other product candidates, and have not manufactured any products other than Genecast IVD – KNBP on a commercial scale.

As a result of our limited operating history, and particularly in light of the rapidly evolving nature of the rapidly evolving oncology molecular diagnostics and testing field, it may make it difficult to evaluate our current business and reliably predict our future performance. Our historical results may not provide a meaningful basis for evaluating our business, financial condition, results of operation and future prospects, and we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors, and may not be able to achieve promising results in future periods. If we cannot address these risks and overcome these difficulties successfully, our business and prospects will suffer.

RISK FACTORS

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

As we seek to advance our product candidates through clinical trials and commercialization, and further our commercialization of approved products, we plan to continue to expand our development, manufacturing, marketing and sales capabilities. For details, see “Business — Our Strategies” in this document. The success of our growth strategy will depend on, among other things, our ability to continue to innovate and develop advanced technologies in the highly competitive oncology molecular diagnostics and testing market in China and globally, maintain our efficient operating model, attract and retain skilled personnel who have the specialized skills needed to design, develop and manufacture oncology molecular diagnostics and testing products, obtain and maintain regulatory approvals and effectively market our products and services using our own sales and marketing team. However, we have limited operational, administrative and financial resources, which may be inadequate to sustain the growth we seek to achieve. In particular, in order to implement our growth strategy, we will need to increase our investment in, among other things, our research and development, manufacturing facilities, marketing and other areas of operations. If we are unable to manage our growth and expansion effectively, our business may be adversely affected.

The oncology molecular diagnostics and testing industry in China is rapidly evolving, and we may be unable to maintain or enhance our market share in this industry for a variety of reasons.

The oncology molecular diagnostics and testing industry in China is rapidly evolving due to economic growth in China, changes in government policies and funding levels and other factors discussed in this document. We invest in research and development activities, build our own robust marketing and sales workforce, establish relationships with hospitals and physicians, as well as adjust our prices from time to time depending on market conditions. However, the industry we operate in is highly competitive. See “— Key Risks Relating to Our Business and Industry — We face substantial competition and rapid market changes, which may result in others discovering, developing or commercializing competing products and services before or more successfully than we do, or respond and adapt to the market changes more quickly and effectively.” in this section.

Our inability to adequately respond to market changes could have a material adverse effect on our market position, and our reputation may be materially and adversely affected which could adversely affect our relationships with physicians and hospital administrators and our long-term ability to effectively market and sell our products or conduct clinical trials for our new products. In this regard, our business, financial condition and results of operation may be materially and adversely affected.

RISK FACTORS

We may be unable to develop and commercialize our product candidates as anticipated if the third parties with which we contract for clinical trials do not successfully carry out their contractual duties or meet expected deadlines.

We rely on third parties, including leading academic institutions, public hospitals, CROs, SMOs and clinical audit firms, among others, to assist us in designing, implementing and monitoring our preclinical research and conducting clinical trials. As of the Latest Practicable Date, we worked with 836 hospitals. As of the Latest Practicable Date, we worked with four CROs and four SMOs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and do not control all aspects of their activities. If any of these parties terminates its agreements with us, we may not be able to enter into arrangements with alternative third parties that meet our standards, or on commercially reasonable terms, or at all, and the development of the product candidates covered by those agreements could be substantially delayed. In addition, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocols, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us from our regulatory responsibilities. However, these third parties may not successfully carry out their contractual obligations, meet expected deadlines or follow clinical and manufacturing guidelines and protocols. Moreover, if any of these parties fail to perform their obligations under our agreements with them in the manner specified in those agreements, the NMPA and/or other comparable regulatory authorities may not accept the data generated by those studies or may require us to perform additional clinical trials before approving our marketing applications, which would increase the cost of and the development time for the relevant product candidate. If any of the pre-clinical studies or clinical trials of our product candidates is affected by any of the above-mentioned reasons, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business and prospects.

We have entered into collaborations, and may establish or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may from time to time establish or seek strategic alliances, form joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and services under development and any future product candidates and services that we may develop.

For any products or product candidates that we may seek to in-license from third parties, we may face significant competition from other medical device companies with greater resources or capabilities than us, and any agreement that we do enter may not result in the anticipated benefits.

RISK FACTORS

Further, collaborations involving our products, services, product candidates and services under development are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or services under development or may elect not to continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new design of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products and services that compete directly or indirectly with our products, services, product candidates or services under development;
- a collaborator with marketing and distribution rights to one or more products and services may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates and services under development, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates and services under development; and/or
- collaborators may own or co-own intellectual property covering our products and services that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, we may not be able to realize the benefit of current or future collaborations, strategic partnerships or the license of our third-party products if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate or service under development, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund

RISK FACTORS

and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

If we cannot maintain relationships with our key business partners, or cannot establish or seek more collaborations and strategic alliances in the future, our results of operations and prospects could be adversely affected.

We may from time to time establish or seek strategic alliances, form joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our products and services and any future products and services that we may develop. We collaborate with certain key business partners in many aspects of our business, such as major hospitals in China, global life sciences and biotechnology companies in the industry and academic institutions. Our success in part depends on our ability to maintain our relationships with our key business partners and establish new collaborations in the future. Collaborations with our key business partners are subject to numerous risks, which may include the following:

- our key business partners may no longer be as competitive in the market as they are now;
- our key business partners have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- our key business partners may not pursue development and commercialization of our products and services or may elect not to continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to the acquisition of competitive products and services, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- our key business partners may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product, repeat or conduct new clinical trials, or require a new design of a product for clinical testing;
- our key business partners could independently develop, or develop with third parties, products and services that compete directly or indirectly with our products and services;
- our key business partners with marketing and distribution rights to one or more products and services may not commit sufficient resources to their marketing and distribution;
- our key business partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

RISK FACTORS

- disputes may arise between us and key business partners that cause the delay or termination of the research, development or commercialization of our products and services, or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products and services.

Acquisitions or strategic partnerships may increase our capital requirements, dilute our Shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

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

- increased operating expenses, including research and development expenses due to an increased number of product candidates, administrative expenses as well as selling and distribution expenses, which result in an increased cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products and product candidates and regulatory approvals;
- 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; and/or
- deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in the acquired business we discover after such acquisition, which may subject us to penalties, lawsuits or other liabilities.

Further, any difficulties in the integration of acquired businesses, product or technologies or unexpected penalties, lawsuits or liabilities in connection with such businesses, product or technologies could have a material adverse effect on our reputation, business, financial condition and results of operation. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

RISK FACTORS

If we fail to maintain effective internal controls, 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 trading 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.

If we become subject to litigation, legal or contractual disputes, governmental investigations or administrative proceedings, our management's attention may be diverted and we may incur substantial costs and liabilities.

