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An [REDACTED] in our H Shares involves various risks. You should carefully consider all the information in this document, including the risks and uncertainties described below, before making an [REDACTED] in our H Shares. In particular, we are a biotechnology company seeking to list on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the industry in which we operate involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your [REDACTED] in our H Shares. These risks could materially and adversely affect our business, financial condition, and results of operations. The trading price of our H Shares could decline due to any of these risks and uncertainties, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given will not be updated after the date hereof and is subject to the cautionary statements in the section headed “Forward-looking Statements” in this document. You should seek professional advice from relevant advisors regarding your prospective investment in the context of your particular circumstances.

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to Our Products and Product Candidates

Our future growth depends substantially on the successful development of our product portfolio. If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our product candidates, or experience significant delays in doing so, our business and financial prospects will be materially adversely affected.

Our business substantially depends on the successful development, obtaining and maintaining the necessary regulatory approvals and commercialization of our current and future products and product candidates. As of the Latest Practicable Date, we had commercialized the GBS for treatment of obesity with certain criteria. The GBS has obtained regulatory approvals in 12 countries and regions including Chinese Mainland. We are in the process of extending indications and introducing more specifications for our GBS. We are also developing new product candidates based on the same technology platforms with GBS, including GBS-SH for MASH with obesity and GBS-DM for T2DM with obesity. See “Business — Product Pipeline” for more details on our complete product pipeline.

We have invested a significant portion of our time and financial resources towards the development and commercialization of our Core Product and other products and product candidates. We incurred research and development expenses of RMB41.1 million, RMB48.7 million, RMB22.0 million and RMB38.7 million in 2024 and 2025 and the six months ended June 30, 2025 and 2026, respectively, accounting for 54.5%, 43.6%, 47.7% and 40.8% of our total operating expenses for the same periods. In 2024 and 2025 and the six months ended June 30, 2025 and 2026, research and development expenses incurred for our Core Product were RMB10.7 million, RMB19.3 million, RMB7.5 million and RMB11.4 million, respectively, accounting for 25.9%, 39.7%, 34.0% and 29.6% of our total research and development expenses for the corresponding periods. We incurred loss for the period of RMB66.0 million, RMB88.3 million, RMB37.7 million and RMB68.3 million in the same periods, respectively. Whether we can generate net profit from our operating activities largely depends on the successful development and commercialization of our Core Product and of our other product candidates under development.

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The success of our products and product candidates will depend on several factors, including but not limited to: (i) successful enrollment in, and completion of, clinical trials and pre-clinical studies; (ii) favorable clinical and pre-clinical safety and efficacy data; (iii) timely regulatory approvals and product launches in target markets, if approved; (iv) compliant performance by third-party service providers and protection of data integrity; (v) obtaining and maintaining intellectual property protection and regulatory exclusivity; (vi) avoiding infringement or misappropriation of third-party intellectual property rights; (vii) appropriate product pricing and timely payment collection; (viii) efficient and cost-effective enhancement of our marketing and distribution capabilities; (ix) maintaining competitiveness against existing and future products; (x) keeping pace with industry and technological developments; and (xi) maintaining an acceptable safety and efficacy profile following approval and commercialization, if received.

If we are not successful in one or more of the above factors in a timely manner, or at all, we could experience significant delays or be unable to obtain the necessary approvals to commercialize our other product candidates, which may have a material and 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 general business operations.

The industry of EMBT for treatment of obesity and metabolic diseases is developing rapidly. If we are not able to develop and launch new products that are competitive in the market, or successfully extend indications and introduce new specifications for the GBS or develop and commercialize any other products or product candidates in a timely manner, our products may become obsolete and our business, operating results and financial condition could be materially adversely affected.

The industry of EMBT for treatment of obesity and metabolic diseases is rapidly evolving, and it is uncertain whether it will achieve and sustain large-scale market adoption and widespread clinical application. Our future financial performance will depend on growth in this market and on our ability to adapt to emerging market demands. It is difficult to predict the future growth rate and size of our target markets. The industry is characterized by rapid technological changes, frequent new product introductions and enhancements, changing patient demands, and evolving industry standards. Social and policy trends on the industry may further evolve, which could lead to changes in need for our products and the need for us to adapt our business model and our product pipelines. Our success therefore depends on our ability to accurately forecast the industry trends and continuously identify, develop and market products that suit the market demand and address unmet clinical needs in a timely manner. Product designs can change with market conditions, as well as demand and preferences of patients, experts, hospitals and medical professionals. We cannot assure you that we will be able to successfully identify new technological opportunities, enhance or adapt to new technologies and methodologies, develop new products, or improve or expand the indication coverage of our existing products in a timely manner. If we do not accurately anticipate patient and physician demands or we are unable to develop, license or acquire new features and capabilities on a timely and cost-effective basis, or if such enhancements do not achieve market acceptance, it could result in adverse publicity, loss of revenue or market acceptance, or claims by patients or healthcare providers brought against us, each of which could have a material and adverse effect on our reputation, business, results of operations and financial condition.

Clinical development is a lengthy, expensive and uncertain process, and unsuccessful clinical trials or procedures relating to products under development could have a material and adverse effect on our prospects.

Obtaining regulatory approval is a complex, time-consuming process that varies by jurisdiction, requiring us to comply with extensive regulations throughout the product lifecycle. For instance, in Chinese Mainland, according to a catalog issued by the NMPA, medical devices in Chinese Mainland are classified into three different categories, corresponding to specific regulatory requirements, Class I medical device

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filing, and Class II and Class III medical device registration certificate, depending on the degree of risk associated with a particular medical device and the extent of control needed to ensure the safety and efficacy of such medical device. Our GBS has received its Class III Certificate from the NMPA in January 2024, which is subject to the highest level of regulatory oversight due to their critical role in supporting or sustaining human life and potential risks to patient safety. See “Regulatory Overview — Overview of the Major Laws, Rules and Regulations Relating to Our Business in the PRC — Regulations and Classification of Medical Devices.” The development, manufacturing, distribution and post-market supervision of Class III medical devices are subject to extensive regulatory requirements, including but not limited to: (i) clinical trial protocols with larger sample sizes and longer follow-up periods; (ii) mandatory compliance with GMP standards for medical devices; (iii) obtaining and maintaining production and other necessary licenses specific to Class III devices; and (iv) establishing and operating a compliant quality management system to ensure full traceability of all products throughout the supply chain. Complying with these stringent regulatory obligations requires investment in research and development, quality control systems, regulatory affairs, manufacturing infrastructure and personnel training. Any failure to maintain full compliance could result in delays in product approvals, suspension or revocation of licenses, product recalls, administrative penalties or litigation, which may have a material adverse effect on our business prospects, results of operations and financial condition.

Furthermore, although early small-scale studies have shown promising trends for many of our product candidates, pivotal registration clinical trials may fail to replicate these results due to larger sample sizes, variability across multi-center enrollment, changes in statistical methodology misalignment of primary endpoints with evolving regulatory or medical standards, or failure to meet Inspection criteria due to divergent audit requirements. Regulatory authorities, including the NMPA, may, based on their assessment of data completeness, authenticity, scientific validity, consistency, and clinical relevance, require us to conduct additional studies, extend follow-up periods, or accept restricted indications upon approval. Any such requirements would delay product launch, increase R&D costs, and potentially weaken market competitiveness. We cannot guarantee that our current or future clinical trials will generate data sufficient to support regulatory approval. If these study results fall short of expectations, we may be forced to revise our development strategy, narrow indication scope, or even discontinue product development, which could have a material adverse effect on our business, financial condition, and prospects.

