

RISK FACTORS

You should carefully read all of the information in this document including the risks and uncertainties described below before making an investment in our [REDACTED]. Our business, financial position or results of operations could be materially and adversely affected by any of the risks mentioned in this section. The [REDACTED] of our [REDACTED] could decline due to any of these risks, and you may lose all or part of your investment. You should pay particular attention to the fact that we are a company incorporated in the PRC, our business is primarily located in the PRC and we are governed by a legal and regulatory environment that may differ from that prevailing in other countries and jurisdictions. For more information concerning the market in which we operate and certain related matters discussed below, please refer to “Regulatory Overview” and “Appendix IV – Summary of Articles of Association” for further details.

RISKS RELATING TO THE DEVELOPMENT OF OUR PRODUCT CANDIDATES

The sales of our NMPA-approved products constituted a significant portion of revenue during the Track Record Period. Our future revenue will depend on the commercialization and further sales of IHepcomf (艾馨甘) and IUriSure (艾光樂) and other product candidates.

During the Track Record Period, a substantial amount of our revenue was derived from our NMPA-approved products, namely IColocomf (艾長康), IColohunter (艾長健), IEsohunter (艾思寧) and IHepcomf (艾馨甘). Our revenue generated from IColocomf (艾長康) and IColohunter (艾長健) accounted for 76.0% and 48.1% of our total revenue in 2024 and 2025, respectively. We obtained the Class III medical device registration approval for IHepcomf (艾馨甘) in January 2025. The revenue contribution from IHepcomf (艾馨甘) 2025 accounted for 29.1% of our total revenue. Our future revenue depends on the future sales of NMPA-approved products as well as the commercialization of our Core Products.

There is no assurance that we will be able to achieve the expected sales growth and profit margin for our Core Products, namely IHepcomf (艾馨甘) and IUriSure (艾光樂), which may be adversely affected by many factors outside of our control, including but not limited to: (i) acceptance of our Core Products as useful and recommended cancer early detection solutions or recurrence monitoring by hospitals, doctors, KOLs and others in the medical community; (ii) downward pricing pressure caused by changes in market competition; expiration of patent protection; (iii) introduction of substitute products marketed by our competitors for cancer early detection with similar or different technologies; (iv) disruptions in manufacturing or sales; (v) obtaining the necessary regulatory approvals for the new indications of IHepcomf (艾馨甘) and IUriSure (艾光樂), in the target markets; and (vi) issues with respect to product quality; potential coverage of medical insurance and disputes over intellectual property or other matters with third parties.

If we are unable to achieve the expected sales volumes, pricing levels or profit margins of our products, our business, financial condition and results of operations may be materially and adversely affected.

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

Our business substantially depends on the successful development, obtaining and maintaining the necessary regulatory approvals and commercialization of our product candidates and future product candidates that we may develop for the early detection of different types of cancer and other diseases. Most of our product candidates are still in the design or clinical development stage. We have invested a significant portion of our time and financial resources

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towards the development and commercialization of our existing product candidates. We incurred research and development expenses accounting for 207.2% and 138.1% of our total revenue for the years ended December 31, 2024 and 2025 respectively. Whether we can generate profit from our business operations largely depends on successful commercialization of our product candidates. The success of our product candidates will depend on several factors, including but not limited to: (a) successful completion of pre-clinical studies; (b) successful enrollment in, and completion of, clinical trials; (c) favorable safety and efficacy data resulting from our clinical trials and pre-clinical studies; (d) obtaining and maintaining the necessary regulatory approvals; (e) third party compliance with our policies, procedures and protocols, and applicable laws; (f) the integrity of our data being continuously protected; (g) obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity; (h) keeping up with industry and technology developments; and (i) successfully launching our product candidates, if and when approved, in a timely manner.

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 the necessary regulatory approval for and/or to successfully commercialize our product candidates, which may have a materially adverse effect on our business and may result in us not being able to generate sufficient revenue and cash flow to continue our research, development and manufacturing operations.

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

With respect to the products that are required to obtain regulatory approval, we must conduct clinical trials to demonstrate the safety and effectiveness of our products. We face uncertainties and potential failures in clinical trials for our product candidates. Depending on the nature of the product candidate, the clinical trials required to be conducted may vary. Successful pre-clinical studies and early clinical trials do not necessarily mean that later clinical trials will also result in data that replicate the results of prior trials and pre-clinical studies and ultimately lead to regulatory approval.

There can be no assurance that the ongoing or planned clinical trials will be completed in a timely or cost-effective manner or result in a commercially viable product. If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates, the commercial prospects of that product candidate may be impacted, and our ability to generate revenue from any of those product candidates may be delayed. In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development process and approval process, and jeopardize our ability to commercialize that product candidate. The occurrence of such events may materially and adversely affect our business, financial condition, results of operations and prospects.

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

The timely completion of clinical trials depends on several factors, including our ability to recruit and retain a sufficient number of participants who meet the eligibility criteria. We may experience difficulties in subject enrollment for a variety of reasons, such as the size and nature of subject population, eligibility criteria defined and patients' perception of the clinical trial. Our clinical trials will likely compete with other trials for similar patient populations.

Any delay in enrollment or retention shortfalls could result in modifying the study protocol, adding additional trial sites or extending the duration of the trial, all of which would materially and adversely affect our ability to advance product development and obtain regulatory approvals on our planned timeline, bringing material negative impact to our business, financial condition, and future prospects.

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

The timely completion of clinical trials in accordance with protocols depends, among other things, on our ability to procure a sufficient number of test samples for our clinical trial. We may experience difficulties in doing so for a variety of reasons, including but not limited to: (a) the number and nature of the samples; (b) the qualified samples defined in the protocol; (c) the size of the study required for analysis of the trial’s primary endpoints; (d) perceived risks and benefits of our products; (e) the design of the trial; and (f) our ability to obtain and maintain the required consent to use the samples.

In addition, our clinical trials may compete with our competitors’ clinical trials. Such competition will reduce the number and types of samples available to us. Even if we are able to procure a sufficient number of test samples in our clinical trials, delays in patient enrolment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our products. Please refer to “– if we encounter difficulties enrolling and retaining participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected” in this section.

If the third parties with whom we contract for clinical trials do not perform in an acceptable manner, or if we suffer setbacks in these clinical trials, we may be unable to develop and commercialize our product candidates as anticipated.

We contract with third parties, including public hospitals, CROs and SMOs, among others, to assist us in designing, implementing, monitoring and conducting clinical trials. If any of these parties terminates its agreements with us, the development of the product candidates covered by those agreements could be substantially delayed. In addition, these third parties may not successfully carry out their contractual obligations, meet expected deadlines or follow regulatory requirements, including clinical, laboratory and manufacturing guidelines. Our reliance on these third parties may result in delays in completing, or in failing to complete, these studies if they fail to perform in accordance with the contractual arrangements. Furthermore, if any of these parties fail to perform their obligations under our agreements with them in the manner specified in those agreements, NMPA and/or other comparable regulatory authorities may not accept the data generated by those studies, which would increase the cost of and the development time for the relevant product candidate. If any of the clinical trials of our product candidates are 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 invest substantial resources in research and development in order to develop our products and enhance our technologies.

For the years ended December 31, 2024 and 2025, our R&D expenses amounted to RMB15.0 million and RMB21.3 million respectively. We expect to continue to invest significant amounts of human and capital resources to develop our products and enhance our technologies that will allow us to advance our pipeline products. We intend to continue to strengthen our technical capabilities in the development and manufacture of our products, which are capital and time intensive. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products or obtain the necessary regulatory approvals in a timely and cost-effective manner, or if such products are introduced, that those products will achieve or maintain market acceptance. Any failure to do so may render our efforts obsolete, which could significantly reduce demand for our products and harm our business and prospects.

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If there is advancement in the industry and we do not introduce new products in a timely manner, our products may become obsolete and our operating results and prospects may suffer.

The disease detection and diagnostic industry, particularly the oncology molecular testing industry, is characterized by technological changes, frequent new product introductions, and evolving industry standards. If we are not able to keep pace with these advancements and continue to develop technologies and products in line with industry and technological advancements, our existing technologies could be rendered obsolete, and our existing products as well as products we are developing, could be rendered less clinically effective, and our future operations and prospects could thus suffer from our diminished competitive position. To remain competitive, we must continuously optimize our existing products and launch new products in a timely manner to keep pace with these developments. We cannot be sure that these efforts will be successful.