We may from time to time become subject to various litigation, legal or contractual disputes, investigations or administrative proceedings arising in the ordinary course of our business, including but not limited to various disputes with or claims from our suppliers, customers, licensors, contractors, business partners and other third parties that we engage for our business operations. On-going or threatened litigation, legal or contractual disputes, investigations or administrative proceedings may divert our management's attention and consume their time and our other resources. In addition, any similar claims, disputes or legal proceedings involving us or our employees may result in damages or liabilities, as well as legal and other costs and may cause a distraction to our management. Furthermore, any litigation, legal or contractual disputes, investigations or administrative proceedings which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. 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. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

RISK FACTORS

We could be subject to criminal sanctions or civil and administrative penalties if we violate any applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in 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 and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》). These laws may impact, among other things, our proposed sales, marketing and education programs. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC government.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, we are subject to equivalents of each of the healthcare laws described above in other jurisdictions, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. There are ambiguities as to what is required to comply with these requirements, and if we fail to comply with an applicable law requirement, we could be subject to penalties.

If any of the physicians 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.

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If our employees engage in bribery, money laundering, corrupt practices or other improper conduct, we may be subject to liability and our reputation and business could be harmed.

We are subject to the anti-bribery laws of various jurisdictions, particularly in China. As our business expands, the applicability of the applicable anti-bribery laws to our operations has increased. Our procedures and controls to monitor compliance with anti-bribery law may fail to protect us from reckless or criminal acts committed by our employees or agents. We could be liable for actions taken by our employees that violate anti-bribery, anti-money laundering, anti-corruption and other related laws and regulations in China or other countries. The government authorities may seize the products involved in any illegal or improper conduct engaged in by our employees. We may be subject to claims, fines or suspension of our operations. Our reputation, our sales activities or the price of our Shares could be adversely affected if our Company is associated with any negative publicity as a result of illegal or improper actions, or allegations of illegal or improper actions, taken by our employees.

It is also possible that the Chinese government or other government authorities in countries where we sell our products could adopt new or different regulations affecting the way in which medical devices are sold to address bribery, money laundering, corruption or other concerns. Any such new or different regulations could possibly increase the costs incurred by us, our employees in selling our products or impose restrictions on sales and marketing activities, which could in turn increase our costs. Any changes in the regulatory environment regarding the sale of medical devices could have a material adverse impact on our business, financial condition and results of operations.

If we or our business partners fail to protect patient data and privacy, our reputation will be damaged and we might be subject to fines or other regulatory punishments.

During the process of clinical trials, we need to collect and store a large quantity of patients’ personal data and information, which require us and our third-party vendors such as clinical trial institutions, hospitals, CROs and SMOs to maintain an effective control system to protect such personal data and information. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. Whilst we have adopted security policies and measures to protect our proprietary data and patients’ privacy, misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of personal data might not be avoided due to human error, employee misconduct or system breakdown. We also cooperate with third parties including principal investigators, hospitals, CROs and SMOs for our clinical trials. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data,

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could cause our customers to lose trust in us and could expose us to legal claims. Whilst we have made efforts to ensure our compliance with the applicable privacy regulations in the relevant jurisdictions, we may not be capable of adjusting our internal policies in a timely manner and any failure to comply with applicable regulations could also result in regulatory enforcement actions against us.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, manufacturing facilities and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable chemical materials and special equipment. Our operations also produce hazardous waste. We have entered into hazardous waste disposal agreements with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We could also incur significant costs associated with civil or criminal fines and penalties.

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 internal computer systems may fail or suffer security breaches. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses and unauthorized access. 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 manage and maintain our applications and data utilizing on-site systems and outsourced vendors. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or vendors that

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provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as physical or electronic break-ins, employee errors, computer viruses and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

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. 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. 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 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

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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 have limited insurance coverage to adequately cover all the risks and hazards associated with our 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 insurance for all of our employees, property insurance and personal accident insurance. For details, see "Business – Insurance" in this document. 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.

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

Our reputation and customer perception of our brand are critical to our business. Maintaining and enhancing our reputation and recognition depend primarily on the quality and consistency of our products, as well as continued promotion efforts. Our promotion efforts may be expensive and ineffective. In addition, our reputation and customer perception of our Company could suffer in events that (i) our products and services fail to gain acceptance by customers, physicians and hospitals; (ii) our products are defective or malfunction; (iii) lawsuits or regulatory investigations are instituted against us or relating to our products and services or industry; (iv) we provide poor or ineffective customer service; or (v) we are subject to product liability claims.

If we are unable to maintain and further enhance our reputation and recognition, our ability to attract and retain customers may be impeded and our business prospects may be materially adversely affected. Any negative incident or negative publicity concerning us, our products and services, our management and our employees, regardless of its veracity, could harm our image and diminish the trust from our customers and the market, which could in turn result in decreased sales of our products and services and materially and adversely affect our business. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our investors and customers.

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If we fail to implement our expansion strategies effectively, our business, financial condition and results of operations may suffer.

As part of our business strategy, we intend to rapidly expand our product and service pipeline through our understanding of clinical pain points gained by our internal independent research and development and to capitalize on our leading business and clinical development capabilities to pursue external in-licensing opportunities. For more details, see “Business — Our Strategies” in this document. Generally, we are subject to the following risks associated with our expansion strategy:

- significant demands on our management’s time and attention and diversion of resources from our expansion may be costly and time-consuming and may require us to obtain third party financing, which may not be available on commercially acceptable terms;
- uncertainties associated with the local rules and regulations which we may not be familiar with;
- failure to achieve the expected operating levels, target return on investment or intended benefits or operating synergies from new business opportunities; and/or
- our due diligence may not uncover all unknown or contingent liabilities or other negative developments with respect to acquired targets.

There is no assurance that our expansion strategies will be successful. To manage and support our growth, we may need to improve our existing operational and administrative systems, as well as our financial and management controls. If we fail to expand at our expected pace, we may face capacity constraints in the future which may adversely affect our business and financial condition. We also need to continue to properly maintain our relationships with our suppliers and customers. All of these endeavors will require substantial management attention and efforts and significant additional expenditures.

We cannot assure you that we will be able to manage any future growth effectively and efficiently, and any failure to do so may materially and adversely affect our ability to capitalize on new business opportunities, which in turn may have a material and adverse effect on our business, financial condition and results of operations.

If we fail to effectively expand our international business, our business prospects may be adversely affected.

