

RISK FACTORS

An [REDACTED] in our H Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before deciding to [REDACTED] in our H Shares. Particularly, we are seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the biotech industry 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. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any such an event, the [REDACTED] of our H Shares could decline, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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

RISKS RELATING TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES

We face substantial competition and rapid market changes, and our competitors may discover, develop or commercialize competing products before or more successfully than we do, or respond and adapt to the market changes more quickly and effectively.

The iNO therapy market, IABP therapy market and FeNO diagnostics market are highly competitive, and characterized by predominance of preexisting therapeutic options, technological changes, frequent new product introductions, and evolving industry standards. For example, globally, iNO therapy grew from US\$892.1 million in 2020 to US\$1,054.1 million in 2025, at a 3.4% CAGR. From 2025 to 2030E, the market is projected to reach US\$1,580.4 million at a 8.4% CAGR, and from 2030E to 2035E, the market is projected to reach US\$2,721.0 million, at 11.5% CAGR. Currently, the market is still dominated by cylinder-based iNO systems, which held 89.3% market share in the global iNO therapy market by revenue in 2025.

Potential competitors include domestic and foreign companies, academic institutions and other public and private research organizations that engage in the research, development and commercialization of cardiopulmonary diagnostic and therapeutic devices. If we do not offer products in competitive quality and prices, or introduce new products in a timely manner, our products may become obsolete and our operating results may suffer.

Given that our products target specific patient subgroups and the currently limited sizes of their addressable markets, our business opportunities could be reduced or eliminated if our competitors develop and commercialize products that have higher quality, are less expensive or more convenient than any products that we commercialize or are developing. Our competitors in the global market may also apply for commercialization approvals in jurisdictions for products with the same intended uses as our products and product candidates. They may obtain approvals from the regulatory authorities more rapidly than we do, which may allow our competitors to establish a strong market position before we are able to enter the market.

Many of our competitors have longer operating history, significantly greater financial resources, expertise and experience in research and development, and are more capable than us in conducting preclinical studies and clinical trials. They may also obtain regulatory approvals more quickly or marketing their products more successfully than we do. Furthermore, mergers and acquisitions in the medical device industries may result in even more resources being concentrated among a small number of our competitors.

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If we are unable to successfully develop our products for new indications or commercialize our products in new jurisdictions, develop and commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business growth depends on our ability to successfully develop our products for new indications or commercialize our products in new jurisdictions. As of the Latest Practicable Date, we have five commercialized products, namely iNOwill, eNOaire, NovaPulse IABP, Reslink and eNOglow. In addition, our business also depends on our ability to successfully develop and commercialize our product candidates. We had a broad pipeline of product candidates that are in various stages of development, including VQfit and NovaVent, among others, as of the Latest Practicable Date.

The development and commercialization of our products and product candidates will depend on several factors, including but not limited to: (i) completion of clinical trials and preclinical studies; (ii) favorable safety and efficacy data from our clinical trials and other studies; (iii) the ability to conduct our clinical trials safely, efficiently, and in accordance with specified laws, regulations trial protocols and policies; (iv) the performance by any third parties we may retain in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data; (v) obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity while making sure we do not infringe, misappropriate or otherwise violate intellectual property rights of third parties; (vi) obtaining required regulatory approvals, commercialization authorizations and successfully launching our product candidates cost effectively in targeted markets, if and when approved, in a timely manner; (vii) obtaining favorable governmental and private medical reimbursement for our products; (viii) appropriately pricing our products and timely collecting payments; (ix) enhancing our marketing and distribution capabilities in an efficient manner; (x) winning competition with other comparable products; (xi) continued acceptable safety profile and efficacy of our products and product candidates following regulatory approval and (xii) allocate resources to pursue product candidates that prove to be more profitable or for which there is a greater likelihood of success. If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or be unable to obtain approval or achieve commercialization for our products and product candidates, which would materially harm our business and financial performance.

Our revenue during the Track Record Period substantially relied on our commercialized products. We may not achieve the expected sales and profit margin for our products, as demand for such products may not reach the levels as anticipated.

Our revenue is primarily derived from the sales of medical devices, which comprise of our commercialized products, including iNOwill, our Core Product, and other medical devices. In 2024, 2025 and the six months ended June 30, 2025 and 2026, sales of medical devices amounted to RMB41.1 million, RMB58.5 million, RMB21.5 million and RMB56.4 million, respectively, accounting for 90.2%, 92.6%, 96.1% and 97.1% of our total revenue in the same periods, respectively. Also, in the same periods indicated, we recorded overall gross profit margins of 59.3%, 55.9%, 49.9% and 59.8%, respectively. We expect that sales of our products will continue to account for a significant portion of our total revenue in the near future.

However, we cannot assure you that demand for our products will continue to reach the levels as anticipated. There is also no assurance that we will be able to achieve the expected sales and profit margin for our products, which may be adversely affected by many factors outside of our control, including introduction of substitute products marketed by our competitors, pricing pressure caused by changes in market competition, shifting customer demands, disruptions in manufacturing or sales, issues with respect to product quality or severe adverse events incurred after the procedure, coverage of medical insurance and disputes over intellectual property or other matters with third parties, and expiration of patent protection. If we are unable to achieve the expected sales volumes, pricing levels or profit margins of the above-mentioned products, our business, financial condition and results of operations may be materially and adversely affected.

Product development involves a lengthy and expensive process with an uncertain outcome, and unsuccessful clinical trials or procedures relating to our products and product candidates could have a material adverse effect on our prospects.

Clinical trials and demonstration procedures can be lengthy, expensive and subject to inherent uncertainties. There can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication.

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If we encounter difficulties in the enrollment of subjects to our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Identifying, screening and enrolling of clinical trial participants are critical to our success. We may not be able to identify and enroll a sufficient number of trial participants with the required or desired characteristics in accordance with the eligibility criteria defined in our protocols to complete our clinical trials in a timely manner. Furthermore, even if we are able to enroll a sufficient number of eligible patients or other subjects in our clinical trials, we may experience enrollment delays related to increased or unforeseen regulatory, legal and logistical requirements at certain clinical trial sites.