RISKS RELATING TO COMMERCIALIZATION AND DISTRIBUTION OF OUR PRODUCTS

Our success depends on our products’ ability to provide reliable, high-quality test results and analysis and to rapidly evolve to meet our customers’ needs. If our products do not meet the expectations of customers, our operating results, reputation and business could suffer.

The accuracy of our products, which use advanced methylation biomarker detection for early liver cancer detection, is critical to the success of our business. However, there is no guarantee that our products will always perform as expected. If our products fail to accurately detect the level of methylation biomarkers associated with cancers, or if they incompletely or incorrectly identified such biomarkers, our reputation and business could be materially and adversely affected.

There could be flaws in the databases, algorithms, software and third-party tools used in the data processing protocol of our customers when performing tests, which could also compromise the performance of our products. If our customers receive poor-quality or degraded clinical samples, our products may be unable to accurately detect or identify the significance of biomarkers, which could significantly impact our business. In addition, end-users also rely on the interpretations by doctors or physicians of testing reports and understand the risk prediction scores, and we are not able to ensure the interpretations will be correct and complete. Inaccurate results or misunderstanding of, or inappropriate reliance on, results of our products could lead to claims against us, or cause us to lose future sales, either of which could have an adverse effect on our business, reputation, financial condition and results of operations.

Failure of our products to achieve market acceptance or maintain a good reputation would have a material adverse impact on our business, financial condition, results of operations and profitability

Our Core Products face keen market and pricing competition with other disease detection and diagnostic test products. If we are unable to successfully complete clinical development, obtain and maintain the necessary regulatory approval, commercialize our product candidates, or keep up with industry and technology developments, or if we experience significant delays in doing so, our business may be materially adversely affected as our Core Products face keen market and pricing competition with other disease detection and diagnostic test products.

The commercial success of our existing and future products and services depends upon the degree of market acceptance they achieve, particularly among hospitals and doctors. Our Core Products also face keen market and pricing competition with other disease detection and diagnostic test products in the market.

If our products and services do not achieve an adequate level of acceptance or if we are unable to improve the market awareness of our products and services, we may not generate significant revenue and may not become profitable, which in turn, would have an adverse impact on our financial conditions, business and results from operations.

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We cannot assure that our sales and marketing efforts will be successful. Brand promotion activities may not lead to increased revenue in the near term, and, even if they do, any revenue increases may not offset the expenses we incur to promote our brand. In addition, our reputation may be undermined as a result of the negative publicity about our Company or our industry in general. Our failure to establish and promote our brand and any damage to our reputation will hinder our growth, and may materially and adversely affect our business, financial condition and results of operations.

If we cannot maintain or develop relationships with hospitals and physicians and health checkup centres, our results of operations and prospects could be adversely affected.

We collaborate with hospitals and physicians in China in many aspects of our business, and our success in part depends on our ability to maintain our relationships with our existing partner hospitals and physicians and continue to build relationships with additional hospitals and physicians. If we fail to enter into collaboration with additional hospitals in a timely and cost-effective manner, our business and prospects could be adversely affected. Moreover, we have, and may from time to time, seek the NMPA and other comparable regulatory authorities’ approval for additional products or new indications of our existing products. Such approvals require, among other things, successful completion of clinical trials for the products. We may rely on our partner hospitals to obtain sufficient data and samples to perform these clinical trials in a cost-effective and timely manner. If we fail to establish or maintain clinical collaboration with our partner hospitals, our business and operations may be adversely affected.

We have a relatively short track record in marketing and sales of our products. There can be no assurance that we will be able to continue to successfully complete the research and development and registration and commercialize our products, and as a result, our revenue and profitability could be materially and adversely affected.

We started marketing our NMPA-approved products, IColocomf (艾長康), IColohunter (艾長健), IEsohunter (艾思寧), IHepcomf (艾馨甘) and IUriSure (艾光樂) in 2022, 2024, 2025, 2025 and 2025, respectively. Despite the successful launch of our NMPA-approved products in China, we cannot assure that we will be able to replicate such success with our other pipeline products in the same global markets. Our early cancer detection products target different types of cancer with varying market potential and competition, utilize distinct technologies, and are subject to substantially different local regulatory compliance requirements.

Additionally, we have a relatively short track record in launching and commercializing our product candidates, as well as in the sales and marketing of our products. For example, we have limited experience in building a commercial team, conducting comprehensive market analysis, obtaining licenses and approvals, or managing a sales force for our product candidates in China. As a result, our ability to successfully commercialize our product candidates in selected new markets may involve inherent risks.

We rely on our in-house sales and marketing personnel and distributors to promote our products. If we fail to maintain an effective sales channel, our business and sales of our products and services could be adversely affected.

We rely on our in-house sales and marketing personnel as well as distributors to market and promote our products and services. We incurred selling and distribution expenses of RMB15.1 million and RMB13.2 million for the years ended December 31, 2024 and 2025, respectively. We plan to expand our sales and marketing network to increase our market share and penetration in the global market, driving future growth. The success of our sales and marketing strategy depends on our ability to maintain and expand our direct sales efforts and our network of distributors.

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Our sales mainly consist of sales of our products directly to medical testing laboratories and private health checkup centers. For the years ended December 31, 2024 and 2025, our direct sales revenue amounted to RMB5.1 million, and RMB10.6 million, respectively, representing 71.0%, and 69.0% of our total revenue in the same periods, respectively.

In the medical device industry, it is customary to use distributors for the sales of medical devices to medical institutions. In line with industry practice, we sell a portion of our products to distributors who resell to their customers, such as public hospitals and primary-level healthcare institutions. As of December 31, 2025, we maintained cooperation with 147 distributors. Our ability to maintain and grow our business will depend on our ability to maintain, expand and optimize effective distribution channels that ensure timely distribution of our products to the relevant markets where we generate market demand through our sales and marketing activities. We also may not be able to identify or engage new distributors with sales networks and qualified skillset. Moreover, if our existing distributors fail to expand or maintain their sales network or otherwise encounter any difficulties in selling our products or promoting our services, our sales will decline and our business, operations and prospects may be materially and adversely affected. Any disruption to our distribution network, including our failure to maintain relationships, form new relationships or renew our existing distribution agreements could negatively affect our ability to effectively sell our products and would materially and adversely affect our business, results of operations, financial condition and prospects.

As we plan to accelerate our commercialization efforts, we may also seek to expand our sales network to other markets where we have limited experience or resources. If we are unable to expand our sales network effectively, the sales volume or profit margin of our existing and future products and services may be adversely affected, which may materially and adversely affect our business, financial condition and results of operations.

We have limited control over the operations of our distributors. Our business may be negatively affected due to risks relating to the acts of our distributors and their potential breach of distribution agreements.

During the Track Record Period, we engaged third-party distributors for the sales of our products and revenue from distributors amounted to RMB2.1 million and RMB4.8 million, representing 29.0% and 31.0% of our total revenue for the respective periods. The performance of our distributors may have a direct impact on our revenue and profitability. There can be no assurance that we will be successful in effectively managing our distributors or detecting any non-compliance of our distributors with the provisions of their distribution agreements. Non-compliance by our distributors could negatively affect our brand reputation and disrupt our sales.

Furthermore, we may be exposed to the risks of fraud or other misconduct committed by our distributors. Fraud or other misconduct by our distributors may involve engaging in unauthorized misrepresentation to our customers, misappropriating third-party intellectual property and other proprietary rights and engaging in bribery or other unlawful payments. In any such event, we could, as a result, incur liability to our customers for fraud or misconduct committed by such distributors. Any claims could subject us to costly litigation and impose a significant strain on our financial resources and the attention of management personnel, regardless of whether the claims have merit, any of which could result in complaints from our customers, regulatory and legal liabilities, as well as serious harm to our reputation.

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

Our business and financial results are dependent on the timely payments and credit worthiness of our customers, including distributors. We generally allow for a credit period of up

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to 120 days. As of December 31, 2024 and 2025, our trade receivables were RMB0.9 million and RMB6.7 million, respectively. For the years ended December 31, 2024 and 2025, the average turnover days of our trade receivables were 42 days and 101 days, respectively.