We have rights of our products, services, product candidates and services under development in China and overseas through patent registration and protection over proprietary technologies. We plan to enter into partnership arrangements to expand our market coverage and maximize the global value of our products and services. However, our limited experience in overseas markets may expose us to risks and uncertainties, including but not limited to the risks associated with the following:

- dealing with regulatory regimes, regulatory bodies and government policies which may differ materially from those in the PRC or with which we may be unfamiliar;

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- substantial time which may be required for us to obtain approval for registering and selling our products and services in additional countries, especially in developed countries;
- commercializing our products and services in new markets where we have limited experience with the dynamics and no sales and marketing infrastructure;
- higher costs for new product and service development and reliance on overseas partners for the development, commercialization and marketing of our products and services;
- product and professional liability litigation and regulatory scrutiny arising from the marketing and sale of products in overseas markets and the costs incurred dealing with such procedures, as well as our ability to obtain insurance to adequately protect us from any resulting liabilities;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness and inflation;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

We may also rely on third parties to conduct clinical trial for registration purpose or apply for regulatory approval overseas. If such parties fail to conduct the trials properly or to meet satisfactory clinical results, or fail to obtain regulatory approval for us, our business may be materially and adversely affected.

We do not own any real property and may incur substantial relocation expenses, subject to fines 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 or is not registered with relevant governmental authority.

We do not own any real property for our operations. As of the Latest Practicable Date, we leased an aggregate area of 19,489 sq.m. in Beijing, Shanghai, Taizhou, Wuhan and Wuxi. Upon expiration of the leases, we will need to negotiate for renewal of the leases and may have to pay increased rent. We cannot assure you that we will be able to renew our leases on terms which are favorable or otherwise acceptable to us, or at all. If we fail to renew any of our leases or if any of our leases are terminated or if we cannot continue to use any of our leased property, we may need to seek an alternative location and incur expenses related to such relocation, and our operation and businesses may also be disrupted or even suspended if we are not able to complete the relocation, including the reconstruction of relevant facilities in the new location, in a timely manner.

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In addition, as of the Latest Practicable Date, certain of our lease agreements had not been registered with the relevant regulatory authorities. Under the relevant PRC laws and regulations, failure to register such lease agreements with the relevant PRC government authorities does not affect the validity and enforceability of such lease 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 within 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.

Moreover, with respect to our manufacturing facilities in Taizhou, although we have completed the acceptance procedure of environmental protection and published such environmental protection acceptance report as required, we may be deemed as not completing such acceptance procedure in time. If we are deemed as not being fully compliant with relevant laws and regulations on environmental protection, we may be subject to fines and/or other administrative actions, which may have a material adverse effect on our business, financial condition and results of operations.

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

Sentiment and distrust by customers of the use of genetic testing may lead to less demand for our products and services. 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 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 customers to refuse to use, or physicians to be reluctant to order, genetic tests even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our products and services or reduce demand for such products and services, either of which could have a material adverse effect on the business, financial condition and results of operations.

RISKS RELATING TO OUR CORPORATE STRUCTURE AND CONTRACTUAL ARRANGEMENTS

We conduct the Relevant Businesses in the PRC through our Consolidated Affiliated Entities by way of Contractual Arrangements, and if the PRC government finds that these Contractual Arrangements 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 penalties or be forced to relinquish our interests in those operations.

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, and oncology clinic business, to which our Relevant Business are relevant. Pursuant to the Special Administrative Measures (Negative

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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 restricted for foreign investment, including the development and application of technologies for diagnosis and treatment of human stem cells and genes and oncology clinic business. To comply with PRC laws and regulations, we conduct our Relevant Business in China through our Consolidated Affiliated Entities.

We are a company incorporated under the laws of the Cayman Islands, and Genecast WFOE is therefore considered a foreign-invested enterprise. To comply with PRC laws and regulations, we currently conduct a majority portion of our business in the PRC through our Consolidated Affiliated Entities, through a series of Contractual Arrangements by and among our Genecast WFOE, our Consolidated Affiliated Entities, as well as the Registered Shareholders. The Contractual Arrangements enable us to (i) have the power to direct the activities that most significantly affect the economic performance of the Consolidated Affiliated Entities; (ii) receive substantially all of the economic benefits from the Consolidated Affiliated Entities in consideration for the services provided by Genecast WFOE; and (iii) have an exclusive option to purchase all or part of the equity interest in the Consolidated Affiliated Entities when and to the extent permitted by PRC law or request any existing shareholders of the Consolidated Affiliated Entities to transfer any or part of the equity interest in the relevant Consolidated Affiliated Entity to another PRC person or entity designated by us at any time at our discretion. Because of the Contractual Arrangements, we are the primary beneficiary of the Consolidated Affiliated Entities and consolidate the results of operations of the Consolidated Affiliated Entities into ours. Our Consolidated Affiliated Entities hold certain licenses, approvals and key assets that are essential for our business operations.

If the PRC government finds that our Contractual Arrangements do not comply with its restrictions on foreign investment in the Relevant Businesses, or if the PRC government otherwise finds that we, the Consolidated Affiliated 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 but not limited to MOFCOM, NMPA and NHC, 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 and/or confiscating any of our income that they deem to have been obtained through illegal operations;
- imposing conditions or requirements with which we or Genecast WFOE and Consolidated Affiliated Entities may not be able to comply;
- requiring us or Genecast WFOE and Consolidated Affiliated Entities to restructure the relevant ownership structure or operations;
- restricting or prohibiting our use of the [REDACTED] from the [REDACTED] or our other financing activities to finance the business and operations of our Consolidated Affiliated Entities; or
- taking other regulatory or enforcement actions that could be harmful to our business.

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Furthermore, any of the assets under the name of any Registered Shareholder, including its equity interest in our Consolidated Affiliated Entities, may be put under court custody in connection with litigation, arbitration or other judicial or dispute resolution proceedings against such Registered Shareholder. We cannot ensure that such equity interest will be disposed of in accordance with the Contractual Arrangements. 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 the Consolidated Affiliated Entities in our consolidated financial statements, if the PRC governmental authorities find our legal structure and 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 Consolidated Affiliated Entity that most significantly impact its economic performance and/or our failure to receive the economic benefits from the Consolidated Affiliated Entities, we may not be able to consolidate the Consolidated Affiliated Entities into our consolidated financial statements in accordance with the IFRS.

Certain provisions in the Contractual Arrangements through which we conduct our business operations in the PRC may not be enforceable under PRC laws.

All the agreements under the Contractual Arrangements are governed by PRC laws. The uncertainties in the PRC legal system could limit our ability to enforce our Contractual Arrangements. In the event that we are unable to enforce the Contractual Arrangements, or if we suffer significant time delays or other obstacles in the process of enforcing them, it would be very difficult to exert effective control over the Consolidated Affiliated Entities, and our ability to conduct our business and our financial condition and results of operations may be materially and adversely affected.