Failure can occur at any time during the procedures or clinical trial process. The results of preclinical studies and previous clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials, and initial or interim results of a trial may not be predictive of the final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In addition, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations or other trial participants, including differences in physical conditions, and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. Severe adverse events and complications may incur in some cases. If our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or if they cause undesirable adverse events, we may incur additional costs, experience delays, or ultimately be unable to complete development, obtain regulatory approval or achieve successful commercialization.

We may experience numerous unexpected events during clinical trials, such as (i) regulators or ethics committees may not authorize us or research partners we may cooperate with to commence a clinical trial or conduct a clinical trial at a prospective trial site; (ii) our inability to reach agreements on acceptable terms with prospective clinical sites and hospitals as trial centers; (iii) the supply or quality of materials and services necessary to conduct clinical trials of our product candidates may be insufficient or inadequate and (iv) regulatory agencies or other authorities may require us to suspend or terminate clinical trials if they find non-compliance incidents or unacceptable health risks.

Even if we successfully complete the clinical trial, successful commercialization is not guaranteed. For example, we may be delayed in obtaining or not obtain regulatory approval for our product candidates or the approval we obtained for indications are not as broad as intended.

Guidelines, recommendations and studies published by various organizations could disfavor our product candidates.

Influential recommendations, guidelines and quality metrics issued by various organizations and government authorities may significantly affect customers’ willingness to purchase our products and services. For example, iNO therapy is recommended by the “Expert Consensus on Clinical Application of Inhaled Nitric Oxide Therapy in Critical Illness” (《吸入一氧化氮治療在急危重症中的臨床應用專家共識》) and the “Expert Consensus on Clinical Application of Inhaled Nitric Oxide Therapy (2024 Edition)” (《一氧化氮吸入療法臨床應用專家共識(2024版)》). If any such recommendations, guidelines and quality metrics that are currently favorable to us are later updated, overturned or modified, or otherwise interpreted in a manner unfavorable to us, our results of operations and prospects may be adversely affected.

Clinical guidelines and clinical practices relating to the use of iNO therapy devices vary across jurisdictions and may continue to develop over time. The adoption of our products by physicians and hospitals in our target markets, including China, may take time. If we are unable to enhance awareness of our products or support their appropriate clinical use through lawful academic and clinical engagement, the market adoption of our products and our results of operations may be adversely affected. We cannot assure you as to the timing or content of any future updates to the relevant clinical guidelines or whether our products will be referenced therein.

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

We sell our cardiopulmonary diagnostic and therapeutic devices to hospitals through our distributors. Physicians and hospitals play important roles in recommending and deciding what products to be used. They not only provide professional advice but also offer help throughout the entire therapeutic procedures from candidate screening, operation assistance to post-operation follow-up visit. Our in-house marketing team works with physicians and hospitals, communicate

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with KOLs, as well as attend industry conventions and academic meetings to introduce and promote our products. However, our efforts to introduce the distinctive characteristics, advantages, safety, efficacy and cost effectiveness of our products may not be successful. If our products and product candidates (upon commercialization) are not widely accepted by physician and hospital communities, our sales of our currently commercialized products may decline, and we may not be able to effectively market our other product candidates, such as other iNO therapy devices, cardiopulmonary circulatory support devices and respiratory diagnosis devices upon commercialization.

In addition, many of our products or product candidates represent novel therapies in China or even globally. Physicians face a learning process to become proficient in the use of some of our products and product candidates, which may take a longer time than we expected. Encouraging physicians to dedicate their time and energy necessary for adequate training remains challenging, and we may not be successful in these efforts. If physicians are not properly trained, they may misuse or ineffectively use our products and product candidates, which may result in unsatisfactory patient treatment outcomes, patient injury, negative publicity or lawsuits against us, any of which could have a significant adverse effect on our reputation, business, financial condition, results of operations and prospects. Following completion of training, we also rely on trained physicians to advocate the benefits of our products in the marketplace. If we are not able to enhance our product awareness and receive recognition from these physicians, other physicians and hospitals may not be inclined to use our products, and our results of operations may be adversely affected.

We rely heavily on our distributors to sell our products, and any failure by them to perform their obligations, including in hospital tender processes, could materially adversely affect our business, results of operations and financial condition.

During the Track Record Period, we primarily relied on our network of distributors to distribute our products, and we expect that sales through distributors will continue to account for a substantial majority of our revenue for the foreseeable future. We generally enter into distribution agreements directly with our tier-one distributors and manage channel coverage on a regional basis. In larger regions, we may appoint multiple regional tier-one distributors, each responsible for designated prefecture-level cities, based on their capability and willingness to undertake coverage and service obligations. Our distributors are responsible for collecting payments from hospitals and medical institutions and assume exposure to operational risk that may arise with end-customers.

We generated the majority of our revenue from sales to our distributors of RMB41.8 million, RMB60.0 million, RMB21.2 million and RMB57.8 million, accounting for 91.7%, 95.0%, 94.4% and 99.5% of our total revenue in 2024, 2025 and for the six months ended June 30, 2025 and 2026, respectively. As of December 31, 2024, 2025 and June 30, 2026, we collaborated with 144, 192 and 212 tier-one distributors worldwide, with whom we generally enter into distribution agreements directly and manage channel coverage on a regional basis. Our ability to maintain and grow our business depends on our ability to maintain, expand and optimize effective distribution channels that ensure timely distribution of our products to the relevant markets.

However, we have relatively limited control over our distributors. Our distributors may fail to distribute our products in the manner we contemplate, breach our agreements with them, sell products outside their designated territories, or fail to comply with applicable regulatory requirements, including but not limited to failing to obtain and maintain requisite licenses, or violating anti-corruption, anti-bribery and competition laws. In addition, our distributors may terminate their relationships with us, and we may be unable to find alternative distributors in a cost-effective and timely manner.

Furthermore, the growth and success of our business significantly depends on the performance of our distributors in hospital tender processes. Hospitals and medical institutions may organize public tenders for procurement of medical devices, the procedures and timing of which may vary from hospital to hospital and from region to region. We may not always be able to locate a sufficient number of experienced local distributors to secure the bids in such tender processes. Even where our distributors participate in such tenders, our products may not be chosen for a number of reasons, including where: (i) our prices are not competitive; (ii) our products fail to meet the technical or quality requirements imposed by the hospitals or are less clinically effective than competing products; (iii) our reputation is adversely affected by unforeseeable events; or (iv) our service quality or any other aspect of our operations fails to meet the relevant requirements.