If our customers’ cash flows, working capital, financial condition or operations deteriorate, they may be unable, or otherwise 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. In addition, we may be unable to enforce our contractual rights and collect outstanding payments due to the complexities of the procedures in different jurisdictions where we distribute our products. If one or more customers default on their payment obligations to us, and the scale of such defaults is significant, our business, financial condition and results of operations may be materially and adversely affected.

We face market competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new early cancer detection products is highly competitive. We face competition from other companies engaging in early cancer detection deploying similar or different technologies. For details, please refer to “Industry Overview” and “Business – Competition” in this document. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are more effective, convenient or less expensive than any products that we commercialize or may develop. Our competitors may also be applying for marketing approvals in the PRC for early cancer detection products with the same intended use as our products and product candidates. The ability of the relevant authorities, such as NMPA, to concurrently review multiple marketing applications for the same type of early cancer detection products may be limited. When our product and its competing products are subject to the regulatory authorities’ concurrent review, the regulatory authorities’ schedule may be affected, and the registration process of our product may be prolonged. Moreover, our competitors may obtain approval from the relevant 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 R&D, manufacturing, pre-clinical 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. Our business, results of operations and prospects may be materially and adversely affected if we fail to compete effectively.

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

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

One of our Core Products, IHepcomf (艾馨甘) has been included in the medical insurance coverage of Beijing and Shanxi and is in the process of being incorporated into the healthcare reimbursement systems of other provinces. We cannot guarantee that our products will be

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included in the healthcare reimbursement systems of other provinces in the near future, that our products will continue to be covered by provincial medical insurance at the current level, or that such coverage will be favorable to us. On the other hand, PRC regulations and medical insurance plans may exert significant influence over our pricing policies, which could affect our profitability. We may need to lower the prices of our products in order to have them included in the medical insurance reimbursement list, and such price cut and reimbursement may not necessarily lead to increase in our sales and our results of operations may be adversely affected.

Downward change in pricing of our products or any competing products or services may have a material adverse effect on our business and operations.

We may face downward change in pricing of our products due to increasing market competition, launch of competitive products, or evolving regulatory regime which may impose pricing control or other restrictive measures. We offer our products mainly to medical testing laboratories and private health checkup centers through direct sales. In line with market practice, we also sell a portion of our products to distributors who resell to their customers, such as public hospitals and primary-level healthcare institutions. For our direct sales customers, we negotiate the price directly with them on a case-by-case basis. With respect to sales through distributors, our distributors negotiate and set retail prices directly with their customers, and such retail prices shall conform to the agreed resale prices set in the distribution agreement. For details, please refer to “Business – Sales and Marketing – Pricing”.

Our direct customers may gain more bargaining power depending on the availability of alternative products, demands of end-users and the preference of physicians. If our direct customers lower the order prices of our products and that results in our profitability reducing, our results of operations could be negatively impacted. For our distributors, if the resale price of our products is having downward pressure and therefore lowers the profitability of our distributors, our distributors may have less incentive to purchase and promote our products. Our distributors may gain more bargaining power due to other reasons. In these cases, we may need to lower the order price we set for our distributors, which in turn could have a material and adverse impact on our business, financial performance and results of operations.

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.

For the years ended December 31, 2024 and 2025, the aggregate revenue generated from our five largest customers for each year of the Track Record Period were RMB5.3 million and RMB11.7 million, representing 73.2% and 75.6% of our revenue, respectively. Sales to our largest customer for each year of the Track Record Period were RMB3.8 million and RMB3.9 million, representing 52.1% and 25.3% of our revenue, respectively. 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.

RISKS RELATING TO MANUFACTURE AND SUPPLY OF OUR PRODUCTS

Obstructions in 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 principal manufacturing facilities are located in Wuhan, China. The facilities may encounter unanticipated expenses due to a number of factors, including maintenance and repairs from sudden breakdowns and changing regulatory requirements. Our manufacturing facilities will be subject to ongoing, periodic inspection by the relevant regulatory agencies. Failure to

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comply with applicable regulations or standards could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, suspensions of 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 adversely affect our business.

Our facilities may be adversely affected or rendered inoperable by physical damage from fire, floods, earthquakes, typhoons, tornadoes, power loss, telecommunications failures, break-ins, and similar events. If our manufacturing facilities or the equipment are damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. 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 have a materially adverse effect on our business, financial condition and results of operation.

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

There is no assurance that further expansion or upgrading works to our manufacturing facilities will not be required, including to meet anticipated market demand for our products and services, we may need to further increase, or scale up, the production capacity and the utilization rate of our manufacturing facilities. Advancements in manufacturing techniques by our competitors may render our facilities and equipment inadequate or obsolete if we do not keep pace with such advancements. In addition, we may also need to develop advanced manufacturing techniques and process controls in order to fully utilize our facilities. To enhance our production capacity to meet the anticipated market demand, we also need to expand our production facilities. 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.

There can be no assurance that our existing and future production facilities will be adequate to keep pace with the potential increase in market demand for our products. If that were to occur, we may have to engage third parties to meet such demand which could cause us to incur additional costs or expose us to risks such as the third parties fail to comply with our specifications or meet market demand. As a result, our profit margins or business operations could be materially and adversely affected.

If we are unable to maintain or enhance the utilization of our production facilities, our profitability may be adversely affected.

High utilization of production facilities is crucial for spreading fixed costs over a larger quantity of products. Consequently, our ability to maintain or improve gross profit margins depends significantly on sustaining high utilization rates. However, various adverse factors, such as excess capacity, equipment malfunction, interruptions in utility availability and quality control deficiencies, could negatively affect our facility utilization. If customer demand declines significantly, parts of our production facilities may become idle. This situation could lead to obsolescence of our facilities over time. Any downturns resulting from production overcapacity or other market demand factors could materially and adversely affect our business, financial condition and results of operations.

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The manufacturing processes of our products are highly complex and subject to strict quality controls. If we or any of our suppliers or logistics partners encounter quality problems, our business could suffer.

The manufacturing processes of our products is highly complex and subject to strict quality controls, partly due to rigorous regulatory requirements. In addition, quality control is extremely important due to the serious and costly consequences of a product failure. For additional information on our quality control measures, please refer to "Business – Quality Control". Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, raw material problems, software problems, sample contamination, or human error. Furthermore, if contaminants are discovered in the supply of our products or product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Other issues relating to the manufacturing of our products could also occur in the future, including disruptions during implementation of new equipment and systems to replace aging ones, as well as product non-conformity or damage due to suppliers' or logistics partners' problems. The occurrence of any of these events may materially and adversely affect our business, financial condition and results of operation.

We may experience supply interruptions or fluctuations in prices of our raw materials that could impact our ability to manufacture products and may have a material adverse effect on us.

During the Track Record Period, our principal raw materials are enzymes, reagents, packaging and labeling materials. We purchase raw materials and components used in the manufacture of our products from external suppliers. General economic conditions could adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products. While we work closely with suppliers to monitor their continuity of supply, and maintain high quality and reliability, these efforts may not be successful.

In addition, due to the rigorous regulations and requirements of the relevant regulatory authorities regarding the manufacture of our products (including the need for approval of any change in supply arrangements), we may have difficulty establishing additional or replacement sources in a timely manner if the need arises. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology, and the loss of any existing supply contract could have a material adverse effect on our business. A reduction in, or lack of availability of, raw materials or interruptions in the supply chain may also impact our profitability to the extent that we are required to pay higher prices for, or are unable to secure adequate supplies of, the necessary raw materials.

In addition, we are subject to the risks associated with fluctuations in prices of raw materials, and reductions in the availability of raw materials may disrupt our operations. We cannot assure that we would be able to procure raw materials in sufficient amounts or at prices that are acceptable for us. The prices of the raw materials may be affected by a number of factors, including market supply and demand, international environmental and regulatory requirements, natural disasters 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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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. As of December 31, 2024 and 2025, the carrying amounts of our inventories were RMB573.0 thousand and RMB829.0 thousand, respectively. For the years ended December 31, 2024 and 2025 and our average inventories turnover days were 71 days and 76 days, respectively. 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 the 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. If we continue to experience inventory write-down, our profitability, financial results and prospects will be negatively affected.

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 GOVERNMENT REGULATIONS

We may be adversely affected by the changes in the regulations of the oncology molecular testing industry and the medical device industry in the markets where we operate.