Under the dispute resolution provisions of the agreements under the Contractual Arrangements, in the event of any dispute relating to the Contractual Arrangements, any party may submit the relevant dispute to the Beijing Arbitration Commission for arbitration, in accordance with the then effective arbitration rules and procedures. The Contractual Arrangements also contain provisions to the effect that the arbitration tribunal may grant any remedies in accordance with the relevant agreement and applicable PRC laws, including preliminary and permanent injunctive relief (such as injunctions against carrying out business activities, or mandating the transfer of assets), remedies concerning the equity interest or assets of our Consolidated Affiliated Entities and awards directing it to conduct liquidation. However, under PRC laws, an arbitral body normally would not grant injunctive relief or winding up order of the Consolidated Affiliated Entities. Interim remedies or enforcement orders granted by overseas courts such as the courts of Hong Kong and the Cayman Islands also may not be enforceable under PRC laws. For details of the enforceability of the Contractual Arrangements, see “Contractual Arrangements — Summary of Material Terms of the Contractual Arrangements — Common Terms of the Contractual Arrangements — Dispute Resolution” in this document. Therefore, in the event that the Consolidated Affiliated Entities or their shareholders breach any of the Contractual Arrangements, we may not be able to obtain sufficient remedies in a timely manner, and our ability to exert effective control over our Consolidated Affiliated Entities and conduct our business could be materially and adversely affected.

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Substantial uncertainties exist with respect to the interpretation and implementation of the PRC Foreign Investment Law, its implementation regulations and how they may impact the viability of our current corporate structure, business, financial condition and results of operations.

The “variable interest entity” structure, or the VIE structure has been adopted by many China-based companies, including us, to obtain licenses and permits necessary to operate in industries that currently are subject to restrictions on or prohibitions for foreign investment in China. In March 2019, the National People’s Congress (the “NPC”) promulgated the Foreign Investment Law (《中華人民共和國外商投資法》), or the PRC Foreign Investment Law, which became effective from January 1, 2020 and has replaced major existing laws and regulations governing foreign investment in the PRC. In December 2019, the State Council promulgated the Implementing Rules of the Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法實施條例》), or the Implementing Rules, to further clarify and elaborate upon relevant provisions of the PRC Foreign Investment Law. For details, see “Regulatory Overview — Regulations Relating to Foreign Investment” in this document. The PRC Foreign Investment Law and the Implementing Rules do not use the concept of “control” in determining whether a company should be considered as a foreign-invested enterprise, nor do they explicitly classify the VIE structure as a method of foreign investment. However, the PRC Foreign Investment Law has a catch-all provision that broadly defines “foreign investments” as those made by foreign investors in China through other methods as specified in laws, administrative regulations, or as stipulated by the State Council. Due to this broad definition of “foreign investments,” since the PRC Foreign Investment Law and the Implementing Rules are newly adopted and relevant government authorities may promulgate additional rules and regulations as to the interpretation and implementation of the PRC Foreign Investment Law, there can be no assurance that the VIE structure adopted by us will not be deemed as a method of foreign investment by other laws, regulations and rules. Accordingly, there are substantial uncertainties as to whether our VIE structure may be deemed as a method of foreign investment in the future. If our VIE structure were to be deemed as a method of foreign investment under any future laws, regulations and rules, and if any of our business operations were to fall under the “negative list” for foreign investment, we would need to take further actions in order to comply with these laws, regulations and rules, which may materially and adversely affect our current corporate structure, business, financial condition and results of operations.

In an extreme scenario, we may be required to unwind the Contractual Arrangements and/or dispose of the Consolidated Affiliated 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 price of our Shares may significantly drop, and the Stock Exchange may take enforcement actions against us which may have a material adverse effect on the trading of our Shares or even result in the [REDACTED] of our Company.

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In addition, if our VIE structure were to be deemed as a method of foreign investment under the PRC Foreign Investment Law or any other laws, regulations and rules, and if any of our business operations were to fall under the “negative list” for foreign investment, we would need to take further actions in order to comply with these laws, regulations and rules, which could also materially and adversely affect our current corporate structure, business, financial condition and results of operations.

Our Contractual Arrangements may not be as effective in providing operational control as direct ownership, and the Consolidated Affiliated Entities or Registered Shareholders may fail to perform their obligations under our Contractual Arrangements.

Due to the PRC restrictions or prohibitions on foreign ownership of the Relevant Businesses in China, we operate a majority portion of our business in China through our Consolidated Affiliated Entities, and we rely on a series of Contractual Arrangements with the Consolidated Affiliated Entities and the Registered Shareholders to control and operate the Relevant Business. For more details of these Contractual Arrangements, see “Contractual Arrangements” in this document.

These Contractual Arrangements may not be as effective in providing control over Consolidated Affiliated Entities as direct ownership. If the Consolidated Affiliated Entities fail to perform their respective obligations under the Contractual Arrangements, we may incur substantial costs and expend substantial resources to enforce our rights. All of these Contractual Arrangements are governed by and interpreted in accordance with PRC laws, and disputes arising from these Contractual Arrangements will be resolved through arbitration in China. However, the legal system in China is not as developed as in other jurisdictions, such as the United States. 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 these Contractual Arrangements. In the event we are unable to enforce these Contractual Arrangements, or we experience significant delays or other obstacles in the process of enforcing these Contractual Arrangements, we may not be able to exert effective control over our Consolidated Affiliated Entities and may lose control over the assets owned by our Consolidated Affiliated Entities. As a result, we may be unable to consolidate our Consolidated Affiliated Entities in our consolidated financial statements and our ability to conduct our business may be negatively affected.

We may lose the ability to use and enjoy licenses, approvals and assets held by our Consolidated Affiliated Entities that are material to our business operations if our Consolidated Affiliated 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 Consolidated Affiliated Entities. If any of our Consolidated Affiliated Entities undergoes an involuntary liquidation proceeding, third-party creditors may claim rights to some or all of its assets and we may not

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have priority over such third-party creditors on the assets of our Consolidated Affiliated Entities. If any of our Consolidated Affiliated Entities liquidate, we may take part in the liquidation procedures as a general creditor under the PRC Enterprise Bankruptcy Law (《中華人民共和國企業破產法》) and claim any outstanding liabilities owed by such Consolidated Affiliated Entity to our Genecast WFOE under the exclusive business cooperation agreement, along with other general creditors.

If the Registered Shareholders of our Consolidated Affiliated Entities were to attempt to voluntarily liquidate our Consolidated Affiliated Entities without obtaining our prior consent, we could effectively prevent such unauthorized voluntary liquidation by exercising our right to request the Registered Shareholders of our Consolidated Affiliated 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 Consolidated Affiliated Entities. In addition, under the Contractual Arrangements signed by, among others, Genecast WFOE, the Consolidated Affiliated Entities and the Registered Shareholders, the Registered Shareholders do not have the right to receive dividends or retained earnings or other distributions from the Consolidated Affiliated Entities without our consent. 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 Consolidated Affiliated 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 may potentially have a conflict of interest with us, and they may breach their contractual arrangements with us or cause such arrangements to be amended in a manner contrary to our interests.