The occurrence of any of the foregoing could disrupt our product sales, result in difficulties in maintaining the existing level of sales of our products and in selling our product candidates upon commercialization, and cause our revenue to decline, which could in turn negatively affect our business operation, financial performance and reputation.

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We have relatively limited experience in marketing and sales of our products.

We have relatively limited experience in launching and commercializing our product candidates and in the sales and marketing of our products. We started to commercialize our Core Product, iNOWill, in May 2022. Our ability to successfully commercialize our product candidates may involve more inherent risks, take longer and cost more than it would if we were a company with sufficient experience commercializing product candidates.

The success of our sales and marketing efforts depends on our ability to attract, motivate and retain more qualified and professional employees in our sales and marketing team who have, among other things, sufficient clinical and marketing experience for medical devices and extensive industry connections with distributors and hospitals, and are able to communicate effectively with medical professionals. However, due to the intense competition for experienced personnel, we may be unable to attract, motivate and retain a sufficient number of qualified sales and marketing employees to support our business development and expansion, and our sales revenue and results of operations may be negatively affected.

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

We plan to broaden our sales and expand our presence globally to benefit from wider market opportunities. We have obtained the Class IIb CE certification with UDEM under the EU MDR in 2025 of our Core Product and have completed a Pre-Submission consultation with the FDA in relation to the proposed U.S. registration of iNOWill. As of the Latest Practicable Date, we had not submitted any marketing application to the FDA, and we cannot assure you that we will obtain FDA approval on a timely basis, or at all. See “— We may not obtain FDA approval for iNOWill in the United States on a timely basis or at all, and the feedback we received from the FDA at the Pre-Submission meeting is not binding on the FDA” below. However, our limited experience in overseas markets may expose us to risks and uncertainties, including the risks associated with dealing with regulatory regimes and government policies that may differ materially from those that we may be familiar with; substantial time that may be required for us to obtain approval for registering and selling our products in multiple countries; high costs in constructing and maintaining effective sales force in jurisdictions with which we have limited experience and established no sales and marketing infrastructure; costs incurred to resolve product liability litigation and regulatory scrutiny and our insurance coverage may be insufficient to protect us; unexpected changes in economic and trade policies and requirements; compliance with relevant laws and regulations, including but not limited to tax, employment, immigration, labor laws for employees traveling abroad; the effects of applicable foreign tax structures and potentially adverse tax consequences; currency fluctuations; workforce uncertainty and labor unrest; and business interruptions resulting from general economic factors.

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

Certain of our current products and product candidates are classified as Class III medical devices. Such classifications represent a high risk to the human body and require a high level of supervision to ensure safety and effectiveness. We may be subject to product liability claims if our products have quality issues. For example, we may be sued if our product candidates are perceived to cause injury or are found to be otherwise unsuitable during clinical testing. Product liability claims may also arise out of allegations of defects in design, component failure, a failure to warn of dangers inherent in the medical device product, negligence or strict liability. Further, we cannot ensure that physicians will strictly and accurately follow our instructions on the proper usage of our products and product candidates. If our product or product candidates are used incorrectly by physicians, injury may result, which could require review and corrective action by us or even give rise to product liability claims against us. Any serious failures or defects could cause us to withdraw or recall products, and subject us to product liabilities, which may damage our brand name and may have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, we provide warranties for our products, committing that product quality complies with the quality standards issued by relevant authorities. If our customers suffers losses due to quality issues with the product, we may be liable for damages. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material customer complaint or product return from customers.

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We have purchased property insurance, which covers, among other things, public liability and product liability. However, our insurance may be unable to cover all the liabilities that may arise. In this regard, if we cannot successfully defend ourselves against, obtain indemnification from our collaborators for product liability claims, or acquire sufficient product liability insurance at an acceptable cost, we may incur substantial liabilities or be required to limit commercialization of our product candidates, and our business, financial condition, results of operations and prospects may be materially adversely affected.

Our ability to sell our products and product candidates, if approved for commercial sale, may be affected by the coverage of price guideline and medical insurance reimbursement list of the medical services utilizing our products.

Hospitals and medical institutions purchase our medical devices through distributors and use them in providing medical services to patients. Having the medical services included in the government price guideline is critical to market demand. Hospitals and medical institutions will be more inclined to adopt our products in offering medical services if such services are included in categories and price guidelines set forth by regulatory agencies. Conversely, if the medical services are not included in price guidance, patients and hospitals may be less inclined to adopt our products for lack of clarity and transparency. In addition, our ability to sell our products and product candidates, if approved for commercial sale, may be affected by the then-available public and private medical insurance coverage. If medical services using our products are not included in the public medical insurance reimbursement list, hospitals may be less inclined to purchase our products, which will adversely affect our sales volume. As of the Latest Practicable Date, medical services utilizing some of our products (such as iNO therapy) have been included in the price guidance and public medical insurance reimbursement list in several provinces in China. However, to be included in such list and reimbursement requires substantial time and cost to demonstrate the safety, efficacy and other aspects of our products, and we cannot assure you that our applications will be granted on time or at all. In the absence of price guideline or sufficient medical insurance coverage, market demand for, and sales of, our products may decline, which could materially and adversely affect our business, financial condition and results of operations.

In addition, we may experience downward pressure in the pricing of our products and product candidates from governmental pricing regulation and adjustment measures and some other sources, many of which may be beyond our control. For example, the PRC government may issue pricing guidance for our products and product candidates, as well as similar products offered by other parties. In this case, such pricing guidance may negatively impact our pricing strategies.

RISKS RELATING TO MANUFACTURE AND SUPPLY OF OUR PRODUCTS

Fluctuations in prices of our raw materials and equipment, and supply interruptions may have a material adverse effect on us.