Government policies relating to the oncology molecular testing industry and the medical device industry in the PRC generally are still evolving and may change significantly in the future. Such future changes, if adopted and implemented, may increase the cost of revenue, intensify competition, or otherwise negatively affect us disproportionately compared to competitors. Unfavorable public opinion or negative media coverage of the oncology molecular testing industry or medical device industry may also trigger the implementation of more stringent policies and heightened scrutiny on quality of medical devices. If we fail to keep up with new policies or best practices, our standard of operation may fall short of the latest standard and we could become more prone to non-compliance, resulting in increased cost of compliance and operation.

In addition, the regulatory framework for the IVD reagents industry in China has evolved in recent years, and we expect it will continue to evolve. For example, the regulatory framework in China for sales and use of IVD products has undergone significant changes, including, with respect to research and development, filing and registration procedures and quality control for IVD products. Our ability to develop and commercialize early cancer detection products may be limited, and our business, financial condition and results of operations may be materially and adversely affected, by changes in government policies or regulations, which may then affect our business, results of operations and financial condition.

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If we, or parties with whom we collaborate, do not obtain and maintain the necessary regulatory approvals, permits, registrations or filings, or experience delays in obtaining such regulatory approvals, permits, registrations or filings, we may not be able to commercialize our product candidates, and our ability to generate revenue may be materially impaired.

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

Our products could fail to receive regulatory approval for many reasons, including but not limited to: (a) failure to begin or complete clinical trials due to disagreements with regulatory authorities; (b) failure to demonstrate that a product is effective; (c) failure of clinical trial results to meet the level of statistical significance required for approval; (d) data integrity issues related to our clinical trials; (e) disagreement with our interpretation of data from preclinical studies or clinical trials; (f) 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; (g) 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 products or other products; (h) our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; (i) clinical sites, PIs 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 (j) rejection by the relevant authorities to approve pending applications or supplements to approved applications filed by us or suspension, revocation or withdrawal of approvals.

In addition, we need to submit the clinical trial reports to the NMPA before we get our approval of new indication for IHepcomf (艾馨甘) and IUrisure (艾光樂). Please refer to “Regulatory Overview – Laws and Regulations Relating to Medical Devices – Permit and GMP for Medical Devices”. We may not be able to successfully complete or timely finish the required clinical trial and may result in postponement or non-renewal of our registration certificate. 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 will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates.

Our products and future products will likely be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products or product candidates.

Our existing products and product candidates are and will likely be subject to ongoing regulatory requirements with respect to manufacturing, testing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China. In addition, our manufacturing facilities are required to comply with regulatory requirements and standards. As such, we are currently, and will likely continue to be subject to

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ongoing review and inspections by the regulators in order to assess our compliance with applicable laws, requirements and standards and adherence to commitments we made in our application materials with the NMPA. Accordingly, we must continue to devote time, financial resources 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 products may be marketed. In addition, the approvals we obtain may also be conditioned on post-marketing testing and surveillance on the efficacy and safety of our products, which may require us to incur significant additional costs. Any such limitations or conditions could adversely affect the profitability of our products.

Following an approval for the commercial sale of our product candidates, certain changes to the product, such as material changes to the design, raw materials, production process, scope of application and method of use thereof, may be subject to additional review and approval by the NMPA. Regulatory approvals for any of our product candidates may also be withdrawn. The NMPA may seek to impose a consent decree or withdraw marketing approval if we fail to maintain compliance with these ongoing regulatory requirements or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our products, product candidates or manufacturing processes may result in revisions to the approved labeling or requirements to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things: (a) restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or voluntary or mandatory product recalls; (b) fines, warning letters, or holds on clinical trials; (c) refusal by the NMPA to approve pending applications or amendments to existing applications filed by us or suspension or revocation of license approvals or withdrawal of approvals; (d) product seizure or detention, or refusal to permit the import or export of our products and product candidates; and/or (e) injunctions or the imposition of civil or criminal penalties.

The NMPA strictly regulates the marketing, labeling, advertising and promotion of medical products and services placed on the market. Our products and testing services may only be promoted for their approved use in accordance with the provisions of the approved label. The NMPA actively enforces the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

The policies of the NMPA 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, since 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. The occurrence of such circumstances may materially and adversely affect our business, financial condition, results of operations and prospects.

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

Our production and manufacturing processes are required to meet certain quality standards such as standards set by relevant governmental authorities as part of the marketing approval of our products. Despite our quality control and assurance system and procedures, we cannot eliminate the risk of product defects or failure. Quality defects may fail to be detected or

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remediated because of many factors, many of which are outside of our control, including: (a) manufacturing errors; (b) technical or mechanical malfunctions in the manufacture process; (c) human error or malfeasance by our quality control personnel; (d) tampering by third parties; and/or (e) quality issues with the raw materials we produce or purchase.

In addition, failure to detect quality defects in our products or to prevent such defective products from being delivered to end-users could result in injury or death, product recalls or withdrawals, license revocation or regulatory fines, product and professional liabilities, increased insurance premiums, or other problems that could damage our reputation and business, expose us to liability, and materially and adversely affect our revenue and profitability.

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

Due to the relatively short history of the oncology molecular testing industry in the PRC, the comprehensive regulatory framework governing our industry is evolving. In accordance with current applicable PRC laws and regulations, including the Administrative Measures for the Registration and Record-filing of IVD Reagents (《體外診斷試劑註冊與備案管理辦法》) and the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), certain instruments, equipment, IVD reagents and calibrators, materials and other similar or related articles for the purposes of medical treatment or diagnosis of human patients that are intended to be used for medical treatment or diagnosis by testing a human body's samples are regulated as medical devices. The manufacture and sales of these products require various certificates, licenses and permits, including but not limited to medical device manufacturing licenses, medical device registration certificates and medical device operation licenses. Since certain of our products are categorized as medical devices under the foregoing regulations, we are required to comply with these regulatory requirements.

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 and factory operations, project constructions, work safety and prevention of occupational diseases, and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Failure to comply with those laws and regulations, or to obtain all applicable registrations, licenses and permits, may result in fines and penalties on us, as well as additional costs and other negative impact on us, which could have a material adverse effect on our business and financial performance.

Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste. We generally contract 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 damage, and any liability could exceed our resources. We could also incur civil or criminal fines and penalties. 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.

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We may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our insurance coverage may be inadequate to protect us from the liabilities we may incur.

We face various risks in connection with our business and may lack adequate insurance coverage or have no relevant insurance coverage. As of the Latest Practicable Date, we did not maintain any business interruption insurance or product liability insurance, which are not mandatory under PRC laws. In addition, we did not maintain keyman insurance, insurance policies covering damages to our network infrastructures or information technology systems, or any insurance policies for our properties. However, any uninsured losses may result in us incurring substantial costs and the diversion of our resources, which could have an adverse effect on our business and results of operations.

We face certain legal and regulatory risks relating to labor-related laws and regulations, which may adversely affect our business and our results of operations.

Pursuant to the relevant PRC laws and regulations, employers are obligated to contribute to the social insurance and housing provident funds for their employees. During the Track Record Period, we did not make adequate social insurances and housing provident fund contributions for certain employees. As advised by our PRC Legal Advisors, if any of the relevant social insurance authorities is of the view that the social insurance contributions we made for our employees do not comply with the requirements under the relevant PRC laws and regulations, it may order us to pay the outstanding balance within a prescribed time period plus a late fee of 0.05% of the total outstanding balance per day. If we fail to do so within the prescribed period as requested by the relevant social insurance authorities, we may be subject to a fine ranging between one to three times of the total outstanding balance. In addition, if any of the relevant housing provident fund authorities is of the view that our contributions to the housing provident funds do not satisfy the requirements under the relevant PRC laws and regulations, it may order us to pay the outstanding balance within a prescribed period. If we fail to do so within the prescribed period, the relevant housing provident fund authority may apply to a PRC court for an order of mandatory payment.