The Registered Shareholders may potentially have a conflict of interest with us, and they may breach their Contractual Arrangements with us. There can be no assurance that the Registered Shareholders of the Consolidated Affiliated Entities will always act in our best interests should any conflicts of interest arise, or that any conflicts of interest will always be resolved in our favor. There also can be no assurance that the Registered Shareholders will ensure that the Consolidated Affiliated Entities will not breach the Contractual Arrangements. If we cannot resolve any of these conflicts of interest or any related disputes, we would have to rely on legal proceedings to resolve these disputes and/or take enforcement action under the Contractual Arrangements. There is substantial uncertainty as to the outcome of any of these legal proceedings. See “— Our Contractual Arrangements may not be as effective in providing operational control as direct ownership, and the Consolidated Affiliated Entities or Registered Shareholders may fail to perform their obligations under our Contractual Arrangements” in this section.

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

Pursuant to the Contractual Arrangements, Genecast WFOE or its designated person(s) has the irrevocable and exclusive right to purchase all or any part of the equity interests in the Consolidated Affiliated Entities from the Registered Shareholders at any time and from time to time in Genecast WFOE’s absolute discretion to the extent permitted by PRC laws. The consideration shall be the lowest price as permitted under applicable PRC laws. In addition, under the Contractual Arrangements, Genecast WFOE or its designated person(s) has the irrevocable and exclusive right, where permitted by PRC law, to purchase from the Consolidated Affiliated Entities all or any part of its equity interests and assets, and the purchase price shall be the lowest price as permitted under applicable PRC laws.

The transfer of equity or assets may be subject to the approvals from SAMR and report submission through the online enterprise registration system to or filings with the MOFCOM, other competent governmental authority and/or their local competent counterparts. In addition, the transfer price may be subject to review and tax adjustment by the relevant tax authorities. The Registered Shareholders will pay the transfer price they receive Consolidated Affiliated Entities or Genecast WFOE under the contractual arrangements. The transfer price to be received by our Consolidated Affiliated Entities under the Contractual Arrangements may also be subject to enterprise income tax, and these amounts could be substantial.

Our 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 investment.

Under applicable 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 adverse tax consequences if the PRC tax authorities determine that the Contractual Arrangements signed by, among others, Genecast WFOE, the Consolidated Affiliated Entities and the Registered Shareholders are not at arm’s-length and adjust Genecast Technology’s 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 Genecast Technology, which could in turn increase its tax liabilities without reducing our tax liabilities. In addition, the PRC tax authorities may impose late payment fees and other penalties to the Consolidated Affiliated Entities for under-paid taxes. Our consolidated net loss may be increased if our tax liabilities increase or if we are found to be subject to late payment fees or other penalties.

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RISKS RELATING TO DOING BUSINESS IN CHINA

The medical device industry in China is highly regulated and such regulations are subject to changes, which may adversely affect our business.

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

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

We are headquartered in Wuxi, China and have major subsidiaries and Consolidated Affiliated Entities in Beijing, Shanghai, Taizhou, Tianjin and Wuhan, China. 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, and control of foreign exchange and allocation of resources.

While the PRC economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. The Chinese government implements various measures intended to encourage economic growth and guide the allocation of resources. These measures may include differential policies towards specific groups of pharmaceutical companies, such as promotion of traditional medicines or state-owned companies, which may have an adverse effect on us. Our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are applicable to us. Further, any adverse change in the economic conditions or government policies in China could have a material adverse effect on overall economic growth and the level of healthcare investments and expenditures in China, which in turn could lead to a reduction in demand for our products and consequently have a material adverse effect on our business.

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

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

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.

The approval, filing or other requirements of the CSRC or other PRC government authorities may be required in connection with this [REDACTED] under PRC laws. Furthermore, the PRC government has recently indicated an intent to exert more oversight and control over overseas securities [REDACTED] and other capital markets activities and foreign investment in China-based companies like us. Any such action, once taken by the PRC government, could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or in extreme cases, become worthless.

According to the M&A Rules, an overseas special purpose vehicle formed for [REDACTED] purposes through acquisitions of PRC domestic companies and controlled by PRC persons or entities shall obtain the approval of the CSRC prior to the [REDACTED] of such special purpose vehicle’s securities on an overseas stock exchange.

On December 24, 2021, the CSRC issued the Provisions of the State Council on the Administration of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (《國務院關於境內企業境外發行證券和上市的管理規定(草案徵求意見稿)》) (the “**Draft Overseas Listing Administration Provisions**”) and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (《境內企業境外發行證券和上市備案管理辦法(徵求意見稿)》) (the “**Draft Overseas Listing Filing Measures**”), which were open for public comments until January 23, 2022. The Draft Overseas Listing Administration Provisions and the Draft Overseas Listing Filing Measures comprehensively improved and reformed the exiting regulatory system for overseas [REDACTED] of domestic companies, and brought all overseas [REDACTED] activities including both direct and indirect overseas [REDACTED] under regulation by adopting a filing-based administration system.

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As of the Latest Practicable Date, the Draft Overseas Listing Administration Provisions and the Draft Overseas Listing Filing Measures have not yet come into effect. The interpretation, application and enforcement of the regulations remain unclear. If CSRC approval under the M&A Rules or if the filing procedure with the CSRC under the Draft Overseas Listing Administration Provisions is required, it is uncertain whether it would be possible for us to obtain the approval or complete the filing procedure.

If it is determined that we are subject to any CSRC approval, filing, other governmental authorization or requirements for this [REDACTED] or future capital raising activities, we may fail to obtain such approval or meet such requirements in a timely manner or at all, or completion could be rescinded. Any failure to obtain or delay in obtaining such approval or completing such procedures for this [REDACTED] or future capital raising activities, or a rescission of any such approval obtained by us, would subject us to sanctions by the CSRC or other PRC regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operating privileges in China, delay or restrict the repatriation of the [REDACTED] from this [REDACTED] or future capital raising activities into China, or take other actions that could materially and adversely affect our business, financial condition, results of operations and prospects, as well as the [REDACTED] of our Shares.

The CSRC or other PRC regulatory authorities may also take actions requiring us, or making it advisable for us, to halt this [REDACTED] or future capital raising activities before settlement and delivery of the Shares offered hereby. Consequently, if you engage in market trading or other activities in anticipation of and prior to settlement and delivery, you do so at the risk that settlement and delivery may not occur. In addition, if the CSRC or other regulatory authorities later promulgate new rules or explanations requiring that we obtain their approvals or accomplish the required filing or other regulatory procedures for this [REDACTED] or future capital raising activities, we may be unable to obtain a waiver of such approval requirements, if and when procedures are established to obtain such a waiver. Any uncertainties or negative publicity regarding such approval, filing or other requirements could materially and adversely affect our business, prospects, financial condition, reputation, and the [REDACTED] of the Shares.