During the Track Record Period, our raw materials and equipment primarily include injection mold component, sheet metal machine, printed circuit board assembly (PCBA), sensor pumps and valves. In 2024, 2025 and for the six months ended in June 30, 2026, we collaborated with 248, 263 and 204 suppliers both domestically and overseas, respectively. Most of our raw materials and equipment are procured from domestic suppliers, and only a small portion of our raw materials and equipment are procured from overseas suppliers. Raw materials and components may be susceptible to fluctuations in price and availability and affected by a number of factors, including market supply and demand, tariffs, and the PRC or international environmental and regulatory requirements, natural disasters, and the global economic conditions. A significant increase in the costs of raw materials or shortage of raw materials may increase our procurement costs, disrupt our product timeline, and negatively affect our business and financial performance. We cannot assure you that such situation will continue in the future.

In addition, general economic conditions could adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products. During the Track Record Period, we relied on a limited number of suppliers for procurement of raw materials and equipment. In 2024, 2025 and for the six months ended June 30, 2026, purchases from our five largest suppliers in aggregate accounted for 30.4%, 40.7% and 36.3% of our total purchases, respectively, and purchases from our largest supplier accounted for 9.2%, 10.0% and 10.4% of our total purchases in each year/period indicated, respectively. If our suppliers fail to supply products that meet our demands or satisfy our quality standards, our product development process, costs, and overall operation and financial performance may be adversely impacted.

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

As of the Latest Practicable Date, we operated a Class III medical device production base in Yangzhou, Jiangsu Province, and a Class II medical device production base in Fangchenggang, Guangxi Province. We may expand our manufacturing facilities in line with our business. If we establish new facilities, we need to apply for a change of our manufacturing permit to include our new facilities, which requires regulatory approval. The facilities may encounter unanticipated expenses due to a number of factors, including complying with ongoing regulatory requirements.

Our facilities may be harmed or rendered inoperable by physical damage from fire, floods, earthquakes, typhoons, tornadoes, power loss, telecommunications failures, break-ins, and similar events. If our manufacturing facilities or the equipment are damaged or destroyed, we may not be able to timely or cost-effectively locate quality replacement manufacturer or at all. Even if we could transfer manufacturing to a qualified third party, such new facility would need to comply with the necessary regulatory requirements and we may need to seek regulatory approval before selling any products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales. In addition, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization, which could materially harm our business, financial condition and operating results.

The manufacture of our products is highly complex and subject to strict quality controls. If we or one of our suppliers encounter manufacturing problems, our business could suffer.

We have limited experience in manufacturing medical device products on a commercial scale. The manufacture of many of our products is highly complex and subject to strict quality controls, due in part to rigorous regulatory requirements. Quality issues may bring serious and costly consequences and 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 the supply of our products or product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Stability failures and other issues relating to the manufacture of our products or product candidates could occur in the future. In addition, 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 and regulatory quality standards, we could become subject to a safety alert or a recall, incur product liability and other costs, experience delayed product approvals, and our reputation and business could be adversely affected.

The size of our addressable markets and the demand for our products and product candidates may not increase as rapidly as we anticipate due to a variety of factors, which could materially and adversely affect our business, results of operations, financial condition and prospects.

According to Frost & Sullivan, instant-generation iNO systems accounted for approximately US\$0.11 billion globally in 2025 and are forecast to reach approximately US\$0.49 billion by 2030 at a CAGR of 34.2%. In China, the IABP market has expanded rapidly from a relatively low base, increasing from RMB313.1 million in 2020 to RMB790.1 million in 2025 at a CAGR of 20.3%, and is expected to reach RMB1,381.6 million by 2030 and RMB2,101.1 million by 2035, at CAGRs of 11.8% from 2025 to 2030 and 8.7% from 2030 to 2035. In China, FeNO diagnostic device market accounted for about RMB226.7 million in 2025 and are forecast to reach approximately RMB953.0 million by 2030 and RMB6,032.3 million by 2035, with CAGRs of 33.3% from 2025 to 2030 and 44.6% from 2030 to 2035. For more details, see “Industry Overview — Global iNO Therapy Market,” “Industry Overview — China IABP Therapy Market,” and “Industry Overview — China FeNO Diagnostics Market.”

However, our projections of the scope of applications and addressable market opportunities of our products and product candidates are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics or market research and may prove to be incorrect. They also depend on several factors, including, among others, acceptance by the medical community and patient access, pricing and reimbursement. Furthermore, new studies and technologies may change the market needs for our products and

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product candidates. As a result, the potentially addressable areas of precision medicine and market size for our product candidates may be smaller than our estimates, which could have a material and adverse effect on the profitability of our products and product candidates when commercialized.

RISKS RELATING TO GOVERNMENT REGULATIONS

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

Obtaining regulatory approvals is a lengthy, expensive and uncertain process. We intend to focus our activities in the major markets of China and other international jurisdictions such as the United States, the EU, the Asia-Pacific region and the Middle East. China has comprehensive regulation on medical devices, including regulation of product development, approval, manufacturing, sales and marketing and distribution of medical devices.

We currently market and intend to continue to market a substantial portion of our products in China in the foreseeable future. We are required to obtain the NMPA's or its local counterpart's approval before we can market our products in China. Significant time, effort and expense are required to bring our products to market in compliance with the regulatory process, and we cannot assure you that any of our products will be approved for sale. After we submit a filing application to the NMPA, the NMPA will decide whether to accept or reject the submission for filing according to relevant laws or regulations. We cannot be certain that any submissions will be accepted for filing and review by the NMPA. The NMPA may also slow down, suspend or cease review of our applications according to relevant laws or regulations, any of which could prolong the registration process of our product candidates. Even if regulatory approval or clearance of our products is granted, the approval or clearance could limit the uses for which our products may be labeled and promoted according to relevant laws or regulations, which may in turn limit the market for our products. Any failure to obtain, or delay in obtaining, regulatory approvals or clearances or to renew registrations for our products could prevent us from successfully commercialization of our products, which could materially and adversely affect our business, financial condition and results of operations.