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

We plan to conduct clinical trials and real-world evidence studies to support extension of indications and introduction of new specification for our GBS and the commercialization of our product candidates, and to meet regulatory requirements in international markets. The timely completion of these studies depends on our ability to enroll a sufficient number of eligible patients who remain compliant to our trial protocols throughout the follow-up period.

Patient enrollment may be challenging due to, among other things: (i) strict inclusion and exclusion criteria, such as specific BMI ranges, metabolic and other profiles; and (ii) limited patient awareness of our products and product candidates, resulting in preference for pharmacological treatments or surgical options that are currently more familiar to patients. Furthermore, given that our device is retrievable some patients may opt for early retrieval due to discomfort or unmet expectations, potentially leading to higher-than-expectation dropout rates and incomplete data collection. Delays in enrollment or high attrition could increase development costs, prolong study duration, and delay regulatory approvals or label expansions, which may have a material adverse effect on our growth strategy and commercial prospects.

Our preclinical studies may experience delays or may never advance to clinical trials.

Many of our product candidates are still in the preclinical development stage, and the risk of failure of preclinical programs is high. Specifically, as of the Latest Practicable Date, we had 13 product candidates in

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development. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies, including strictly regulated type testing and animal studies, to satisfy regulatory requirements to initiate human clinical trials. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the competent regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to complete the necessary filings or obtain necessary approvals for the contemplated clinical development of our preclinical product candidates on the timelines we expect, if at all. Failure to pass type testing or obtain satisfactory animal study results would prevent us from initiating clinical trials. Furthermore, we may have to discontinue the development of a candidate if evolving market dynamics or regulatory changes diminish its commercial value or feasibility.

Risks Relating to Commercialization and Distribution of Our Products

We have limited experience in the commercialization of medical devices.

Our Core Product, the GBS, received NMPA approval in early 2024 and is currently in the early commercialization phase. We rely on our in-house sales and marketing teams to drive hospital adoption, physician training, and scientific promotion. However, we have limited experience in large-scale commercial operations and face potential challenges such as a shortage of specialized sales personnel, complex hospital procurement processes, and a steep physician learning curve. If we fail to effectively scale our sales force, deepen relationships with key hospitals, or accelerate physician training, the rollout of our product in target hospitals may be delayed, adversely affecting revenue growth.

Our GBS offers a minimally invasive and reversible alternative for patients with obesity and the relevant market is still nascent in China, with no established clinical practice standards and limited awareness among physicians and patients. Currently, the mainstream management of obesity relies on lifestyle modification, pharmacological treatments and surgical bariatric procedures. As an innovative endoscopic intervention, our product face challenges in demonstrating distinct advantages over existing therapies in terms of efficacy, safety, accessibility, and cost-effectiveness to achieve broad market adoption. For example, compared to the convenience of widely accessible GLP-1 injections, our GBS requires endoscopic implantation under anesthesia. Furthermore, unlike bariatric surgery which offers permanent results, our GBS is a temporary implant requiring subsequent retrieval, with a risk of weight regain if patients fail to maintain a healthy lifestyle.

Market acceptance will depend on a number of factors, including: the scope of indications approved by regulatory authorities; whether physicians, hospitals and patients perceive our product as a safe and effective treatment option; the extent to which the potential benefits and limitations of our product are understood relative to alternative therapies and procedures; the availability of long-term safety data; any usage restrictions or warnings in the product labeling; the timing of market launch relative to competing products; treatment cost and affordability compared to alternative therapies; the availability of coverage and reimbursement from medical insurance or commercial payors; patient willingness to pay out-of-pocket in the absence of reimbursement; and the effectiveness of our medical education and scientific promotion efforts. If our product fails to build clinical credibility among key opinion leaders or lacks robust real-world evidence and expert consensus, it may result in delayed hospital adoption. Even if initial acceptance is achieved, we may face erosion of market share if future innovations offer superior cost-effectiveness or ease of deployment. Any failure to achieve or sustain market acceptance could materially impair our revenue growth, profitability, and long-term competitive position.

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Our revenue is currently concentrated in the GBS, and if market demand for this product falls short of expectations or is adversely affected by external factors, our business and results of operations could be materially and adversely affected.

Our GBS is currently our major source of revenue and is expected to remain the primary source of our revenue in the foreseeable future. We have not yet achieved profitability and expect to remain reliant on sales of this product to fund R&D, manufacturing, and commercialization activities for the foreseeable future. Consequently, any factor that negatively impacts market demand, pricing, hospital adoption, or clinical uptake of the GBS could have a material adverse effect on our overall financial condition and business prospects. Additionally, the product faces competition from other treatments, such as GLP-1 RA weight-loss drugs, traditional bariatric surgery, and other interventional therapies. If competitors introduce more cost-effective or easier-to-deploy alternatives, or if physicians and patients develop concerns regarding the long-term efficacy or safety of our product, market demand may decline. Any such developments could significantly impair our revenue growth and path to profitability.

If our products cause, or are perceived to cause, severe adverse events, our reputation, revenue and profitability could be materially and adversely affected.

Our GBS, as an endoscopically delivered interventional medical device, may be associated with unintended severe adverse events during clinical use, many of which are beyond our direct control. These include long-term complications not fully revealed in clinical trials, severe idiosyncratic reactions in individual patients, undetected manufacturing defects, misuse due to improper physician technique or poor patient adherence, among others. Furthermore, even in the absence of a conclusive causal link, if clinical reports or public perception associate adverse events with our product, such perception may potentially undermine physician and patient confidence in its use. Notably, if future similar devices using comparable stent systems are reported to have safety issues by regulatory authorities such as the NMPA or the FDA, our product may be indirectly affected due to a class-effect perception, despite design and material differentiation, potentially leading to hospital suspensions or delayed clinical adoption.

In the event of confirmed or widely perceived severe adverse events linked to our products, we may face a range of significant consequences, including but not limited to: severe patient injury; sharp decline in demand and sales volume; product recall or voluntary market withdrawal; revocation of product registration or manufacturing licenses by regulators; damage to brand reputation; removal from medical insurance reimbursement lists; and exposure to litigation or regulatory investigations resulting in liabilities, fines, or penalties. Any of these outcomes could have a material adverse effect on our business, financial condition, and future prospects.

Our commercialization may be affected by the level of medical insurance reimbursement end patients receive.

Up to the Latest Practicable Date, our GBS has been included in local medical insurance reimbursement lists in 28 provincial-level regions, such as Sichuan, Shandong, Hebei, Henan, Shanghai, Guangdong, and Jiangsu, marking initial policy recognition. However, China currently lacks a unified national access and pricing framework for high-value medical devices. There are variations across regions in terms of reimbursable indications, patient eligibility criteria, reimbursement rates, and annual payment caps. This fragmented reimbursement landscape results in inconsistent out-of-pocket costs for patients, complicates clinical decision-making for physicians, and increases the complexity of formulating a cohesive national commercialization strategy. Furthermore, local reimbursement policies are highly dynamic and may be revised or rescinded due to fiscal pressures, budget reallocations, or the emergence of new therapies. We cannot guarantee the long-term stability of existing reimbursement status, nor can we ensure that future expansions into new regions will achieve comparable or favorable terms. If certain regions reduce reimbursement rates or narrow eligible indications, patient conversion rates may decline, adversely affecting

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sales growth. At the same time, securing inclusion in additional regions may require further price concessions, potentially compressing gross margins.