You may experience difficulties in effecting service of legal process and enforcing judgments against us and our management based on Hong Kong or other foreign laws.

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, and substantially all their assets are located within the PRC. As a result, it may not be possible to effect service of process within the United States or elsewhere outside the PRC upon our Directors and senior management personnel. Furthermore, the PRC does not have treaties providing for the reciprocal enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong

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Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in the PRC or Hong Kong of judgments of a court obtained in the United States and any of the other jurisdictions mentioned above may be difficult or impossible.

On July 14, 2006, 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”), which took effect as of August 1, 2008. Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment.

On January 18, 2019, the Supreme People’s Court and the Hong Kong Government 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政區法院相互認可和執行民商事案件判決的安排) or 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.

We may be deemed to be a Chinese resident enterprise under the EIT Law in which case our global income may be subject to Chinese corporate tax under the EIT Law, dividends paid on our ordinary shares may be subject to PRC withholding tax and gains from disposition of our shares may be subject to PRC tax.

We are a holding company incorporated under the laws of the Cayman Islands and indirectly hold interests in our PRC subsidiaries. Pursuant to the Enterprise Income Tax Law of China (中華人民共和國企業所得稅法) and the Regulation on the Implementation of the Enterprise Income Tax Law of China (中華人民共和國企業所得稅法實施條例), or collectively the EIT Law, dividends payable by a foreign-invested enterprise to its foreign corporate investors who are not deemed a Chinese resident enterprise are subject to a 10% withholding tax, unless such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding tax arrangement.

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The EIT Law provides that if an enterprise incorporated outside China has its “de facto management bodies” within China, such enterprise would generally be deemed a “Chinese Resident Enterprise” for tax purposes and be subject to an Enterprise Income Tax (“EIT”) rate of 25% on its global income. “De facto Management Body” is defined as the body that has actual overall management and control over the business, personnel, accounts and properties of an enterprise. On April 22, 2009 the State Taxation Administration (the “STA”) issued the Notice Regarding the Determination of Chinese — Controlled Offshore — Incorporated Enterprises as PRC Tax Resident Enterprises on the basis of de facto management bodies (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) (the “Circular 82”), which was further amended on December 29, 2017, to clarify the certain criteria for the determination of the “De facto Management Bodies” for foreign enterprises controlled by Chinese enterprises. These criteria include: (1) the primary location of the day-to-day operational management is in the PRC; (2) decisions relating to the enterprise’s financial and human resource matters are made or subject to approval by organizations or personnel in the PRC; (3) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholders’ meeting minutes are located or maintained in the PRC; and (4) 50% or more of voting board members or senior executives of the enterprise habitually reside in the PRC. According to these regulations, we may be deemed as a Chinese resident enterprise by Chinese tax authorities and pay Chinese EIT at a rate of 25% on all of our global income.

Currently, members of our management team as well as the management team of all of our offshore holding companies are predominantly located in China. However, Circular 82 only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreign corporations like us. In the absence of detailed implementing regulations or other guidance determining that offshore companies controlled by PRC individuals or foreign corporations like us are Chinese resident enterprises, we do not currently consider our Company or any of our overseas subsidiaries to be a Chinese resident enterprises.

However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and it remains unclear how China’s tax authorities will treat a case such as ours. We cannot assure you that we will not be considered a Chinese resident enterprise for Chinese EIT purposes and be subject to the uniform 25% EIT rate on our global income. Furthermore, if the PRC tax authorities determine that we are a Chinese resident enterprise for enterprise income tax purposes, dividends paid on our ordinary shares may be subject to PRC withholding tax at a rate of 10% in the case of non-PRC enterprise shareholders or 20% in the case of non-PRC individual shareholders 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 enterprise shareholders or 20% in the case of non-PRC individual shareholders, if such dividends or gains are deemed to be from PRC sources. Any such PRC tax liability may be reduced under an applicable income tax treaty. However, it is unclear whether, if we are deemed a Chinese resident enterprise, our shareholders may be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or jurisdictions. In addition, although the EIT Law provides that dividend payments between qualified Chinese resident

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enterprises are exempt from enterprise income tax, due to the relatively short history of the EIT Law, it remains unclear as to the detailed qualification requirements for this exemption and whether dividend payments by our China-incorporated subsidiaries to us will meet such qualification requirements if we are considered as a Chinese resident enterprise for tax purposes.

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, unemployment insurance and housing provident fund. During the Track Record Period, some of our PRC subsidiaries engaged third-party human resources agencies to pay social insurance premium and housing provident funds for certain of our employees. Pursuant to the agreements entered into between such third-party human resources agencies and our relevant PRC subsidiaries, the third-party human resources agencies have the obligation to pay social insurance premium and housing provident funds for our relevant employees. However, if such human resource agencies fail to pay the social insurance premium or housing provident funds for and on behalf of our employees as required by applicable PRC laws and regulations, or if our PRC subsidiaries were deemed as not in full compliance with relevant PRC laws and regulation for engaging third-party human resources agencies to pay social insurance premium and housing provident funds for certain of our employees, we may be subject to additional contribution, late payment fee and/or penalties imposed by the relevant PRC authorities for failing to discharge our obligations in relation to payment of social insurance and housing provident funds as an employer or be ordered to rectify. This in turn may adversely affect our financial condition and results of operations.

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.

PRC laws and regulations impose significant regulatory approval and review requirements, which could make it more difficult for us to pursue growth through acquisitions in China.

PRC laws and regulations, such as the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (the “**M&A Rules**”) which came into effect on September 8, 2006 and was amended on June 22, 2009, Anti-Monopoly Law of the PRC and the Rules of Ministry of Commerce (the “**MOFCOM**”) on Implementation of the Security Review System of Mergers and Acquisitions of Domestic Enterprises by Foreign Investors,

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promulgated by the MOFCOM in August 2011, or the MOFCOM Security Review Rules, which came into effect on September 1, 2011, established additional procedures and requirements that are expected to make merger and acquisition activities in China by foreign investors more time-consuming and complex, including requirements in some instances that MOFCOM be notified in advance of any change of control transaction in which a foreign investor takes control of a PRC domestic enterprise, or that the approval from MOFCOM be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies. PRC laws and regulations also require certain merger and acquisition transactions to be subject to merger control review or security review.

The MOFCOM Security Review Rules are formulated to implement the Notice of the General Office of the State Council on Establishing the Security Review System for Mergers and Acquisitions of Domestic Enterprises by Foreign Investors promulgated on February 3, 2011, or Circular No. 6. According to these circulars and rules, a security review is required for mergers and acquisitions by foreign investors having “national defense and security” concerns, and for mergers and acquisitions by which foreign investors may acquire the “de facto control” of domestic enterprises that have “national security” concerns. In addition, when deciding whether a specific merger or acquisition of a domestic enterprise by foreign investors is subject to the security review, the MOFCOM will look into the substance and actual impact of the transaction. The MOFCOM Security Review Rules further prohibit foreign investors from bypassing the security review requirement by structuring transactions through proxies, trusts, indirect investments, leases, loans, control through contractual arrangements or offshore transactions.