Our product candidates could fail to receive the regulatory approval of the NMPA or a comparable regulatory authority in other jurisdictions for many reasons, including but not limited to: (i) disagreement with the design or implementation of our clinical trials; (ii) failure to demonstrate that a product candidate is safe and effective and potent for its proposed indication; (iii) failure of our clinical trial results to meet the level of statistical significance required for approval; (iv) failure of our clinical trial process to pass relevant regulatory inspections; (v) failure to report any serious or potentially serious incidents; (vi) disagreement with our interpretation of data from preclinical studies or clinical trials; (vii) insufficient data collected from the clinical trials of our product candidates; (viii) failure of our product candidates to pass current regulatory inspections during the regulatory review process or across the production cycle of our product candidates; (ix) failure of our clinical sites to pass audits carried out by regulatory authorities, resulting in a potential invalidation of our research data; (x) changes in approval policies or regulations that render our preclinical and clinical data insufficient for obtaining approvals; or (xi) failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

Comparably, regulatory authorities outside of China also have requirements for approval of medical devices for commercial sale with which we must comply prior to marketing in those areas. However, regulatory requirements can vary widely from jurisdiction to jurisdiction. Obtaining regulatory approval in one jurisdiction does not mean that the regulatory approval will be obtained in any other jurisdiction. Approval processes vary among jurisdictions and can involve additional product testing and validation, and additional administrative review periods. Seeking foreign regulatory approval may include all of the risks associated with obtaining NMPA approval, and could require additional nonclinical studies or clinical trials. For these reasons, we may incur substantial time and financial resources to bring our products to targeted markets overseas in compliance with different regulatory processes. The introduction of our product candidates in these targeted markets could be delayed or prevented, and we may not obtain relevant regulatory approvals on a timely basis, or at all.

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We may not obtain FDA approval for iNOWill in the United States on a timely basis or at all, and the feedback we received from the FDA at the Pre-Submission meeting is not binding on the FDA.

In late May 2026, we submitted a Pre-Submission to the FDA in relation to the proposed U.S. registration of iNOWill for PH, ARDS and COPD. The FDA provided written feedback in July 2026 and held a Pre-Submission meeting with us in August 2026, at which the FDA indicated that iNOWill would be regulated as a Class III medical device requiring premarket approval (“PMA”) and advised that the PH, ARDS and COPD indications would require new clinical evidence generated through clinical trials. For the neonatal PPHN indication, the FDA considered it reasonable for a PMA application to rely on comparative evidence consisting of existing published literature, the precedent of the comparable FDA-approved device, non-U.S. real-world evidence, post-market registry data and device nonclinical testing, and based on such feedback we currently expect that a new U.S. clinical trial under an Investigational Device Exemption (“IDE”) will not be required before submission of a PMA application for that indication. See “Business — Material Communications with Competent Authorities — United States — The FDA”.

However, feedback provided by the FDA at a Pre-Submission meeting is advisory in nature and does not constitute a binding commitment by the FDA to accept, review or approve any specific submission, and the FDA may modify or depart from its prior feedback, including as a result of new scientific or safety information, changes in FDA policies, guidance or personnel, or the content of our eventual submissions. Upon review of a PMA application, the FDA may disagree with our interpretation of the published literature, real-world evidence or registry data on which we intend to rely, may determine that such evidence is insufficient to demonstrate a reasonable assurance of safety and effectiveness, or may require additional nonclinical testing or one or more clinical trials in the United States under an IDE, any of which could substantially delay or increase the cost of, or prevent, FDA approval of iNOWill. The PMA review process is lengthy and resource-intensive, and the FDA may refer an application to an advisory committee, require pre-approval inspections of our manufacturing facilities in the PRC (which could be delayed or prevented by geopolitical tensions or travel restrictions), or impose post-approval requirements, conditions or restrictions on labeling.

In addition, our U.S. commercialization will initially depend on obtaining PMA approval for the neonatal PPHN indication, and the expansion of iNOWill’s U.S. indications to PH, ARDS and COPD will require clinical trials for which the design and evidence requirements remain subject to further FDA feedback, and which will require substantial time and financial resources and may not yield favorable results. We have limited experience in interacting with the FDA and in preparing, submitting and supporting a PMA application, and we rely on external U.S. regulatory and legal advisers in this regard. Any failure to obtain, or delay in obtaining, or restriction or condition imposed on, FDA approval for iNOWill could materially and adversely affect our overseas expansion strategy, business, financial condition, results of operations and prospects.

Our products and any product candidates will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses.

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 manufacturing, labeling, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy and other post-market information, and other requirements of regulatory authorities in jurisdictions where we market or sell our products.

Regulatory approvals for our products and any approvals that we receive for our product candidates are and may be subject to limitations on the indicated uses for which our product may be marketed. The approvals we obtain may also be subject to other conditions that may require potentially costly post-market testing and surveillance to monitor the safety and efficacy of our products or product candidates. Such limitations and conditions could adversely affect the commercial potential of our products. The NMPA and other comparable regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products placed on the market. As such, 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.

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Later discovery of previously unknown problems with our products or product candidates or with our manufacturing processes may result in revisions to the approved labeling or requirements to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions. All of these could result in significant additional expenses.

We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in various jurisdictions, where the regulatory environment is constantly evolving. If we are slow to adapt to changes in existing requirements or the adoption of new requirements or policies, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

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

Our business partners, including research institutions, clinical research organizations (“CROs”), distributors, suppliers and lessors, are required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products. Any failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our reputation, business, financial condition, results of operations and prospects. Specifically, companies producing medical devices in China are required to obtain permits and licenses issued by various government authorities, including but not limited to the medical device production permit (《醫療器械生產許可證》) and medical device production record-filing (《醫療器械生產備案》). For details, see “Regulatory Overview — Relevant Laws and Regulations in the PRC.”