Guidelines, recommendations and studies published by various organizations may not favor our product candidates.

The clinical adoption of our GBS is dependent on treatment guidelines and expert consensus issued by authoritative bodies, such as the Guideline for Diagnosis and Treatment of Obesity (2024 edition) issued by the NHC. Currently, these guidelines primarily recommend lifestyle intervention, pharmacotherapy, and surgical bariatric procedures as standard treatments for moderate-to-severe obesity, while our Core Product is included in the relevant guidelines and recommendations, it has not been widely incorporated into first-line treatment pathways. Given the strong influence of guidelines, recommendations and consensus on clinical practice, any unfavorable changes in authoritative recommendations regarding our products or product candidates could significantly affect physician prescribing behavior, hospital procurement decisions, and patient treatment choices, thereby materially and adversely affecting our sales growth, market share, and long-term competitiveness.

Our ability to enter other markets will depend, among other things, on our ability to navigate various regulatory regimes with which we have limited experience.

We have obtained regulatory approvals for the GBS in certain markets outside China, including but not limited to, Hong Kong, Thailand, and Malaysia, and have received the FDA Breakthrough Device Designation for our product candidate GBS-SH, marking the initial execution of our global expansion strategy. However, regulatory requirements, clinical practice standards, and market access pathways vary significantly across jurisdictions; if we fail to sustain the necessary resources to meet local compliance obligations or effectively manage cross-border operational complexities, it could impact the pace and profitability of our international growth.

Although we have obtained regulatory approvals in certain overseas markets, the global medical device regulatory landscape remains highly fragmented. Major and mature overseas markets, such as the United States, typically impose stringent requirements on clinical data and quality management systems, while regulatory frameworks and market environments in other international regions may vary significantly and are subject to change. Moreover, steps subsequent to regulatory approval such as pricing negotiations, reimbursement applications, establishment of local distribution networks, building technical support capacity, and physician training remain complex and resource-intensive. We also face risks related to geopolitical tensions, trade restrictions, economic instability, and natural disasters, which could disrupt supply chains or impair our ability to operate effectively across borders.

Our international commercialization efforts are still in the early stages, with limited team size and experience in commercializing high-value interventional devices in mature markets such as the United States. If we are unable to timely expand our team with expertise in global regulatory affairs, market access, compliance, and sales, or fail to establish effective collaborations with strategic partners possessing local capabilities, it could result in slower-than-expected market uptake, rising operational costs, or even regulatory non-compliance, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We currently operate a hybrid sales model in Chinese Mainland, combining sales with certified distributors and direct sales, with distributorship taking up 99.1%, 99.6%, 99.6% and 99.7% of our revenue in 2024 and 2025 and the six months ended June 30, 2025 and 2026, respectively. Furthermore, revenue

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from our top five distributors accounted for 60.8%, 56.2% and 44.8% of our total revenue in 2024 and 2025 and the six months ended June 30, 2026, respectively. As of December 31, 2024 and 2025 and June 30, 2026, we had 44, 70 and 87 distributors, respectively. The technical expertise, promotional efforts, financial strength, and compliance awareness of our distributors directly impact our product adoption speed, and physician training outcomes. Although we have established qualification assessments, training programs, and compliance monitoring for them, our control over their day-to-day operations is limited.

If any key distributor terminates its relationship due to financial distress, strategic shifts, or reduced margins, our market coverage could be disrupted or our growth in specific regions slowed. Additionally, some distributors may engage in price undercutting to gain market share, our pricing structure could be disrupted, relationships with other partners damaged, and hospital perceptions of our product’s value potentially undermined. More seriously, if a distributor engages in improper clinical support, false advertising, or unauthorized efficacy claims, our brand reputation could be damaged, and medical disputes or regulatory scrutiny could be triggered. While we believe alternative distributors are available, identifying suitable replacements and completing the necessary onboarding and training processes may take several months, during which sales losses may occur. Therefore, if we fail to maintain a stable, efficient, and compliant distribution network, it could have a material and adverse effect on our business, financial condition, and future growth prospects.

Risks Relating to Extensive Government Regulations

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

We focus our activities in the major market of Chinese Mainland and plan to expand our market overseas. These geopolitical areas all have strict regulation on medical devices, and in doing so they employ broadly similar regulatory frameworks, including regulation of product development, approval, manufacturing, sales and marketing and distribution of medical devices. However, there are differences in the regulatory regimes in different regions, which makes regulatory compliance in all of these regions more complex and costlier.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations require substantial time and resources. Failure to comply with the applicable requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial consequences, including a regulator’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, fines, or civil or criminal penalties. The failure to comply with these regulations could have a material and adverse effect on our business, financial condition and prospects.

Ongoing changes in medical device regulations, reimbursement policies, and centralized procurement systems in China may increase our compliance costs, delay market access, and exert downward pressure on our pricing power and profitability.

We develop and commercialize in China our GBS, a Class III medical device subject to stringent regulation by the NMPA and other competent authorities. In recent years, the Chinese government has advanced healthcare reforms aimed at strengthening lifecycle oversight of innovative devices and controlling costs for high-value consumables. While the NMPA has streamlined review processes, it has also raised requirements for clinical evidence quality, real-world data collection, post-market safety monitoring, and quality management systems. Any further tightening of regulatory standards or shifts in enforcement practices could delay our product submissions, necessitate additional clinical studies, or increase post-approval compliance burdens.

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Meanwhile, the NHSA continues to reform the governance of high-value medical consumables, encouraging local governments to pilot volume-based procurement programs. Although our Core Product, being a Class III Innovative Medical Device in China, is currently eligible for a temporary exemption and not included in any provincial or national centralized procurement list, it may eventually be subject to inclusion in future procurement lists amidst the rising demand for obesity and other metabolic disease treatments and advancements in competing technologies. In the event that our product is included in such lists, we would face intense price competition, potentially leading to significant price reductions, and our gross margins and profitability could be materially compressed. Consequently, our business, financial condition, and results of operations could be materially and adversely affected.

Our products or product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, or result in significant negative consequences following regulatory approval, if any.

Our GBS is delivered via endoscopy, designed to modulate metabolism through multiple mechanism of action. While this approach is minimally invasive, as a device in direct contact with human tissue, it carries inherent risks. Based on clinical experience, potential adverse events may include stent migration or dislodgement, gastrointestinal perforation, or inflammatory reactions.

For our products and future product candidates, if unexpected serious adverse events occur during pivotal clinical trials, trial for expanded indications, or post-market surveillance, regulatory authorities may require clinical holds, additional data submissions, label modifications, black-box warnings, or even deny or revoke marketing approvals. Additionally, we may be required to issue safety communications to hospitals and physicians, conduct active monitoring programs, or initiate product recalls. More seriously, if patients suffer physical harm from using our product in any current or potential markets, we could face personal injury claims or class-action litigation, resulting in significant financial liabilities and management distraction. Even if ultimately resolved in our favor, the litigation process itself could cause lasting damage to our public image and investor confidence. Therefore, any significant safety issue could hinder market access, reduce physician adoption, and have a material adverse effect on our business, financial condition, and future prospects.

If our current and future products are not produced in compliance with the quality standards required under applicable laws, our business and reputation could be harmed, and our revenue and profitability could be materially and adversely affected.