Furthermore, according to the Measures for the Security Review of Foreign Investment, or the New Security Review Measures, promulgated by NDRC and MOFCOM on December 19, 2020, a foreign investment security review working mechanism will be established to be responsible for organizing, coordinating and guiding the security review of foreign investment. If a proposed foreign investment meets the conditions as stipulated in the New Security Review Measures, the foreign investor or the relevant domestic party shall report such case to the review working mechanism, in order to obtain the security review clearance before proceeding with the proposed foreign investment. However, as the New Security Review Measures was newly issued, there are still substantial uncertainties as to its interpretation and implementations in practice.

We may grow our business in part by acquiring other companies operating in our industry. Complying with the requirements of the relevant regulations to complete such transactions could be time consuming, and we may face substantial uncertainties as to whether we can complete any required approval processes. Failure to take timely and appropriate measures to cope with any of these or similar regulatory compliance challenges may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain our market share.

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Any failure to comply with PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly-Listed Companies (關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知) (“SAFE Circular 7”). Under the 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 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 [REDACTED] 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. Also, SAFE Circular 37 stipulates that PRC residents who participate in a share incentive plan of an overseas non-publicly-[REDACTED] special purpose company may register with SAFE or its local branches before they exercise the share options. We and our PRC employees who have been granted share options will be subject to these regulations upon the completion of this [REDACTED]. Failure of our PRC share option holders 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 subsidiaries, limit our PRC subsidiaries’ ability to distribute dividends to us, or otherwise materially and adversely affect our business.

The STA has also issued relevant rules and regulations concerning employee share incentives. Under these rules and regulations, our employees working in the PRC will be subject to PRC individual income tax upon exercise of the share options. Our PRC subsidiary has obligations to file documents with respect to the granted share options or restricted shares with relevant tax authorities and to withhold individual income taxes for their employees upon exercise of the share options or grant of the restricted shares. If our employees fail to pay or we fail to withhold their individual income taxes according to relevant rules and regulations, we may face sanctions imposed by the competent governmental authorities.

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

We are a holding company, and we rely on dividends and other distributions on equity that may be paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to the holders of our ordinary shares and service any debt we may incur. If any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us.

Under PRC laws and regulations, each of our PRC subsidiary is required to set aside at least 10% of its after-tax profits each year, after making up previous years’ accumulated losses, if any, to fund certain statutory reserve funds, until the aggregate amount of such a fund reaches 50% of its registered capital. Furthermore, under PRC law, each of our PRC subsidiary cannot distribute any profits until all of its losses from prior fiscal years have been offset. At its discretion, each of our PRC subsidiary may allocate a portion of its after-tax profits based on PRC accounting standards to a discretionary reserve fund. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other distributions to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends, or otherwise fund and conduct our business.

In response to the persistent capital outflow in China and the Renminbi’s depreciation against the U.S. dollar in the fourth quarter of 2016, the People’s Bank of China and SAFE promulgated a series of capital control measures in early 2017, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments. The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends, or otherwise fund and conduct our business.

Our operations are subject to and may be affected by changes in PRC tax laws and regulations.

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. Although we believe that in the past we had acted in compliance with the requirements under the relevant PRC tax laws and regulations in all material aspects and had established effective internal control measures in relation to accounting regularities, we cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC

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government from time to time adjusts or changes its tax laws and regulations. For example, under the Individual Income Tax Law (the “**IIT Law**”) which was last amended on August 31, 2018 and came into effect on January 1, 2019, foreign nationals which have domiciles in the PRC, or have no domicile in China but have resided in the PRC for a total of 183 days or more in a tax year, would be subject to PRC individual income tax on their income gained within or outside the PRC. Should such rule be strictly enforced, our ability to attract and retain highly skilled foreign scientists and research technicians to work in China may be materially affected, which may in turn have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. Further adjustments or changes to PRC tax laws are regulations, together with any uncertainty resulting therefrom, could also have an adverse effect on our business, financial condition and results of operations.

We may be restricted from transferring our scientific data abroad.

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

Government control of currency conversion and future fluctuations in Renminbi exchange rates could have a material adverse effect on our business, results of operations, financial condition and prospects, and may reduce the value of, and dividends payable on, our Shares in foreign currency terms.

Our revenue and expenses are substantially denominated in Renminbi, which is currently not a freely convertible currency. A portion of the revenue must be converted into other currencies in order to meet our foreign currency obligations. For example, we will need to obtain foreign currency to make payments of declared dividends, if any, on our Shares.

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Under China’s existing foreign exchange regulations, we are able to make payments of current account items, including paying dividends in foreign currencies without prior approval from SAFE, by complying with certain procedural requirements. However, in the future, China’s government may take measures, at its discretion, to restrict access to foreign currencies for capital account and current account transactions under certain circumstances. If such measures are implemented, we may not be able to pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under our capital account are subject to significant foreign exchange controls and require the SAFE’s approval. These limitations could affect our ability to obtain foreign exchange through offshore financing.

The value of the Renminbi against the Hong Kong dollar and the U.S. dollar and other currencies fluctuates, and is subject to changes resulting from government policies (including those of the PRC government) and depends to a large extent on domestic and international economic and political developments, as well as supply and demand in the local market. We cannot assure you that the Renminbi will not experience significant appreciation or depreciation against the U.S. dollar or other foreign currencies in the future.

Our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in a decrease in the value of our foreign currency-denominated assets and our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on our Shares in foreign currencies. There are limited instruments available for us to reduce our foreign currency risk exposure at reasonable cost in China, and we have not utilized, and may not in the future utilize, any such instrument. Furthermore, currently we are also required to obtain SAFE’s approval before converting significant sums of foreign currencies into Renminbi. All of these factors could materially and adversely affect our business, results of operations, financial condition and prospects, and could reduce the value of, and dividends payable on, our Shares in foreign currency terms.

Regulations relating to offshore investment activities by PRC residents may subject us to fines or sanctions imposed by the PRC government, including restrictions on our PRC subsidiaries’ abilities to pay dividends or make distributions to us and our ability to increase our investment in our PRC subsidiaries.

The SAFE has promulgated several regulations requiring PRC residents to register with PRC government authorities before engaging in direct or indirect offshore investment activities, including Circular of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by domestic Residents in China via Special-Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (“SAFE Circular 37”), issued and effective on July 4, 2014. SAFE Circular 37 requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the

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purpose of overseas investment and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle.” SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. In February 2015, SAFE promulgated a Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment (“SAFE Notice 13”), effective from June 2015. Under SAFE Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound overseas direct investments, including those required under SAFE Circular 37, will be filed with qualified banks instead of SAFE. The qualified banks will directly examine the applications and accept registrations under the supervision of SAFE. If a shareholder who is a PRC citizen or resident does not complete the registration under the SAFE Circular 37 and SAFE Notice 13, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital or liquidation to the special purpose vehicle, and the special purpose vehicle may be restricted to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC resident under PRC laws for evasion of applicable foreign exchange restrictions.