Third parties with whom we cooperate may be also subject to regular inspections, examinations, inquiries or audits by regulatory authorities, an adverse outcome of which may result in the loss or nonrenewal of the relevant permits, licenses and certificates. Moreover, the interpretation and enforcement of existing laws and regulations may be subject to future implementations, or new regulations may come into effect. There can be no assurance that our business partners will be able to adapt to these changes in a timely and efficient manner, and obtain and maintain permits, licenses and certificates that are material to the operation of their businesses. If our business partners fail to to maintain or renew material permits, licenses and certificates, or failure to comply with the regulatory requirements, their ability to conduct business could be materially impaired, which may materially affect our business operation, performance and financial condition.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

We seek to protect our product candidates and technologies that we consider commercially important primarily by filing patent applications in China, the U.S., EU and other countries or regions as well as relying on trade secrets, regulatory protection or employing a combination of these methods. However, filing, prosecuting, maintaining and defending patents in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than do those in some other countries. We may not be able to file and prosecute all necessary or desirable patent applications and secure other intellectual property protection in all relevant jurisdictions in a timely manner. It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

We cannot assure you that all of our patent applications will be granted. Patent applications may not be granted for a number of reasons, including a late application date, known or unknown prior art, deficiencies in the patent application or the lack of novelty or non-obviousness of the underlying invention or technology. China, the U.S. and Europe have adopted the “first-to-file” system, under which the first inventor to file a patent application will be awarded the patent if all other patentability requirements are met. Moreover, patent applications in China, the U.S. and other

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jurisdictions are typically not published until an 18-month waiting period after filing, or in some cases, at all. In addition, under the PRC Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to file in advance to the China National Intellectual Property Administration (“CNIPA”) for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we were the first to file for patent protection of such inventions.

In addition, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid and will be paid to the CNIPA, the United States Patent and Trademark Office and other applicable patent agencies in several stages over the lifetime of a patent. Such applicable patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include the failure to respond to official actions within prescribed time limits, non-payment of fees, and the failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material and adverse effect on our business.

We may not be able to protect our intellectual property rights or prevent unfair competition by third parties.

The scope and enforcement of intellectual property rights differ across jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing products made using our inventions in and into certain jurisdictions. Competitors may use our patented technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may be able to circumvent our patents by developing similar or alternative products and technologies in a non-infringing manner, may develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, or may export otherwise infringing products to certain jurisdictions where we have patent protection, but where enforcement rights differ from those in certain other countries. These products may compete with our products and product candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

The legal systems of some countries provide different levels of protection and enforcement for patents, trade secrets and other intellectual properties, particularly those relating to medical device products, which could make it difficult in those jurisdictions for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, put our patents at risk of being invalidated or interpreted narrowly, put our patent applications at risk of not issuing, and provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial benefit from the intellectual property that we develop or license. Any of the foregoing could materially and adversely affect our business, financial conditions, operating results and prospects.

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

Competitors may infringe or misappropriate our intellectual property, and enforcing our rights may require costly and time-consuming litigation that diverts management and scientific resources. Such actions could prompt counterclaims alleging infringement of third-party rights, and there is a risk that our patents or trademarks could be found invalid, unenforceable or narrowly construed, limiting our ability to exclude competitors or, in the case of trademarks, forcing us to cease use of certain marks. Even if we prevail, litigation may not result in commercially meaningful damages and could require extensive discovery that risks disclosure of confidential information. In addition, we may lack sufficient resources to pursue or sustain prolonged IP enforcement actions, and the costs and distractions associated with such proceedings may outweigh any potential benefits, adversely affecting our competitive position, business prospects and financial condition.

RISK FACTORS

We may be subject to intellectual property infringement claims or other disputes, which could be costly and time-consuming to defend, and could prevent or delay us from developing or commercializing our product candidates.

We may receive in the future, notices that claim our technologies or certain other aspects of our business have infringed, misappropriated or misused other parties' intellectual property rights. Whether third-party intellectual property claims are with or without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction may hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates or technologies covered by the asserted third-party patents. Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and thus it could be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could result in a substantial diversion of management resources and burden us with substantial unanticipated costs. Moreover, some of our competitors are larger than we are and are able to mobilize substantially greater resources than we do. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material and adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research projects, in-license needed technologies, or enter into strategic partnerships that would help us bring our product candidates to market.

We may not have the right to control the preparation, filing, prosecution, maintenance, extension, enforcement and defense of patents and patent applications covering the technologies that we license from third parties, which could have a material and adverse effect on us.

As of the Latest Practicable Date, we had 85 patents and 196 registered trademarks, as well as 73 patent applications in the Chinese mainland and 13 overseas jurisdictions, such as Canada, United States, Indonesia, Israel, Brazil and South Korea. Among these, we in-licensed a total of six patents and patent applications. We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the technologies that we have in-licensed or may in-license from third parties in the future. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If we continue to enter into in-licensing agreements in the future, and such future licensing partners fail to prosecute, maintain, enforce or defend the patents we license in, or lose rights to those patents or patent applications, the rights we will have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products and product candidates that are subject of such potential licensed rights could be adversely affected.

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

The scope of patent protection varies across jurisdictions. Changes in patent laws or their interpretations may diminish our ability to protect our inventions, obtain, maintain, defend, or enforce our intellectual property rights and, more generally, could affect the value of our intellectual property. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will provide us with sufficient protection. The coverage claimed in patent applications can be significantly reduced before the patents are issued, and their scopes can be reinterpreted after issuance.

Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us. In addition, the patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years.

RISK FACTORS

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

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

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

In addition to our issued patents and pending patent applications, we rely on trade secrets, including unpatented know-hows, technologies and other proprietary information, to maintain our competitive position and to protect our product candidates. We entered into non-disclosure and confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, advisers and other third parties. Such agreements with our employees, adviser and other third parties may not adequately prevent disclosures of our trade secrets and other proprietary information. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed. Further, our employees, advisers or other third parties may be subject to claims by their former employers or other business partners, which could result in additional costs, litigation, or restrictions on our ability to commercialize our products.

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

Our intellectual property rights may not be sufficient to prevent third parties from developing or commercializing competing products or technologies, and our patent applications may not result in issued patents or provide meaningful competitive protection. If we fail to maintain or enforce effective intellectual property protection, our competitive position, business, financial condition, results of operations and prospects could be materially and adversely affected.

RISKS RELATING TO OUR GENERAL OPERATIONS

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

We rely on third parties, including clinical sites we contract with to collect data for improving our products, and clinical trial institutions, public hospitals, and/or CROs, to assist us in designing, implementing and monitoring our clinical trials. We rely on these parties for execution of our algorithm training, pre-clinical studies and clinical trials and do not control all aspects of their activities. If any of these parties terminates its agreements with us, we may not be able to enter into arrangements with alternative third parties that meet our standards, or on commercially reasonable terms, or at all, and the development of the product candidates covered by those agreements could be substantially delayed. In addition, these third parties may not successfully carry out their contractual obligations, meet expected deadlines or follow regulatory requirements, including clinical and laboratory guidelines. Our reliance on these third parties may result in delays in completing, or in failing to complete, these studies if they fail to perform in accordance with the contractual arrangements. Furthermore, if any of these parties fail to perform their obligations under our agreements with them in the manner specified in those agreements, the NMPA or other comparable regulatory authorities may not accept the data generated by those studies or may require us to perform additional clinical trials before approving our commercialization applications, which would increase the cost of and the development time for the relevant product candidate. If any of the pre-clinical studies or clinical trials of our product candidates is affected by any of reasons described above, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business and prospects.