Medical device quality management spans the entire lifecycle, from design, raw material sourcing, manufacturing control, sterilization validation, labeling, to post-market traceability. We have established a quality management system compliant with ISO 13485 and China’s GMP standard for medical devices, and have passed on-site inspections by the NMPA. However, specific quality requirements vary across jurisdictions.

As we scale production and expand to more markets, we may need to engage third-party manufacturers or add new production lines. In such cases, inadequate design transfer, incomplete process validation, or weak quality agreement enforcement could lead to batch-to-batch variability or regulatory non-compliance. Furthermore, a significant quality incident in any market, such as a sterilization failure or labeling error leading to misuse, could trigger scrutiny from other regulators, even if the issue is localized, potentially resulting in additional reviews or temporary restrictions. We lack practical experience in managing cross-jurisdictional quality crisis coordination. Therefore, any significant quality issue could hinder market access, reduce physician adoption, and have a material adverse effect on our business, financial condition, and future prospects.

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Our products and any future products will be subject to ongoing regulatory obligations and continued regulatory review.

Our products and any additional product candidates that are approved by the regulators are and will be subject to ongoing regulatory requirements with respect to advertising, promotion, sampling, record-keeping, post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China and other jurisdictions where we may market or sell our products. We are and will be subject to continual review and inspections by the regulators to assess our compliance with applicable laws, requirements, and adherence to commitments we made in any application materials with the NMPA or other comparable regulatory authorities. Accordingly, we must continue to devote time, money and effort to all areas of regulatory compliance.

We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in all relevant jurisdictions. 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. Any of these events could significantly disrupt our operations and materially and adversely affect our business, financial condition, and results of operations.

Failure to pay the social insurance and housing provident funds on behalf of our employees in accordance with the Labor Contract Law or comply with other PRC regulations may have an adverse impact on our financial conditions and results of operation.

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and other applicable PRC regulations, any employer operating in China must open social insurance registration accounts and contribute social insurance premium for its employees. Any failure to make timely and adequate contribution of social insurance premium for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium within a specified period of time, and the competent authority may further impose fines or penalties.

During the Track Record Period, we did not make full contributions to the social insurance and housing provident fund with respect to certain employees as required by relevant PRC laws and regulations. For the years ended December 31, 2024 and 2025 and the six months ended June 30, 2026, the aggregate shortfall in our contributions to social insurance amounted to approximately RMB1.9 million, RMB2.6 million and nil, respectively. In the six months ended June 30, 2026, we made up for approximately RMB1.3 million of our social insurance contribution shortfalls. For the years ended December 31, 2024 and 2025 and the six months ended June 30, 2026, the aggregate shortfall in our contributions to housing provident funds amounted to approximately RMB0.8 million, RMB1.0 million and RMB1.5 million, respectively. As advised by our PRC Legal Advisors, an employer that has not made social insurance contributions in full and on time as prescribed by the law, may be ordered by relevant authorities to rectify and pay the required contributions within a stipulated deadline and be subject to a late payment fee of up to 0.05% per day. If the employer fails to rectify the failure to make social insurance contributions within the stipulated deadline, it may be subject to a fine ranging from one to three times the amount overdue. Accordingly, the aggregate maximum potential penalty that could be imposed on us for such shortfalls during the Track Record Period is approximately RMB13.5 million. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any administrative penalties in terms of the contribution of social insurance premium and housing provident funds. We cannot assure you that our employment practices will always be deemed in full compliance with the evolving PRC labor laws and regulations, or that we will not be subject to any such challenges in the future. If we are deemed to have failed to comply with relevant laws and regulations, we may be required to pay the outstanding amount and could be subject to late payment penalties or enforcement applications. Any such penalties or orders could have a material adverse effect on our business, financial condition, and results of operations.

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We face certain risks relating to the properties that we lease, which may disrupt our operations and incur relocation costs.

As of the Latest Practicable Date, we leased 12 properties across several cities and provinces in China with an aggregate gross floor area of approximately 26,500 sq.m., which were primarily used for office functions and production facilities. Any limitations on the leased properties, or lessors’ title to such properties, may impact our use of the offices, or in extreme cases, result in relocation, which may in turn adversely affect our business operations.

Pursuant to applicable PRC laws and regulations, all lease agreements are required to be registered with the local competent authorities. As of the Latest Practicable Date, three of our leased properties in China had not been registered with the relevant PRC government authorities. Although failure to do so does not in itself invalidate the leases, we may be subject to fines if we fail to rectify within the prescribed time period after receiving notices from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority, indicating a maximum potential fine of RMB30,000 for us as of the Latest Practicable Date. As of the Latest Practicable Date, we had not been subject to any administrative penalties by the relevant competent authorities. If we are challenged by third parties or government authorities upon any of the circumstances stated above with respect to our leased properties, we may be subject to fines and may be required to relocate, as the case may be, and, as a result, our results of operations and financial condition may be adversely affected. Furthermore, if we are required to relocate and we are not able to find a suitable location with commercially reasonable terms or on a timely basis or at all, our operations will be interrupted.

Privacy and data protection laws and regulations could have an implication on our reputation and customer preference.

When conducting our business, we may have access to certain patient data. The personal information of patients or participants for our clinical trials and other clinical and business activities is highly sensitive and we are subject to strict requirements under the applicable data privacy and protection regulations. Privacy leakage incidents might not be avoided due to human error, employee misconduct or system breakdown. In addition, we collaborate with third parties, including principal investigators, hospitals, CROs, CMOs, and other external partners, for our clinical trials. Any security breach, data leakage, or misuse of data by these third parties could be attributed to us, thereby damaging our reputation.

Furthermore, the regulatory landscape for data privacy in China and other jurisdictions is complex, rapidly evolving, and subject to varying interpretations. Strictly adhering to this shifting framework demands significant management attention and financial resources. Any actual or perceived failure to comply with these regulations, or to protect sensitive data, could result in regulatory investigations, fines, or litigation. Any occurrence of such events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Relating to Our Intellectual Property Rights

If we and our current or future business partners are unable to protect our intellectual property rights throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us and our ability to successfully commercialize our products and product candidates may be adversely affected.

We rely on patents, trade secrets and regulatory protections to safeguard the exclusivity of our core technologies, but we cannot ensure these measures will effectively prevent third parties from copying or replicating our products and innovations in all jurisdictions. As of the Latest Practicable Date, we owned 88 granted patents in China and 23 granted patents overseas. We had 66 pending patent applications in China

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and 43 pending patent applications overseas as of the same date. While we have filed further patent applications for our Core Product, and key products, technologies and product candidates, the grant of patents is uncertain, and some applications may be rejected or granted with limited scope that does not provide meaningful protection. Early disclosure, delayed identification of patentable inventions or suboptimal filing strategies may also result in loss of intellectual property rights. If we fail to secure adequate protection, competitors may develop similar or alternative products that directly compete with ours.

Even if patents are granted, their validity, scope and enforceability may be challenged by third parties through legal or administrative proceedings in various jurisdictions, which could lead to narrowing, invalidation or unenforceability of our patent rights. Such proceedings can be costly and time-consuming and may divert significant management and technical resources. Additionally, unauthorized disclosure of confidential information by collaborators, employees or third parties could compromise our trade secrets.

Furthermore, our ability to protect our intellectual property rights may depend on our business partners or collaborators. If our business partners fail to properly maintain or protect such rights, decide not to enforce them against infringers due to strategic differences or resource constraints, or if they fail to provide us with sufficient rights to exclude competitors, our competitive position could be harmed.