As of the Latest Practicable Date, we had not been imposed any administrative penalties in relation to social insurance and housing provident fund contributions, nor had we received any notifications from the relevant competent government authorities requiring us to make a centralized supplementary payment for any historical shortfalls. In addition, we were not aware of any employee complaints or claims with respect to inadequate social insurance and/or housing provident fund contributions which could have a material and adverse effect on our financial condition or results of operations. As advised by our PRC Legal Advisors, under the premise that there have been no significant changes in the policies on social insurance contributions and enforcement and supervision requirements by the relevant government authorities, and no major complaints from employees, the likelihood that we would be required by relevant authorities to make a centralized supplementary payment for any historical shortfalls for social insurance and housing provident fund contributions due to failure to make full contributions is remote, based on the foregoing and (i) interviews with the competent governmental authorities; and (ii) the Implementation of a Number of Measures for Further Supporting and Serving the Development of the Private Economy Notice by the State Administration of Taxation (Taxation General

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Administration [2018] No. 174) (國家稅務總局關於實施進一步支持和服務民營經濟發展若干措施的通知(稅總發[2018]174號)), which provides for similar prohibitions for relevant tax authorities; and (iii) during the Track Record Period and as of the Latest Practicable Date, we have not received (a) any order of correction from competent authorities that require us to make a centralized supplementary payment for any historical shortfalls, nor (b) any employee reports or complaints alleging inadequate contributions remain outstanding as of the Latest Practicable Date. However, we cannot assure you that the relevant government authorities will not require us to pay the shortfall and late fees or impose fines on us, in which case our business, results of operations and financial condition could be adversely affected.

In addition, during the Track Record Period and up to the Latest Practicable Date, we engaged certain third-party human resources agencies to make social insurance and housing provident fund contributions for certain employees. We adopted the arrangements primarily because these employees worked outside of the cities where our operating entities are registered and the third-party human resources agency was engaged to pay social insurance and housing provident fund contributions for these employees in cities where they worked. We had not been subject to any labor dispute relating to such arrangements as of the Latest Practicable Date. Under the contracts entered into between the third-party human resources agency and us, such agency has the obligations to pay social insurance and housing provident fund for our relevant employees. Furthermore, as of the Latest Practicable Date, we had not received any administrative penalties regarding our arrangements with any third-party human resources agencies, nor any notice from the relevant competent government authorities which required us to rectify such practice. As such, our PRC Legal Advisors are of the view that under the premise that there have been no significant changes in the policies on social insurance contributions and enforcement and supervision requirements by the relevant government authorities, and such third-party agency fulfills its obligations to make social insurance and housing provident fund contributions for the relevant employees and no major complaints from employees, and we comply with the requirement within a prescribed period if being ordered by the relevant government authorities, the likelihood that we would be being subject to material administrative penalties in relation to our arrangement of paying social insurance and housing fund contributions for some employees through third-party human resources service agencies is remote. However, as there remains uncertainties over the interpretation and implementation of labor-related laws and regulations, we cannot assure you that our arrangements with the third-party agency are and will at all times be deemed to be in full compliance with relevant laws and regulations, which may subject us to labor disputes or government investigations. In addition, if such agency fail to fulfill its obligations to make social insurance and housing provident fund contributions for the relevant employees, or if such arrangements are challenged by relevant regulatory authorities, we may be subject to additional contribution obligations, late fees and/or penalties imposed by relevant regulatory authorities for failing to discharge our obligations as an employer or be ordered to rectify. We might also be subject to potential labor disputes arising from such arrangements with the relevant employees. The occurrence of any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

If we are unable to obtain and maintain patent protection in certain markets for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, or if our intellectual property rights are determined to be invalid or not enforceable, third parties may compete directly against us.

The success of our business operation depends in large part on our ability to protect our proprietary technology, products and product candidates from competition by obtaining,

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maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technology, products and product candidates that we consider commercially important by filing patent applications in the markets where we operate, relying on trade secrets or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in a timely manner or at all. There can be no assurance that pending patent applications will be issued, that patents issued to or licensed to us will not be challenged or circumvented by competitors or that such patents will be found to be valid or sufficiently broad to protect our technology or to provide us with a competitive advantage. The validity and breadth of claims in medical technology patents involve complex legal and factual questions. Our patents may be invalidated, and patent applications may not be granted for several reasons, including known or unknown prior deficiencies in the patent application or the lack of novelty of the underlying invention or technology. We may also fail to identify patentable aspects of our R&D output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Our employees, consultants, advisors and other third parties, may breach such agreements and disclose such output before a patent application is filed, jeopardizing our ability to seek patent protection. In addition, the publication of discoveries in the scientific or patent literature may be substantially later than the date on which the underlying discoveries were made and the date on which patent applications were filed. Patent applications in China and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions.

However, many jurisdictions 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 be unable to determine with certainty whether any of our products, processes, technologies, inventions, improvement and other related matters have infringed upon the intellectual property rights of others, because such third party may have filed a patent application without our knowledge while we are still developing that product, 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.

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

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized, and enter the public domain. As a result, our patents and patent applications may not provide us with sufficient rights to exclude

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others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any 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 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 market position, business, financial conditions, results of operations and prospects.

Maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and we may not be able to effectively protect our intellectual property rights in the jurisdictions where we operate.

Filing, prosecuting, maintaining and defending patents on products and product candidates in jurisdictions throughout the world could be prohibitively expensive for us, and our intellectual property rights in some jurisdictions can have a different scope and strength from those in other jurisdictions. The various governmental patent agencies require compliance with a number of procedurals, documentary, fee payment, and other similar provisions during the patent application process. 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 could have a material adverse effect on our business.

The legal systems of some jurisdictions do not favor the enforcement of patents, trade secrets and other intellectual property. Consequently, we may not be able to prevent third parties from practicing our inventions in all jurisdictions, or from selling or importing medical products made using our inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to certain jurisdictions where we have patent protection but where enforcement rights are not as strong as those in certain other jurisdictions. These products may compete with our products and product candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing. During the Track Record Period and as of the Latest Practicable Date, we had not experienced material difficulties in protecting our intellectual property rights. Moreover, if we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business.

Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Our patent terms may not be sufficient to effectively protect our business, and intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.

In most jurisdictions, including China, where we plan to file applications for patents, the term of an issued patent is generally ranging from 10 years to 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable jurisdictions. The life of a patent and the protection it affords are limited. Even if patents covering our services and

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products are obtained, we may be open to competition from other companies once our patent rights expire.

As of the Latest Practicable Date, we owned 82 registered patents and 80 patent applications pending registration in China and overseas relating to our product portfolio, with expiration dates ranging from May 2027 to March 2043. If patents are issued on these pending patent applications, the resulting patents will be expected to expire 10 years to 20 years from the filing date of the relevant patent applications, excluding any potential patent term extension or adjustment. Upon expiration of our issued patent or patents that may issue from our pending patent application, and without patent term extensions, we will not be able to assert such patent rights against potential competitors and our business and results of operation may be adversely affected.

In addition, 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.

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 or infringed by third parties.

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. Lawsuits and proceedings are expensive and would consume time and resources and divert the attention of our managerial and scientific personnel even if we were successful in stopping the infringement of such intellectual property rights. There is a risk that the courts will decide that such intellectual property rights are not valid and that we do not have the right to stop third parties from using our inventions. There is also the risk that, even if the validity of such intellectual property rights is upheld, the courts may refuse to stop the other party on the grounds that such other party’s activities do not infringe our intellectual property rights. Any failure to enforce our intellectual property rights or to defend any legal proceedings regarding our intellectual property rights, including those patents covering the technologies involved in our early cancer detection, such as those leveraging DMLT, iTBFinder, MLP Cancer Classifier, SEM-PCR and AS-Cap, may materially and adversely affect our business, financial condition and results of operations.

Defendant counterclaims alleging invalidity or unenforceability are commonplace, and a third party can assert invalidity or unenforceability of a patent on numerous grounds. Third parties may also raise similar claims before administrative bodies, 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. Such a loss of patent protection would have a material adverse impact on our business.

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We may also be unaware of third-party patents or patent applications, and given the dynamic area in which we operate, additional patents are likely to be issued that relate to aspects of our business. Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalties and other fees and

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expenses on us. As the medical device industry expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An unfavorable result in any litigation proceeding could put our patents, as well as any patents that may be issued in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the market price of our Shares. 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and market position may be adversely affected. 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 market position and to protect our products and product candidates. We seek to protect these trade secrets, in part, by entering into explicit or implicit non-disclosure and confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into employment agreement with our employees that includes undertakings regarding assignment of inventions and discoveries. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our market position may be adversely affected.