RISK FACTORS

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

We may from time to time establish or seek strategic alliances, form joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our existing product candidates and any future product candidates that we may develop. For example, we commenced patient enrollment for pediatric postoperative PH clinical trial in collaboration with Shanghai Children’s Medical Center to support the EU CE certification for our Core Product. We also entered into patent license agreement with the Regents of the University of Michigan to obtain sublicenses for certain patents and patent applications relating to NO-releasing polymers and gas-delivery devices capable of generating and delivering NO containing gas streams.

We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. For any products or product candidates that we may seek to in-license from third parties, we may face significant competition from other medical device companies with greater resources or capabilities than us, and any agreement that we do enter may not result in the anticipated benefits.

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

We may from time to time become subject to various litigations, legal or contractual disputes, investigations or administrative proceedings arising in the ordinary course of our business, including but not limited to various disputes with or claims from our current and former employees, suppliers, customers, contractors, business partners and other third parties that we engage for our business operations. On-going or threatened litigations, legal or contractual disputes, investigations or administrative proceedings may divert our management’s attention and consume their time and our other resources. We cannot assure you that we will not be subject to any similar claims, disputes or legal proceedings, related to, or in connection with, our share incentive scheme, or other aspects in the ordinary course of business in the future. Any such claims, disputes or legal proceedings involving us or our employees may result in damages or liabilities, as well as legal and other costs and may cause a distraction to our management.

Any failure to offer patient support may adversely affect our relationships with our existing and prospective patients, and in turn our business, results of operations and financial condition.

Our patients and healthcare professionals will depend on our customer and patient support to properly use and upgrade our iNO therapy, FeNO detection and IABP products, and resolve issues in a timely manner. We may be unable to respond quickly enough to accommodate short-term increases in demand for customer and patient support. Increased demand for support could increase costs and adversely affect our results of operations and financial condition. Any failure to maintain high-quality customer and patient support, or the market perception that we do not maintain high quality customer and patient support, could adversely affect customer and patient satisfaction and their willingness to continue to use our products or the willingness of physicians to prescribe or recommend our products, which in turn could harm our business, results of operations and financial condition.

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

Our future success depends on the continued service of our senior management and other key personnel. The loss of any such individuals, including due to departures to competitors or the inability to replace them in a timely manner, could materially and adversely affect our business, financial condition and results of operations. We may also face challenges in attracting and retaining senior management and key personnel on acceptable terms. In addition, our growth depends on our ability to recruit and retain qualified personnel with expertise in medical devices and life sciences. Competition for such talent is intense across industry, academia and research institutions, and high turnover could limit our ability to develop our technologies, pursue collaborations and execute our business strategy.

RISK FACTORS

Our operations and business plans may be adversely affected by natural disasters, civil and social disruption.

Any future occurrence of force majeure events, natural disasters or outbreaks of epidemics and contagious diseases, including avian influenza, severe acute respiratory syndrome, swine influenza caused by the H1N1 virus, or H1N1 influenza or the Ebola virus, may materially and adversely affect our business, financial condition and results of operations. An outbreak of a contagious disease or other adverse public health developments in China or elsewhere could have a material adverse effect on our business operations. These events could cause temporary suspension of our manufacturing facilities, laboratory operations, or clinical trials, and could disrupt our supply chain and sales activities. For instance, our operations could be disrupted if any of our employees or employees of our distributors or other business partners were suspected of contracting or contracted a contagious disease, since this could require us and our distributors and other business partners to quarantine some or all of these employees and disinfect facilities used for operations. In addition, the commencement of new clinical trials for product candidates in our development pipeline could also be delayed or prevented by any delay or failure in subject recruitment or enrollment. Our commercialization plan for commercial-ready or near commercial-ready assets could also be disrupted.

Moreover, geographies where we market our products have experienced natural disasters such as earthquakes, floods and droughts in the past few years. Any future occurrence of severe natural disasters in these geographies may materially and adversely affect its economy and our business. We cannot assure you that any future occurrence of natural disasters or outbreaks of epidemics and contagious diseases or the measures taken by the government in response to such contagious diseases will not seriously disrupt our operations or those of our customers, which may materially and adversely affect our business, financial condition and results of operations.

We are subject to risks relating to leased properties.

We do not own the real property for our current major operations. As of the Latest Practicable Date, we had six leased properties in the PRC, with a total aggregate gross floor area of approximately 11,541.45 sq.m. Upon expiration of the leases, we will need to negotiate for renewal of the leases and may have to pay increased rent. We cannot assure you that we will be able to renew our leases on terms which are favorable or otherwise acceptable to us, or at all. If we fail to renew any of our leases or if any of our leases are terminated or if we cannot continue to use any of our leased property, we may need to seek an alternative location and incur expenses related to such relocation, and our operations and businesses may also be disrupted or even suspended if we are not able to complete the relocation, including the reconstruction of relevant facilities in the new location, in a timely manner.

We are subject to other risks related to our leased properties. Pursuant to the applicable PRC laws and regulations, property lease agreements must be registered with the local branch of the Ministry of Housing and Urban-Rural Development of the PRC. As of the Latest Practicable Date, we had not completed the relevant property leasing registrations for five of our leased properties, which are used for our operating center and manufacturing facilities. For details relating to such noncompliance, see “Business — Legal Proceedings and Compliance.”