If we are unable to maintain strong and enforceable intellectual property protection in key markets, or if our core technologies, especially those in relation to our Core Product, are circumvented, replicated or invalidated, our ability to commercialize products and sustain competitive advantage may be significantly impaired, which could have a material adverse effect on our business, financial condition and prospects.

Claims that our existing products or the sale or use of our future products infringes, misappropriates or otherwise violates the patents or other intellectual rights of third parties could have a negative impact on us.

Third parties may allege that our existing products or future product candidates infringe their intellectual property rights. As the medical technology sector becomes increasingly competitive and the number of granted patents grows, such claims may arise even if our technologies are independently developed. These allegations could come from competitors, non-practicing entities or other rights holders, and may lead to disputes or legal proceedings regardless of their merit. While we are not currently subject to any material intellectual property litigation, we cannot provide assurance that we will not face such claims in the future.

Defending against such claims would involve significant expenses and divert the attention of our management, technical and scientific personnel from core operations. Even if we seek to license the disputed technology to avoid litigation, such licenses may not be available on commercially reasonable terms, or at all. If a claim is successful, we could be prohibited from developing or commercializing the affected products or product candidates, be required to pay substantial damages, incur legal costs, or undertake costly and time-consuming product redesigns. Adverse publicity during litigation, even if ultimately resolved in our favor, could negatively affect investor perception and the market price of our shares.

If we are found to infringe a third party’s intellectual property rights and are unable to obtain a license or modify our products in a timely and cost-effective manner, it could significantly delay or prevent product development and market access, which could have a material adverse effect on our business operations, financial condition and prospects.

Patent terms are limited and thus may be inadequate to protect our competitive position on our products and product candidates for an adequate amount of time.

In most jurisdictions in which we plan to file applications for patents, the term of a granted patent is generally 10 to 20 years from the earliest claimed filing date of a non-provisional patent application in the

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applicable jurisdictions. Although various extensions may be available, the life of a patent and the protection it affords are limited. Even if patents covering our products are obtained, we may be open to competition from other companies once our patent rights expire. As of the Latest Practicable Date, we had been granted 111 patents. We also had 66 pending patent applications in China and 43 pending patent applications overseas as of the same date. If patents are granted based on these pending patent applications, the resulting patents will expire at the end of their respective statutory terms, excluding any potential patent term extension or adjustment. Upon expiration of our granted patents or patents that may be granted 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 materially and adversely affected.

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

Depending on decisions by the NPC and the CNIPA, the laws and regulations governing patents in Chinese Mainland could change in a way that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The U.S. may also implement wide-ranging patent reform legislation. Furthermore, the U.S. Supreme Court rulings could narrow the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. Consequently, any such changes in laws, regulations, or judicial interpretations may increase the uncertainty and costs surrounding the prosecution of our patent applications and the enforcement or defense of our granted patents, potentially diminishing the value of our intellectual property and materially and adversely affecting our business.

If we are unable to protect the confidentiality of our trade secrets, or if third parties assert that our employees or partners have wrongfully used confidential information, our business and competitive position would be materially adversely affected.

We rely on trade secrets, unpatented know-how, and proprietary information to maintain our competitive position. We seek to protect these intellectual property rights by entering into confidentiality and invention assignment agreements with our employees and external third parties. However, these agreements may not provide adequate protection. They may be breached, or we may fail to execute them with parties involved in our development of products and product candidates, leading to potential disputes over ownership. Enforcing claims for misappropriation is difficult, expensive, and unpredictable. Furthermore, if our trade secrets are independently developed by competitors, we would have no right to prevent them from using such information. In addition, we may be subject to claims that our employees have wrongfully used or disclosed the trade secrets of their former employers. Litigation may be necessary to defend against such claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or key personnel. Even if we are successful, such litigation could result in substantial costs and be a distraction to our management. Any failure to protect our trade secrets or any successful claim against us regarding proprietary information could severely damage our competitive position and, consequently, have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may become involved in lawsuits to protect or enforce our intellectual property.

We may need to initiate legal proceedings to enforce or defend our intellectual property rights, but such actions could be costly, time-consuming and may not succeed. If third parties infringe our patents or misappropriate our trade secrets, we may be required to pursue litigation to protect our products and technologies. However, intellectual property disputes often involve significant expenses and can trigger counterclaims alleging infringement of the other party’s rights. Many of our competitors have substantially

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greater legal and financial resources than we do, which could place us at a disadvantage in any such proceedings. Even when we assert our rights, our patents may be challenged and found invalid, unenforceable or narrowly interpreted, limiting their protective value. Litigation may also expose confidential information through disclosure requirements. Furthermore, we may face difficulties in protecting our trade secrets in certain jurisdictions where legal protections are less robust. These challenges could undermine our ability to maintain exclusivity over our key technologies and reduce the competitive advantage we seek to derive from our intellectual property. If we are unable to effectively enforce our intellectual property rights or suffer adverse outcomes in legal proceedings, it could lead to loss of patent protection, unauthorized use of our technology, delays in product development or restrictions on commercialization, which could have a material adverse effect on our business operations, financial condition and prospects.

Risks Relating to Manufacture and Supply of Our Products

Delays in completing and receiving applicable regulatory approvals for our production 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 at our headquarters in Hangzhou, Zhejiang province. As of the Latest Practicable Date, we leased an aggregate area of approximately 4,385 sq.m. for manufacturing facilities in Hangzhou, which we plan to mainly use for the development and manufacture of our Core Product and pipeline product candidates. Any expansion or modification of the site requires regulatory authorization, which involves compliance assessments and inspections. Delays or failure in obtaining such approvals or completing the construction could disrupt our production timelines and adversely affect product development and market launch schedules. Our facilities are vulnerable to damage or operational disruption caused by natural disasters, accidents, power failures or other unforeseen events. Given the specialized nature of our manufacturing processes, we may not be able to rapidly restore capacity or transfer production to third parties in the event of a significant incident, potentially leading to supply delays, clinical trial interruptions or reduced commercial availability. If our manufacturing capabilities are significantly impaired or suspended and we are unable to recover operations in a timely manner, or if insurance coverage proves insufficient to offset losses, it could materially disrupt our supply chain and have a material adverse effect on our ability to advance product development, achieve commercial milestones and maintain financial stability.

If we fail to increase our production capacity to meet customer demand, our business prospects could be materially and adversely affected.

Our future growth is contingent upon our ability to scale manufacturing capacity in line with anticipated market demand. The designed annual production capacity for our GBS during the Track Record Period was 8,000 units. For the years ended December 31, 2024 and 2025 and the six months ended June 30, 2025 and 2026, our production facilities produced 3,401, 4,823, 1,790 and 2,905 units, respectively, representing a 42.5%, 60.3%, 44.8% and 72.6% utilization rate over the same periods. If we are unable to expand production capacity or improve operational efficiency in a timely manner, we may face supply constraints that could hinder commercialization and limit market adoption. Our products involve certain production processes that are highly dependent on skilled labor, and delays in workforce recruitment, training or process optimization may adversely affect output, delivery timelines and cost efficiency.