Furthermore, many of our employees, including our senior management, were previously employed at other medical device companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. 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. 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.

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

RISKS RELATING TO OUR GENERAL OPERATIONS

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

Our business and growth depend on the continued service of our senior management and personnel in our R&D team to develop products and our sales and marketing team to promote our products. These agreements do not prevent them from terminating their employment with us at any time. We do not maintain key person insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To incentivize valuable employees to remain at our Company, in addition to salary and cash incentives, we have granted and plan to continue to grant equity interests in our Company to certain eligible 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. Any of our employees could leave our employment at any time, with or without notice. In addition, we rely on consultants and advisors, including our medical advisory board, to assist us in formulating our 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.

Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, 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 R&D and clinical personnel from universities and research institutions. Our consultants and advisors 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 entered into out-licensing arrangements with HybriBio Biotech and may seek additional collaboration opportunities and strategic alliances or enter into licensing arrangements in the future, but we may not realize the benefits of such collaboration, alliances or licensing arrangements as expected.

We have in the past formed, and may in the future, seek to form strategic alliances and collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our current and future products. In May 2018, we entered into a technology collaboration agreement

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(the “**Out-licensing Agreement**”) with HybriBio Biotech which was subsequently amended in March 2019. According to the Out-licensing Agreement, we granted HybriBio Biotech the exclusive rights to utilize the patents, patent applications and know-how to develop, manufacture and commercialize ICervsure (艾宫舒), an early cancer detection product for cervical cancer, in the PRC, for a period of 10 years after obtaining the Class III medical registration of ICervsure (艾宫舒). For details, please refer to “Business – Research and Development – Licensing Arrangement”.

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

Further, collaborations involving our products and product candidates are subject to numerous risks. 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. 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, delay its potential commercialization or reduce the scope of any sales or marketing activities. If we elect to fund 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, which may adversely affect our business, financial condition and results of operations.

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

We face an inherent risk of product and professional liability as a result of the commercialization of our products, the provision of our services, the clinical testing and any future commercialization of our product candidates in China. Any product and professional liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the medical device product, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product and professional liability claims, we may incur substantial liabilities or be required to limit commercialization of our products and product candidates and provision of our services. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: (a) decreased demand for our products; (b) injury to our reputation; (c) withdrawal of clinical trial participants and inability to continue clinical trials; (d) initiation of investigations by regulators; (e) costs to defend the related litigation; (f) a diversion of management’s time and our resources; (g) substantial monetary awards to trial participants or subjects, product recalls, withdrawals or labeling, marketing or promotional restrictions; (h) loss of revenue; (i) exhaustion of any available insurance and our capital resources; and/or (j) the inability to commercialize any product candidate.

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If we are unable to obtain sufficient product and professional liability insurance at an acceptable cost, potential product and professional liability claims could prevent or inhibit the commercialization of our products and product candidates. Other than a group insurance policies for our end users who purchase and use our products, we currently do not hold any product and professional liability insurance coverage, and we may be unable to acquire such insurance at a reasonable cost or in an amount adequate to cover any liability that may arise, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product and professional liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceeds our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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, contractors, business partners, current or former employees and other third parties that we engage for our business operations.

Ongoing 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. If any verdict or award is rendered against us or if we settle with any third parties, we may be required to pay monetary damages, assume other liabilities and even to suspend or terminate the related business projects, which may have a negative impact on our tests and products. 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 operations may be materially and adversely affected.

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.

We depend on our information technology for a significant portion of our operations. Our information technology systems store and process a variety of sensitive data, including but not limited to, legally protected personal health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We also manage and maintain our applications and data utilizing on-site and cloud-based systems. These applications and data encompass a wide variety of business-critical information including R&D information, commercial information and business and financial information. Thus, it is essential that our information technology infrastructure remains secure and is perceived by hospitals, patients and our research partners to be secure. We seek to preserve the security of our information technology infrastructure by maintaining physical security of our premises and physical and electronic security of our information technology systems by measures such as installing antivirus software, establishing firewalls, backing up data on a stand-alone workstation with password protection, and saving physical copy of data when appropriate.

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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, including personal information of our employees and end-users, and company and vendor confidential data. In the event of any confidential information is leaked, stolen or misused by any of our employees, inadvertently or not, or due to failure of our information technology systems, we may be subject to lawsuits and other proceedings. 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. Like other companies, we have, on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. 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 credibility could be damaged. We may incur significant expenses 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.

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

We primarily conduct our business in the PRC. We have proprietary rights in respect of our products and product candidates in licensing arrangements, patent registration and protection over proprietary technologies. To grow our business, we intend to expand our business operations internationally. We plan to enter into partnership arrangements to expand our market coverage and maximize the global value of our products.

Our success in expanding our business and providing services internationally, and competing in international markets is subject to our ability to manage various risks and difficulties. Our profitability and ability to implement our business strategies, maintain our market share and compete successfully in international markets may be compromised if we are unable to manage the foregoing risks and other international risks successfully.

Changes in geopolitical relationships, barriers to trade or escalation of trade disputes, including the imposition of export control and sanctions, could negatively affect demand for our products or the supply of raw materials or machineries required in our operations, and consequently could have a material adverse effect to our business, financial condition and results of operation.

During the Track Record Period, our products were mainly sold in China, and overseas sales only accounted for 3.9% of total annual revenue in 2024 and 3.76% in 2025. Our overseas sales are subject to the risk of deterioration in of geopolitical relationships, as well as sanctions and export controls administered by government authorities applicable to our operations. We cannot predict whether the countries to which we made sales would become subject to new or additional trade restrictions and sanctions, including the type or effect of such restrictions and sanctions imposed by the United States or other governments. We cannot assure you that we, our suppliers and customers, or the other parties with whom we collaborate will not be impacted in the future.

In particular, the United States government imposed economic and trade sanctions against certain countries or against targeted industry sectors, groups of companies or persons, and/or organizations within certain countries. The United States has increased export controls restrictions through the Export Administration Regulations (the “EAR”), administered by the

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Bureau of Industry and Security (the “**BIS**”) of the United States Department of Commerce. The EAR may apply to items of U.S. origin as well as certain foreign-made items that incorporate U.S. content or are produced using specified U.S. technology (including under “foreign direct product” rules). The BIS also maintains a list of foreign persons that are subject to specific license requirements for the export, reexport, or in-country transfer of items subject to the EAR, and foreign persons on the list includes businesses, research institutions, government and private organizations, individuals and other types of legal persons (the “**Entity List**”), some of which are based in China. The scope of the license requirement, applicable license exceptions, and the applicable review policy (including, in some cases, a presumption of denial) are determined by the language of each individual Entity List entry. Exporting, re-exporting or transferring items subject to the EAR without satisfying the applicable licensing requirements could result in criminal and/or civil penalties.

During the Track Record Period, one of our suppliers was added to the Entity List on September 12, 2025. Under the EAR, an Entity List party that is merely a supplier in a procurement transaction is not automatically a “party to the transaction” which requires a BIS license. Our transactions with this supplier are limited to procurement and do not involve any sales or service arrangements. We have also obtained written certifications from this supplier confirming that the specific materials and related services supplied to us are not subject to the EAR, are not classified under any Export Control Classification Number (ECCN) on the Commerce Control List (CCL), and do not involve any circumstances requiring a U.S. export license for export, reexport, or transfer (in-country) to China. Based on the above facts and subject to our implementation of appropriate export control and sanctions compliance measures, our legal advisor as to U.S. export control and international sanctions laws is of the view that our procurement from this supplier did not appear to trigger a BIS license requirement under the EAR.

In addition, our products were sold to certain military hospital end customers during the Track Record Period. Based on their official names and publicly available information, each of the military hospital customers would likely fall within the scope of “military end users” for purposes of the EAR. We use a set of U.S.-origin system with ECCN 3A999.f classification for internal quality control testing of our diagnostic test kit products, including those sold to the military hospital customers. Pursuant to Supplement No. 1 to Part 774 of the EAR, items classified under ECCN 3A999 are controlled for Anti-Terrorism (“**AT**”) reasons. In general, AT controls under ECCN 3A999 do not create a general licensing requirement for exports, reexports or transfer to, or in-country transfer within China, unless another control applies (such as Entity List, military end user, or military use). Based on screening conducted, none of the military hospital customers appears on the Entity List and other U.S. sanctions lists as of the search date. Furthermore, we have not sold, transferred, or otherwise provided the controlled equipment itself to any of these customers; nor do our testing kits incorporate any U.S.-origin goods or are direct products of U.S.-controlled technology or software. Accordingly, based on the above facts and information and subject to our implementation of appropriate export control and sanctions compliance measures, our legal advisor as to U.S. export control and international sanctions law is of the view that sales of test kit products to the military hospital customers during the Track Record Period did not appear to raise a material BIS license issue solely because the kits were tested using controlled ECCN 3A999.f equipment for internal quality assurance purposes.