We may not at all times be fully aware or informed of the identities of all our beneficiaries who are PRC residents, and may not always be able to compel our beneficiaries to comply with the requirements of SAFE Circular 37 and other relevant regulations. As a result, we cannot assure you that all of our Shareholders or beneficiaries who are PRC residents will at all times comply with, or in the future make or obtain and applicable registrations or approvals required by SAFE Circular 37 or other related regulations.

PRC regulations of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the [REDACTED] of the [REDACTED] to make loans or additional capital contributions to our PRC subsidiaries, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

We may transfer funds to our PRC subsidiaries or finance our PRC subsidiaries by means of Shareholders’ loans or capital contributions after completion of the [REDACTED]. Any loans to our PRC subsidiaries, which are foreign-invested enterprises, cannot exceed statutory limits, are subject to PRC regulations and foreign exchange loan registration.

Furthermore, if we make any capital contributions to Genecast WFOE, Genecast WFOE is required to register the details of the capital contribution with the local branch of SAMR and submit a report on the capital contribution via the online enterprise registration system to the MOFCOM.

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On March 30, 2015, the SAFE promulgated the Circular on Reforming the Administration Measures on Conversion of Foreign Exchange Registered Capital of Foreign-invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (“**Circular 19**”), which took effect from June 1, 2015. SAFE further promulgated the Circular of the State Administration of Foreign Exchange on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (“**Circular 16**”), effective on June 9, 2016, which, among other things, amend certain provisions of Circular 19. According to Circular 19 and Circular 16, the flow and use of the Renminbi capital converted from foreign currency denominated registered capital of a foreign-invested company is regulated such that Renminbi capital may not be used for business beyond its business scope, or to provide loans to persons other than affiliates, unless otherwise permitted under its business scope. Circular 19 and Circular 16 may limit our ability to transfer the net [REDACTED] from the [REDACTED] to our PRC subsidiaries and convert the net [REDACTED] into RMB.

The international political relationships, including that between China and other countries, may affect our business operations.

During the Track Record Period, we purchased raw materials for our products, services, product candidates and services under development from certain overseas suppliers. We may also engage in cross-border sales of our products and services between the U.S. and China in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. Recently, the military conflict between Russia and Ukraine has been bringing uncertainty to the global economy, trade and regulatory environments and any continuance or deterioration to the situation may further implicate the geopolitical landscape, including causing economic, social and political repercussions on a number of regions, which may give rise to a significant expansion of sanctions and trade restrictions among different countries. In the event that China and/or the United States impose import tariffs, trade restrictions, export controls or other trade barriers affecting the importation of such components or raw materials, we may not be able to obtain a steady supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. Our products may be subject to punitive tariffs or other trade barriers, if we engage in cross-border sales between the U.S. and China. Although as of the Latest Practicable Date, none of our products or product candidates was subject to any punitive tariff due to the trade tension between the U.S. and China, the governments may impose such tariff or even restrict the sales of our products in the future.

Tensions and political concerns between China and the relevant foreign countries or regions may adversely affect the macroeconomic conditions of the PRC which may in turn have a material adverse impact on our business, financial condition, results of operations, cash flows and prospects. China’s political relationships with foreign countries and regions may also affect the prospects of our relationship with third parties. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions.

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RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our Shares and there can be no assurance that an active market would develop. The [REDACTED] volume of our Shares may be volatile, which could lead to substantial losses to investors.

Prior to this [REDACTED], there has been no public market for our Shares. The [REDACTED] for our [REDACTED] was the result of negotiations among us and the [REDACTED] (for themselves and on behalf of the [REDACTED]) and the [REDACTED] may differ significantly from the market price for our Shares following this [REDACTED]. We have applied for [REDACTED] of and permission to deal in our [REDACTED] on the Stock Exchange.

A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for the Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will not decline following the [REDACTED]. In addition, the [REDACTED] of the Shares may be subject to significant volatility in responses to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the [REDACTED] of our Shares. In addition to market and industry factors, the [REDACTED] of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting the oncology molecular diagnostics and testing markets, business model, or corporate structure, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors or ourselves.

Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in price not directly related to our performance.

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

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] consolidated net tangible asset value. There can be no assurance that if we were to immediately liquidate after the [REDACTED], any assets will be distributed to Shareholders after the creditors' claims. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants

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limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, limitations on our ability to acquire or license intellectual property rights or declaring dividends, or other operating restrictions.

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

The [REDACTED] of our Shares sold in the [REDACTED] is expected to be determined on the [REDACTED] Date. 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] Date. As a result, investors may not be able to sell or otherwise [REDACTED] in the Shares before the commencement of trading. Accordingly, holders of our Shares are subject to the risk that the price of the Shares when trading begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time trading begins.

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

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

We cannot assure you that we will declare and distribute any amount of dividends in the future. If we do not pay dividends after the [REDACTED], you must rely on price appreciation of our Shares for a return on your investment.

There can be no assurance that we will declare and pay dividends because the declaration, payment and amount of dividends are subject to the discretion of our Directors, depending on, among other considerations, our operations, earnings, cash flows and financial position, operating and capital expenditure requirements, our strategic plans and prospects for business development, our constitutional documents and applicable law. Accordingly, the return on your investment in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your investment in our Shares and you may even lose your entire investment in our Shares. For more details of our dividend policy, see “Financial Information — Dividend” in this document.

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

Our management may spend the net [REDACTED] from the [REDACTED] in ways with which you may not agree or which do not yield a favorable return to our shareholders. We plan to use the net [REDACTED] from the [REDACTED] to further develop and commercialize Genecast IVD – KNBP, enhance our other product offerings to strengthen our product and service portfolio, continue to invest in technology to strengthen core competencies and strengthen our commercialization capabilities, among others. For details, see “Future Plans and [REDACTED] — [REDACTED]” in this document. However, our management will have discretion as to the actual application of our net [REDACTED]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net [REDACTED] from this [REDACTED].

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.

Facts, forecasts and statistics in this document relating to the oncology molecular diagnostics and testing industry may not be fully reliable.

Facts, forecasts and statistics in this document relating to the oncology molecular diagnostics and testing industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Joint Sponsors, [REDACTED] nor our or their respective affiliates or advisers have verified the information from official government sources, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong when making your investment decision regarding our Shares. Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for the accuracy or completeness of any such press articles or other media coverage, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us in any such press articles or media coverage. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information. By applying to purchase our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document.