We are currently expanding our manufacturing footprint to support future production needs. As of the Latest Practicable Date, we had a production facility under construction located in Quzhou, Zhejiang province to support our future commercial scale-up. We also intend to establish two potential production facilities in Wuxi, Jiangsu and Mianyang, Sichuan, which were both still at an early planning stage and no

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construction had commenced as of the Latest Practicable Date. The construction and commissioning of this new facility involve inherent risks, including potential construction delays, cost overruns, and challenges in obtaining necessary regulatory approvals and certifications in a timely manner, and is subject to timely hiring of qualified personnel. Delays in obtaining necessary authorizations for the new facility could postpone product launches or limit supply capacity. Any sustained inability to meet customer demand could result in lost sales, reputational damage and diminished competitive positioning, which could have a material adverse effect on our business development, financial performance and growth prospects.

The manufacture of our products is complex and subject to strict quality controls.

The manufacture of many of our products is complex and subject to strict quality controls, due in part to the serious and costly consequences of a product failure and regulatory requirements. Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, raw material problems, software problems, or human error. Furthermore, if contaminants are discovered in our 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. Stability failures and other issues relating to the manufacture of our products or product candidates could occur in the future. Although closely managed, disruptions can occur during implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions. As we expand into new markets, we may face unanticipated surges in demands for our products which could strain our production capacity. If these problems arise or if we otherwise fail to meet our internal quality standards or those of the competent regulatory authorities, which may include detailed record-keeping requirements, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product liability and other costs, our progress on obtaining product approvals or CE Marking certification could be delayed, and our business could otherwise be adversely affected. In addition, our manufacturing and warehousing facilities, as well as those of our suppliers and logistics partners, could be materially damaged by earthquakes, hurricanes, volcanoes, fires, and other natural disasters or catastrophic circumstances, which could have a material adverse effect on our business operations.

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 inventory risks and holding costs.

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 immediate delivery when required. Furthermore, we are required to maintain an appropriate level of inventory of our raw materials for our commercial production. However, we maintain our inventory levels based on our internal forecasts which are inherently uncertain. If our forecast demand is lower than actual demand, we may not be able to maintain an adequate inventory level of our products or produce our products in a timely manner, and may lose sales and market share to our competitors. On the other hand, excess inventory levels may increase our inventory holding costs, risk of inventory obsolescence or write-offs. For the years ended December 31, 2024 and 2025 and the six months ended June 30, 2026, our inventory turnover days were 634 days, 305 days and 325 days, respectively. We recorded inventory provisions of RMB40,000, RMB349,000 and RMB294,000 for the same periods. We actively monitor our inventory level and track the flow of our products. However, there is no guarantee that the inventory information we collect is complete and accurate or that such information would allow us to effectively manage our inventory level. If we fail to maintain and predict inventory levels in line with the level of demand for our products, our business, financial condition and results of operations will be materially and adversely affected.

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RISKS RELATING TO OUR FINANCIAL CONDITION AND ADDITIONAL CAPITAL REQUIREMENTS

We have been in a net loss position since our inception and may continue to incur net losses for the foreseeable future, and you may lose substantially all your investments in us given the high risks and uncertainties associated with our business operations.

We have incurred net losses since inception and expect to continue to do so for the foreseeable future. In 2024 and 2025 and the six months ended June 30, 2025 and 2026, our incurred net losses was RMB66.0 million, RMB88.3 million, RMB37.7 million and RMB68.3 million, respectively. Our business is in the research-driven and early commercialization phase, requiring substantial and ongoing investment in product development, clinical trials, regulatory submissions and market launch activities. Our operating expenses are expected to increase as we advance our pipeline, expand into new markets and prepare for commercialization. The extent of future losses will depend on the scope of our development programs, associated costs, commercialization efforts and our ability to generate meaningful revenue. We may encounter unforeseen challenges, including unfavorable clinical outcomes, regulatory delays or lower-than-expected market adoption. Even if our products receive approval, there is no assurance that revenue will be sufficient to achieve or sustain profitability. If we achieve profitability in the future, there can be no guarantee that it will be sustained. Continued losses may affect investor perception, limit our access to capital and constrain our ability to maintain R&D activities, scale operations or execute strategic initiatives. In addition, we will incur new costs related to compliance and corporate governance as a Hong Kong-listed company. If we are unable to transition to a self-sustaining business model over time, it could have a material adverse effect on our ability to fund our operations and execute our growth strategy.

The amount of our future losses or potential profits is uncertain, and our annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts.

The magnitude of our future losses or potential profits is highly uncertain, and our annual operating results may fluctuate significantly from period to period, potentially falling short of investor or analyst expectations. This volatility is driven by the inherently uneven nature of R&D advancement, timing of clinical trial outcomes, regulatory review cycles, pace of commercial launch, market adoption rates and fluctuations in operating expenses. As we remain pre-profitability, our market valuation will be largely based on forward-looking expectations, making our stock price particularly sensitive to any deviation from anticipated performance. Furthermore, our revenue recognition may be affected by hospital procurement cycles, reimbursement policy changes, distribution network development and customer uptake timelines, leading to uneven quarterly revenue patterns. At the same time, significant R&D expenditures, strategic commercial investments and post-[REDACTED] compliance costs may deepen near-term losses, amplifying financial volatility. If our results fail to meet market expectations, it could result in significant stock price fluctuations or sustained declines, eroding shareholder value and impairing our ability to raise capital in the future. Given the long development cycles and high degree of uncertainty inherent in the medical devices sector, investors should not rely on the financial results of any single period as an indicator of future performance. This level of unpredictability could have a material adverse effect on our valuation, liquidity and reputation in the public markets.

We had net operating cash outflows throughout the Track Record Period.

We have generated negative operating cash flows during the reporting periods and will continue to require substantial external financing to fund our research and development, regulatory submissions, commercialization activities and general operations. In 2024 and 2025 and the six months ended June 30, 2025 and 2026, we incurred net cash outflows from our operations of RMB43.6 million, RMB72.9 million, RMB34.7 million and RMB56.0 million, respectively. Our ability to secure timely and favorable funding is subject to significant uncertainty. If we are unable to raise capital when needed or on acceptable terms, we

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may be forced to delay or scale back development programs, curtail commercial initiatives or reduce operational capacity, which could have a material adverse effect on our financial condition and business prospects.

Our results of operations may fluctuate significantly due to a range of factors, many of which are beyond our control and difficult to predict. These include the progress and outcomes of clinical trials, the timing and scope of regulatory approvals, challenges in patient recruitment, shifts in the competitive landscape, investment levels in pipeline development, demand for our products post-approval, reimbursement dynamics and our ability to attract and retain key personnel. In addition, macroeconomic volatility, inflationary pressures and potential changes in accounting principles may further impact our financial performance. Given our early-stage profile, short-term deviations from market expectations can lead to significant stock price volatility and reduced access to capital markets. Investors should not rely on historical or interim financial results as indicators of future performance. Failure to effectively navigate these uncertainties could impair our strategic execution, delay commercialization and undermine our ability to deliver long-term value to shareholders.

As we are investing heavily in our research and development efforts, our profitability and operating cash flows in the short term may continue to be impacted and we may not generate the results we expect to achieve.

Our technological capabilities and infrastructure are critical to our success. We have been investing heavily in our research and development efforts. We incurred research and development expenses of RMB41.1 million, RMB48.7 million, RMB22.0 million and RMB38.7 million in 2024 and 2025 and the six months ended June 30, 2025 and 2026, respectively. The industry in which we operate is evolving rapidly in terms of technological innovation. We need to invest significant resources, including financial resources, in research and development to lead technological advances in order to make our current and future products innovative and competitive in the market. As a result, we expect that our research and development expenses will continue to increase. Furthermore, development activities are inherently uncertain, and we might encounter practical difficulties in commercializing our development results. Our significant expenditures on research and development may not generate corresponding benefits. Given the fast pace at which technologies have been and will continue to be developed, we may not be able to timely upgrade our technologies in an efficient and cost-effective manner, or at all. New technologies in our industries could render our technologies, our technological infrastructure or products that we are developing or expect to develop in the future obsolete or unattractive, thereby limiting our ability to recover related product development costs, which could materially and adversely affect our revenue, profitability and market share.