However, export control and sanctions law and policies are evolving and subject to constant changes. If our products – even though manufactured in China – incorporate U.S.-origin controlled items or are the “direct product” of specified U.S.-origin technology or software, they may be subject to the EAR and we might be required to obtain licenses from BIS for in-country transfers or sales to certain end users. Our inability to obtain required authorizations could force us to suspend or terminate sales to affected customers. In addition, tightened controls or new listings could create licensing requirements, require product design adjustments, lengthen

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qualification or sourcing cycles, require modification of sourcing or customer engagement, and increase compliance and procurement costs. Any of these occurrences could adversely affect our business and results of operations.

We do not own any real property and may incur substantial relocation expenses and face risks of operation disruption, and we may be subject to potential material and adverse effects in respect of defects in our leased properties.

We do not own any real property for our operation and leased two properties in the PRC with an aggregate gross floor area of approximately 4,146.7 sq.m. as of the Latest Practicable Date. Upon expiration of the leases, we will need to negotiate for renewal of the leases and may have to pay increased rent. Please refer to the section entitled “Business – Our Properties and Facilities” for more details. We cannot assure that we will be able to renew our leases on terms which are favorable or otherwise acceptable to us, or at all.

In addition, pursuant to the applicable laws and regulations in mainland China, property lease agreements must be registered with the relevant local branches of the PRC Ministry of Housing and Urban-Rural Development. Two of our lease agreements in the PRC were not registered with the relevant competent authorities as of the Latest Practicable Date. As advised by our PRC Legal Advisors, we may be ordered by the relevant government authorities to register the relevant lease agreements within a prescribed period, failing which we may be subject to a fine of RMB1,000 to RMB10,000 for each of the unregistered lease agreement. There can be no assurance that the relevant competent authorities would not impose administrative penalties on us as a result of the non-registration of these lease agreements.

Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation and, as a result, our business, financial condition and results of operations may be negatively affected.

We, our Shareholders, Directors, officers, employees and business partners may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our employees and business partners were incompliant with any laws or regulations, we may also be the subject of negative publicity or reputational damage. 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.

If we fail to maintain or implement an effective internal control system, our financial reporting accuracy and our [REDACTED] may be adversely affected.

If we fail to maintain or implement an effective internal control system over financial reporting, we may make 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, impact our operations and lead to a decline in the [REDACTED] of our Shares. Additionally, ineffective internal control measures in respect of financial reporting obligations could expose us to increased risk of fraud or misuse of corporate assets, and result in potential penalties, regulatory investigations and civil or criminal sanctions being imposed.

Our operations and business plans may be adversely affected by natural disasters, health epidemics and pandemics, civil and social disruption and other outbreaks.

Health pandemics may cause a long-term adverse impact on the economy and social conditions globally and in China, which may have an indirect 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

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and operations. If we are not able to effectively and efficiently develop and commercialize our product candidates as planned, we may not be able to grow our business and generate revenue from sales of our product candidates as anticipated, our business operations, financial condition and prospects may subsequently be materially and adversely affected.

Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to delay or cease development or commercialization of some or all of our product candidates. Our insurance might not cover all losses under such circumstances and we may not have all the required insurance policies in place, and therefore our business may be impacted by such delays and interruptions. We cannot assure that any future occurrence of natural disasters or outbreaks of epidemics and contagious diseases or the measures taken by the governments of the jurisdictions where we operate or plan to enter in response to such contagious diseases will not seriously disrupt our operations or those of our customers, which may materially and adversely affect our business, financial condition and results of operations.

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

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. For further details, please refer to “Business – Our Development Strategies – Selectively Pursue Investment, Acquisition or Partnership Opportunities to Integrate Industry Resources”. Any completed, ongoing or potential acquisition or strategic partnership may entail numerous risks.

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. In addition, we may not be able to integrate any future acquisition targets to achieve the expected synergies with our existing operations and to fulfill the contemplated purposes of these acquisitions. We may not achieve the operational or economic synergies expected from such acquisitions.

Furthermore, our future acquisition targets may not provide us with the intellectual property rights, technology, R&D capability, production capacity or sales and marketing infrastructure we had anticipated, or they may be subject to unforeseen liabilities. Hence, there can be no guarantee that we will be able to enhance our post-acquisition performance or grow our business through our recent or future acquisitions.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred net losses during Track Record Period and may incur net 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.

Investment in medical device development entails substantial upfront capital expenditures and significant risk that a product candidate may fail to obtain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. As a result, we incurred losses during the Track Record Period. We incurred loss of RMB38.6 million and RMB49.0 million for the years ended December 31, 2024 and 2025, respectively. Substantially all of our operating losses were resulted from costs incurred in connection with our R&D programs and from selling, general and administrative expenses associated with our operations.

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We may continue to incur losses for the foreseeable future, and the losses may increase as we expand our development of, and seek regulatory approvals for, our product candidates, and commercialize our products and related services. If any of our product candidates fails in clinical trials or does not obtain the necessary regulatory approvals, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would reduce the value of our Company and could impair our ability to raise capital, maintain our R&D efforts, expand our business or continue our operations.

We had net liabilities positions in the past and may not be able to achieve or maintain net assets and net current assets position in the future.

As of December 31, 2024, we recorded net liabilities of RMB216.0 million. There is no assurance that we will not record net liabilities in the future. Having significant net current liabilities or net liabilities could constrain our operational flexibility and adversely affect our ability to expand our business. If we do not generate sufficient cash flow from our operations to meet our present and future liquidity needs, we may need to rely on additional external borrowings for funding. If adequate funds are not available, whether on satisfactory terms or at all, we may be forced to delay or abandon our growth plans, and our business, financial condition and results of operations may be materially and adversely affected.

We recorded net operating cash outflows during the Track Record Period and there can be no assurance that we will not have net operating cash outflow in the future.

We recorded net cash used in operating activities of RMB23.5 million and RMB23.8 million in each period during the Track Record Period, primarily attributable to our loss before taxation. For a more comprehensive discussion of our liquidity and capital resources, please refer to “Financial Information – Liquidity and Capital Resources – Cash Flows”. We cannot guarantee that prospective business activities of our Group and/or other matter beyond our control will not adversely affect our operating cash flows and lead to net operating cash outflows in the future. If we encounter long-term and continuous net operating cash outflow in the future, we may not have sufficient working capital to cover our operating costs, and our business, financial position and results of operations may be materially and adversely affected.

We may need to obtain additional financing to fund our operations. Raising additional capital may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. In addition, if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our product candidates.

Our product candidates will require completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can generate revenue. Our operations have consumed substantial amounts of cash since inception and we incurred operating cash outflows throughout the Track Record Period. Our net cash used in operating activities amounted to RMB23.5 million and RMB23.8 million in the years ended December 31, 2024 and 2025, respectively. Our commercialized early cancer detection products including IColocomf (艾長康), IColohunter (艾長健), IEsohunter (艾思寧) and IHepcomf (艾馨甘), have contributed a meaningful portion of our cash flow for the year ended December 31, 2025. However, we cannot assure that we will be able to leverage other revenue-generating sources to generate positive cash flows from operating activities in the future. For additional information, please refer to “– Risks Relating to our Business – The sales of our NMPA-approved products constituted a significant portion of revenue during the Track Record Period. Our future revenue will depend on the commercialization and further sales of IHepcomf (艾馨甘) and IUrisure (艾光樂) and other product candidates”. Our liquidity and financial condition may be materially and adversely

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affected by negative net cash flows, and we cannot assure that we will generate sufficient cash flows from other sources to fund our operations. 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 R&D, advancing the clinical development of our product candidates, commercializing our products and related services and launching and commercializing any product candidates for which we receive regulatory approval, including building our own commercialization capabilities to address the PRC's market. We incurred research and development expenses of RMB15.0 million and RMB21.3 million for the years ended December 31, 2024 and 2025, which accounted for 207.2% and 138.1% of our total revenue for the same period, respectively. Our future funding requirements will depend on many factors, including: (a) revenue and cash generated from our commercialized products; (b) selling and marketing costs associated with our products and any existing or future product candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities; (c) 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; (d) the outcome, timing and cost of regulatory approvals of our product candidates; (e) the number and characteristics of product candidates that we may develop; (f) the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; (g) the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish; (h) cash requirements of any future acquisitions and/or the development of other product candidates; (i) the cost and timing of development and completion of commercial-scale internal or outsourced, if any, manufacturing activities; and/or (j) our headcount growth and associated costs.