We had net liabilities position and net current liabilities 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 and 2025, we had net liabilities of RMB44.9 million, RMB7.4 million, respectively. We also had net current liabilities of RMB66.7 million, RMB40.2 million as of the same dates, respectively. There is no assurance that we will not record net liabilities and/or net current liabilities in the future. Having significant net liabilities or net current 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 are exposed to credit risk regarding trade receivables from certain customers.

We generally adopt a payment-in-advance model for a significant portion of our sales, which helps mitigate our overall exposure to credit risk. However, we may grant credit terms to certain qualified

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customers under certain circumstances. As of December 31, 2024 and 2025 and June 30, 2026, our trade receivables were RMB2.0 million, RMB0.2 million and RMB0.3 million, respectively. Although we actively manage our credit exposure, we cannot assure you that these customers will settle their obligations on time or at all. If the financial condition of these customers deteriorates, or if they face liquidity issues, they may delay or default on their payments. While our reliance on credit sales is relatively limited due to our prevailing payment policies, any significant default by major customers to whom we have extended credit could still severely impact our liquidity. If we are unable to collect these receivables efficiently, or if one or more major customers default on their payment obligations, our business, financial condition and results of operations may be materially and adversely affected.

We may not be able to obtain additional capital when desired on favorable terms or at all.

We intend to raise necessary capital through the [REDACTED] to ensure a successful product launch and establish initial market coverage. However, global capital market volatility, shifts in investor sentiment toward the biotechnology sector, evolving competitive dynamics, or delays in our clinical or regulatory progress could lead to a postponed timeline of the [REDACTED], or reduced [REDACTED] amount. If the [REDACTED] is delayed or undersubscribed, we may need to rely on bank loans, strategic investor funding, or other debt financing, which could carry more restrictive terms or may not be available on a timely basis. Furthermore, as a pre-profit innovative medical device company, we had net operating cash outflows during the Track Record Period and will remain reliant on external financing for the foreseeable future. If we are unable to secure sufficient funding on a sustained basis, we may be forced to delay or cancel new indication and product development, reduce market investment, suspend R&D programs and overseas market expansion, or even disrupt ongoing operations. Therefore, uncertainty in our ability to raise capital represents a material risk to the sustainability and growth of our business.

Our business and results of operations may be subject to seasonal fluctuations.

During the Track Record Period, our operations were subject to certain seasonal fluctuations, with typically increased sales during the fourth quarter. This trend is primarily driven by the initial commercialization ramp-up in early 2024 to build our distribution and hospital networks, and distributors preparing inventory toward year-end to prevent supply disruptions during public holidays. As a result of these seasonal fluctuations, our revenue and operating results for any particular quarter may not be indicative of our performance for the full year. If we fail to accurately forecast our sales and manage our inventory and production schedules accordingly to accommodate such seasonality, our business, financial condition and results of operations could be materially and adversely affected.

Raising additional capital may cause dilution to our shareholders’ equity, restrict our operations or require us to relinquish rights to our technologies or products.

We may need to pursue bank loans, convertible bonds, or other forms of debt financing. Such arrangements often come with stringent financial or non-financial covenants which could constrain management’s flexibility in business expansion, M&A, or R&D decisions. We currently hold full intellectual property rights to our GBS and other products and have no plans to transfer technology or product rights to third parties. However, if we face severe cash shortages or sustained losses, we may be compelled to consider bringing in strategic investors and granting them technology licensing rights, co-development rights, or even partial ownership in exchange for critical funding. While such transactions could alleviate short-term liquidity pressures, they risk technology leakage, shifts in competitive dynamics, or long-term value erosion. Therefore, the choice of future financing methods will entail an ongoing trade-off between capital needs and the preservation of control and proprietary rights.

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RISKS RELATING TO OUR GENERAL OPERATIONS

Our future success depends on our ability to retain key executives and key personnel in our R&D team, sale and marketing team, and our ability to attract, train, retain and motivate qualified and highly skilled personnel especially R&D, clinical related, sales and marketing staff.

Our business and growth depend on the continued service of our senior management and key personnel in our R&D team to develop products and product candidates, as well as our sales and marketing team to promote our products and services. In particular, Mr. Zuo, the chairman of our Board, chief executive officer and our sole executive Director, is primarily responsible for the overall strategic planning, management and coordination of our Group. Although we have entered into formal employment agreements with our employees, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any of these employees could impede the achievement of our research, development and commercialization objectives. To retain valuable employees, in addition to salary and cash incentives, we have provided share awards to our employees. However, there is no assurance that our salary and benefits will be sufficient to attract and retain the personnel we require. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and impact our ability to successfully implement our business strategy. Furthermore, replacing executive officers or key employees may be difficult and may take an extended period of time. We also experience competition for the recruiting of R&D and clinical personnel from universities and research institutions. If we are unable to continue to attract and retain high quality personnel, we may experience delays in our research and development, fail to develop and commercialize our products and product candidates in a timely manner, which could have a material adverse effect on our business and future prospects.

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

Our business is significantly dependent on our brand reputation and the trust of hospitals, physicians, patients and other stakeholders. As our GBS represent a relatively new and evolving treatment paradigm, market acceptance is still developing, and our success hinges on our ability to establish and maintain a strong, credible brand identity. If we fail to effectively communicate the clinical value, safety and reliability of our products, it could impair physician adoption, delay reimbursement decisions and hinder commercial growth, and may have material adverse effects on our financial performance. Our reputation may be damaged by events such as product malfunctions, service failures, regulatory inquiries, litigation, or negative publicity, regardless of factual accuracy. Even isolated incidents or unverified allegations concerning our products, management or operations could erode trust and trigger reputational harm. Maintaining brand reputation requires sustained investment in clinical validation, professional engagement, patient education and compliant promotional activities. If these efforts prove ineffective or are undermined by external challenges, we may experience reduced customer retention, increased competitive pressure and higher costs associated with crisis management. Given that brand trust is difficult to rebuild once compromised, any significant reputational damage could have a lasting negative impact on our operation results, business prospects, investor confidence and long-term market position.

Our information technology infrastructure may experience unexpected system failure, interruption, inadequacy, security breaches or cyberattacks.

Our business operations are highly dependent on internal IT systems and network infrastructure, which store and process critical data including research and development records, commercial information, and financial data. Although we have implemented security measures such as firewalls, access controls and encryption, our systems remain vulnerable to cyber threats including malware, ransomware, phishing

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attacks and unauthorized access. Any significant security incident could lead to operational disruption, data loss or system failure, materially and adversely affecting our development programs, commercial activities and financial reporting. Failure to detect or respond to emerging threats in a timely manner could result in the compromise of sensitive data, unauthorized system access or service outages. Any such event could have a material adverse effect on our operational resilience, regulatory compliance, investor confidence and long-term business prospects.

We may be involved in lawsuits, claims, administrative proceedings or other legal proceedings against us.