Our existing cash and cash equivalents may not be sufficient to enable us to complete all development or commercially launch all of our current product candidates for the anticipated uses and to invest in additional programs. Accordingly, we may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. If we resort to such financing activities to generate additional cash, we may incur financing costs and we cannot guarantee that we will be able to obtain financing on terms acceptable to us, or at all. To the extent that we raise additional capital through the sale of equity or convertible securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares.

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 R&D programs or future commercialization efforts.

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 the years ended December 31, 2024 and 2025, we recognized government grants as other income of RMB6.6 million and RMB1.4 million, respectively. The timing, amount and criteria of government grants and other favorable policies are determined within the discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. 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 favorable policies may materially adversely affect our business, financial condition, results of operations and prospects.

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RISKS RELATING TO THE [REDACTED]

No [REDACTED] currently exists for our H Shares, and an active [REDACTED] market for our H Shares may not develop.

No [REDACTED] currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and Joint Representatives (on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of the Shares following the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] market for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will rise following the [REDACTED].

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

The [REDACTED] and [REDACTED] of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the [REDACTED] of the shares of other companies engaging in similar business may affect the [REDACTED] and [REDACTED] of our Shares. In addition to market and industry factors, the [REDACTED] and [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 our industry, 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.

Potential investors will experience immediate and substantial dilution as a result of the [REDACTED].

As the [REDACTED] of our H Shares is higher than the consolidated net tangible assets per share immediately prior to the [REDACTED], purchasers of our H Shares in the [REDACTED] will experience an immediate dilution in [REDACTED] adjusted consolidated net tangible assets. Our existing Shareholders will receive an increase in the [REDACTED] adjusted consolidated net tangible asset value per share of their shares. Please refer to Appendix II to this document for details. In addition, holders of our H Shares may experience further dilution of their interest if the [REDACTED] exercise the [REDACTED] or if we issue additional H Shares in the future to raise additional capital. In addition, holders of our H Shares may experience further dilution of their interests if the [REDACTED] exercise the [REDACTED] or if we obtain additional capital in the future through equity offerings.

Future sales or perceived sales of a substantial number of H Shares in the [REDACTED] could materially and adversely affect the prevailing [REDACTED] of our H Shares and our ability to raise additional capital in the future.

The future sale of a significant number of our H Shares in the [REDACTED] after the [REDACTED], or the perception or anticipation of such sales, by any one of our Shareholders could materially and adversely affect the [REDACTED] of our H Shares and could impair our future ability to raise capital in the future at a time and [REDACTED] that we deem appropriate. Any major disposal of our Shares by the Controlling Shareholders upon expiry of the relevant lock-up periods or the perception that these disposals may occur may cause the [REDACTED] of our H Shares to fall which could negatively impact our ability to raise equity capital in the future.

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Payment of dividends is subject to restrictions under the PRC law and there is no assurance whether and when we will pay dividends.

No dividend had been paid or declared by our Company since our inception. We cannot guarantee when and in what form dividends will be paid on our H Shares following the [REDACTED]. Future determination of dividends will also depend on various factors, including but not limited to our results of operations, cash flows and financial conditions, capital adequacy levels, operating and capital expenditure requirements, distributable profits as determined under the PRC GAAP, the IFRSs, our Articles of Association, the PRC Company Law, market conditions, our strategic plans and prospects for business development, contractual limits and obligations, taxation, regulatory restrictions and any other factors from time to time to be relevant to the declaration or suspension of dividend payments. We may not have sufficient or any profits to enable us to make dividend distributions to our Shareholders in the future, even if our financial statements indicate that our operations have been profitable. Please refer to “Financial Information – Dividends” in this document for details.

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

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

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

Our management may spend the [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return to our Shareholders. Please refer to the section headed “Future Plans and Use of [REDACTED] – Use of [REDACTED]” in this document for more information. However, our management will have discretion as to the actual application of our [REDACTED]. You are entrusting your funds to our management, upon whose judgment you must depend, for the specific uses we will make of the [REDACTED] from this [REDACTED].

Forward-looking statements contained in this document are subject to risks and uncertainties.

This document contains forward-looking statements. All statements, other than statements of historical facts included in this document, including, without limitation, those regarding our financial position, business strategies, growth prospects, plans and objectives for future operations are forward-looking statements. Such forward-looking statements are made based on numerous assumptions that we believe to be reasonable as of the date of this document.

Forward-looking statements can be identified by the use of forward-looking terminologies, such as the words “may”, “will”, “would”, “could”, “believe”, “expect”, “anticipate”, “intend”, “estimate”, “aim”, “plan”, “forecast” or similar expressions, and include all statements that are not historical facts. Such forward-looking statements are subject to known and unknown risks, uncertainties and other contingencies that may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future. Such factors include,

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among others, general economic and business conditions, competition, the impact of new laws and regulations affecting our industry and initiatives of the governments of the countries in which we operate.

In light of these uncertainties, the inclusion of such forward-looking statements in this document should not be regarded as a representation or warranty by us or our advisors that such plans and objectives will be achieved.

The industry data, forecasts and statistics in this document are derived from various government publications and may not be accurate, complete or up to date.

Facts, forecasts and statistics in this document relating to the cancer early detection and diagnostic industry in and outside the PRC are obtained from official government publications. Neither we, the Joint Sponsors, the [REDACTED] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from official government documents or statements. These studies and estimates are based on a number of factors, including, without limitation, the size of target market populations, the number of individuals who are at a higher risk for developing cancer, infectious diseases or cardiovascular diseases, and the assumed prices at which we can sell the relevant products and services in such markets. We believe that the sources of the information are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. However, 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, and no representation is given to their accuracies.

We may need additional capital, and the sale and issue of additional H Shares or other equity securities could result in additional dilution to our Shareholders.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the [REDACTED] of our Shares to decline. 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.

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

Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the

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disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective [REDACTED] are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.

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

Our Controlling Shareholders may exert substantial influence over our operation and may not act in the best interests of [REDACTED].

Immediately following the completion of the [REDACTED], our Controlling Shareholders will be entitled to exercise voting rights of [44.36%] of the total issued share capital of our Company. The interests of our Controlling Shareholders may differ from the interests of our other Shareholders. Our Controlling Shareholders could have significant influence in determining the outcome of any corporate transaction or other matters submitted to our Shareholders for approval. This concentration of ownership, as a result, may discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for their Shares in a sale of our Company or may reduce the [REDACTED] of our H Shares. In addition, to the extent the interests of our Controlling Shareholders conflict with the interest of our other Shareholders, the interests of our other Shareholders may be disadvantaged or harmed.

We have a dispersed shareholder base and there is a lack of agreement among our Shareholders or their respective shareholders regarding the arrangement on the disposal of our Shares.

We have a dispersed shareholder base with 15 corporate Shareholders and three individual Shareholders. There is no shareholder agreement among these Shareholders or their respective shareholders regarding the arrangement or restrictions on the disposal of our Shares. The Shares held by Controlling Shareholders are subject to lock-up undertakings commencing from the [REDACTED]. Please refer to “[REDACTED] – [REDACTED] Arrangements and Expenses – Undertakings to the Stock Exchange pursuant to the Listing Rules – Undertakings by our Controlling Shareholders” in this document. In the event that any of these Shareholders dispose of the Shares after the expiry of the relevant lock-up periods, it could negatively impact the [REDACTED] of our Shares or lead to volatility in the [REDACTED] or [REDACTED] of our Shares, affecting the value of your investment.