We may be subject to lawsuits, claims, regulatory investigations or other legal proceedings arising from the current or future development and commercialization activities of our products and product candidates. We could be sued if our products or product candidates are alleged to cause harm, fail to deliver expected therapeutic benefits, or are perceived as defective in design, manufacturing, having inadequate instructions for use, warnings, or training, even if such allegations are unfounded.

Although we have not experienced any material product or professional liability claims during the Track Record Period, the risk of such claims increases as our products reach more patients and healthcare providers. Defending against litigation, regardless of its merit, requires significant management time and financial resources, diverting attention from core business operations. If we are unable to successfully defend against such claims or obtain indemnification from collaborators, we may face restrictions on commercialization, suspension of clinical trials, or the need to withdraw products from the market, all of which could materially impair our development timelines and revenue potential.

Legal proceedings may lead to a range of adverse outcomes, including regulatory scrutiny, reputational damage within the medical community, loss of patient and physician confidence, withdrawal of clinical trial participants, and negative media coverage. We may incur substantial costs in defending claims, and any adverse judgment or settlement could result in significant monetary liabilities, product recalls, or marketing restrictions. Our current insurance coverage may not be sufficient to cover all potential claims, and certain policies contain exclusions that could leave us exposed. If required to pay damages exceeding our insurance limits or for uncovered claims, we may have to use substantial portions of our capital, potentially affecting our liquidity and financial stability.

Our insurance coverage may not completely cover the risks related to our business and operations, which could expose us to significant costs and business interruptions.

Our operations are subject to hazards and risks associated with our research and development, as well as other aspects of our operations, which may cause significant harm to persons or damage to properties. We maintain different types of insurance policies, including social insurance for all of our employees and personal accident insurance. See “Business— Insurance.” While we maintain insurance policies that cover our assets and losses arising from accidents in clinical trials, the availability, cost and scope of coverage may vary across jurisdictions and could become increasingly expensive or limited as we expand globally. If we are unable to secure adequate insurance at reasonable cost, or if a major claim arises that is not covered or exceeds policy limits, it could have a material adverse effect on our business, financial condition, results of operations and share price.

We face risks related to natural disasters, health epidemics, civil and social disruption and other outbreaks, which could significantly disrupt our operations.

Significant natural disasters, such as earthquakes, extreme weather conditions, could materially impact our business in the future. In the event of a major disruption caused by a natural disaster or man-made problem, such as power disruptions, computer viruses, data security breaches or terrorism, we may be unable to continue our operations and may endure system interruptions, reputational harm, delays in our

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development activities, lengthy interruptions in service, breaches of data security and loss of critical data, any of which could adversely affect our business, results of operations and financial condition. In addition, our business could be affected by public health epidemics and pandemics. Even if we are not directly affected, such a disaster or disruption could affect the operations or financial conditions of our suppliers, customers or other business partners, which could harm our results of operations. Any occurrence of these events may restrict economic activities in affected regions, resulting in reduced business volume, temporary closure of our offices or research or production facilities, or otherwise disrupt our business operations and materially and adversely affect our financial condition and results of operations.

RISKS RELATING TO THE [REDACTED]

Any possible conversion of our Unlisted Shares into H Shares in the future could increase the supply of our H Shares in the market and may negatively impact the market price of our H Shares.

Subject to the approval of the CSRC, all of our Unlisted Shares may be converted into H Shares in the future, and such converted Shares may be listed or traded on an overseas stock exchange, provided that prior to the conversion and trading of such converted Shares any requisite internal approval by our Shareholders and approval from relevant PRC regulatory authorities shall have been obtained. However, the PRC Company Law provides that in relation to the public [REDACTED] of a company, the shares of that company which are issued prior to the public [REDACTED] shall not be transferred within one year from the date of the [REDACTED]. Therefore, upon obtaining the requisite approval, our Unlisted Shares may be traded, after the conversion, in the form of H Shares on the Stock Exchange after one year of the [REDACTED], which could further increase the supply of our H Shares in the market and may negatively impact the market price of our H Shares.

No public market currently exists for our H Shares, and an active trading market for our Shares may not develop and the market price for our H Shares may decline or become volatile

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

The price and trading volume of our H Shares may be volatile, which could lead to substantial losses to investors.

The price and trading volume of our H 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 market price of the shares of other companies engaging in similar business may affect the price and trading volume of our H Shares. In addition to market and industry factors, the price and trading volume of our H Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting 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. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and our H Shares may be subject to changes in price not directly related to our performance.

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Future sales or market perception of sales of a substantial number of our H Shares on the public market could adversely affect the trading price of our H Shares.

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

In addition, our Shareholders would experience dilution in their shareholdings upon offer or sale of additional share capital or share capital-linked securities by our Company in future offerings. If additional funds are raised through our issuance of new share capital or share capital-linked securities other than on a *pro rata* basis to existing Shareholders, the shareholdings of such Shareholders may be reduced and such new securities may confer rights and privileges that take priority over those conferred by the [REDACTED]

Purchasers of our H Shares in the [REDACTED] may experience immediate dilution upon such purchases, and may also experience further dilution in shareholding if we issue additional Shares in the future.

The [REDACTED] of the H Shares is higher than the net tangible asset value per H Share immediately prior to the [REDACTED]. Therefore, purchasers of the H Shares in the [REDACTED] will experience an immediate dilution in pro forma net tangible asset value, and our existing Shareholders will receive an increase in the pro forma adjusted consolidated net tangible assets per H Share of their H Shares. In order to expand our business, we may consider offering and issuing additional H Shares in the future. Purchasers of the H Shares may also experience dilution in the net tangible asset value per share of their H Shares if we issue additional H Shares in the future at a price that is lower than the net tangible asset value per Share at that time.

We cannot assure you that we will declare and distribute any amount of dividends in the future.

We intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the commercialization of our products, the research and development activities of our product candidates and to expand our product portfolio. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our H Shares as a source for any future dividend income. Our Board has complete discretion as to whether to distribute dividends. Even if our Board declares and pays dividends, the timing, amount and form of future dividends, if any, will depend on our future operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your investment in our H Shares will likely depend entirely upon any future price appreciation of our H Shares. There is no guarantee that our H Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the H Shares. You may not realize a return on your investment in our H Shares and you may even lose your entire investment in our H Shares.

We cannot guarantee that our H Shares will remain listed on the Stock Exchange.

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

RISK FACTORS

We cannot make fundamental changes to our business without the consent of the Stock Exchange.

On April 30, 2018, the Stock Exchange adopted new rules under Chapter 18A of the Listing Rules. Under the new rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Chapter 18A of the Listing Rules. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

The industry facts, statistics and forecasts in the document obtained from various government publications have not been independently verified.

The industry facts, forecasts and statistics in this document have been obtained from various sources that we believe are reliable, including official government publications. However, we cannot guarantee the quality or reliability of the information derived 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 these official government sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the information derived from official government publications in this document may be inaccurate and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

Forward-looking information contained in this document is subject to risks and uncertainties.

This document contains certain future plans and forward-looking statements about us that are made based on the information currently available to our management. The forward-looking information contained in this document is subject to certain risk and uncertainties. Whether we implement those plans, or whether we can achieve the objectives described in this document, will depend on various factors including the market conditions, our business prospects, actions by our competitors and the global financial situations.

You should read the entire document carefully and should not rely on any information contained in press, media or internet 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 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 investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information. 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 investment decision regarding our H 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

RISK FACTORS

expressed by the press or other media regarding our H Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective investors 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 H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and the [REDACTED].