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses and unauthorized access. If any material system failure or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

Our internal computer systems store a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenue. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

RISK FACTORS

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

Physicians and other healthcare service providers play a primary role in the recommendation and use of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-bribery laws, anti-kickback laws, false claims laws, fraud and abuse laws or similar healthcare and security laws and regulations in China, including, without limitation, Criminal Law of the PRC and the PRC Anti-Unfair Competition Law. These laws may impact, among other things, our proposed sales, marketing and education programs. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC or other government.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, we and our business partners are subject to equivalents of each of the healthcare laws described above in other jurisdictions, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. There are ambiguities as to what is required to comply with these requirements, and if any of the physicians or other healthcare service providers with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

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.

We maintain insurance policies that are required under PRC laws and regulations as well as other insurance policies based on our assessment of our operational needs and industry practice. We have elected not to maintain certain types of insurances, such as cargo insurance for goods. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any uninsured risks may result in substantial costs and the diversion of resources, which could adversely affect our business, financial condition, and results of operations.

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 brand Novlead is important to attracting and retaining partners and our success depends on our ability to maintain and enhance our brand image and reputation. Maintaining, promoting and growing our brands depend largely on the success of our ability to provide consistent, high-quality services, our marketing efforts and our ability to successfully secure, maintain, and defend our rights to use our brands and trade names. Our brand could be harmed if we fail to achieve these objectives.

Our brand value also depends on our ability to maintain a positive perception of our corporate integrity, purpose and brand culture. Any negative publicity concerning us, our management, employees, affiliates and partners, even if untrue, could adversely affect our reputation and business prospects. There can be no assurance that negative publicity about us or any of our management, employees or affiliates and partners would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition.

RISK FACTORS

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant net loss from operations historically. We may continue to incur significant net loss from operations in the near future, which may materially adversely affect our business operations, results of operations, financial position and profitability.

We have a history of significant operating expenses and net losses and have experienced, and expect to continue to experience, negative operating cash flows, requiring us to finance our operations primarily through equity investments. In 2024, 2025 and for the six months ended June 30, 2025 and 2026, we recorded net losses of RMB86.2 million, RMB95.3 million, RMB43.8 million and RMB51.9 million, respectively. Our net loss position primarily resulted from costs incurred in connection with our research and development, selling activities and administrative expenses associated with our operations, as well as finance costs in connection with redemption right granted to our investors. In particular, we have invested heavily in our research and development efforts. We incurred research and development expenses of RMB33.0 million, RMB34.7 million, RMB13.7 million and RMB20.3 million in 2024, 2025 and for the six months ended June 30, 2025 and 2026, respectively. As we expect to further expand our product pipeline, we expect that our R&D expenses to increase in the absolute amount. See “Financial Information — Description of Key Components of Consolidated Statements of Profit or Loss.”

We expect our net losses to continue in the foreseeable future as we expand our development of, and seek regulatory approvals for, our product candidates, and commercialize our products. Typically, it takes many years to develop one new product from the time it is designed to when it is available for commercial sales. We will also incur costs in support of our growth. The size of our future net losses will depend, in part, on the number and scope of our product development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenue and the timing and amount of milestones and other payments we make or receive with arrangements with third parties. If we are unable to effectively manage increases in operating expenses or net losses, our business, results of operations and financial position could be materially and adversely affected.

We incurred net liabilities during the Track Record Period and may continue to incur net liabilities in the future.

We incurred net liabilities during the Track Record Period. Our net liabilities were primarily due to our significant amounts of redemption liabilities. As of December 31, 2024, 2025 and June 30, 2026, we recorded redemption liabilities of RMB429.9 million, RMB519.5 million and RMB540.8 million, respectively. Our redemption liabilities are in relation to our redemption obligations arising from the redemption rights granted to certain Shareholders. Immediately upon the completion of the [REDACTED], the redemption rights shall be automatically terminated and our redemption liabilities shall be converted into equity.

Net liabilities may constrain our operational flexibility. If we continue to incur net liabilities, we may curtail or defer our business expansion plans, or encounter difficulties in obtaining loans or external financing, which could materially and adversely impact our business, financial position and results of operations.

We may be exposed to liquidity risk due to a long cash conversion cycle.

Our cash conversion cycle was 178 days, 155 days and 125 days in 2024, 2025 and for the six months ended June 30, 2026, respectively. The cash conversion cycle is calculated by adding inventory turnover days and trade receivables turnover days, then subtracting trade payable turnover days. The decrease of our cash conversion cycle throughout the Track Record Period was primarily driven by our inventory turnover days, which decreased from 204 days in 2024 to 172 days in 2025 and further to 129 days for the six months ended June 30, 2026, respectively. The decrease of inventory turnover days was primarily due to (i) improved inventory management efficiency, including negotiating with suppliers to provide requested materials in batches and shorten the supply cycle and (ii) refined manufacturing processes which improve production efficiency and optimize our demands for inventory. See “Financial Information — Discussion of Certain Selected Items From the Consolidated Statements of Financial Position — Assets” for more information. A long cash conversion cycle may increase our reliance on working capital or external financing to support our operations and growth. If we are unable to manage our inventory and receivables efficiently or to secure adequate financing on acceptable terms, our liquidity position, financial condition, and results of operations could be materially and adversely affected.

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

Our product candidates will require completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Our operations have consumed substantial amounts of cash since inception. We had net cash flows used in operating activities of RMB52.8 million, RMB48.0 million, RMB30.6 million and RMB46.3 million in 2024, 2025 and for the six months ended June 30, 2025 and 2026, respectively. We cannot assure you that we will be able to generate positive cash flows from operating activities in the future. Our liquidity and financial condition may be materially and adversely affected by negative net cash flows, and we cannot assure you that we will have sufficient cash from other sources to fund our operations. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that we will be able to obtain the financing on terms acceptable to us, or at all, and if we raise finance by issuing further equity securities, your interest in us may be diluted. If we continue to have negative operating cash flows in the future, our liquidity and financial condition may be materially and adversely affected.

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

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

To operate our business successfully and meet our customers’ demands and expectations, we must maintain a certain level of inventory for our products to ensure timely delivery as required. In 2024, 2025 and for the six months ended June 30, 2026, our average inventory turnover days were 204 days, 172 days and 129 days, respectively. We maintain our inventory levels based on our internal forecasts which are inherently uncertain. If our forecast demand is lower than actual demand, we may 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.

We have adopted a share incentive plan and will continue to grant share-based awards in the future, which may increase expenses associated with share-based compensation, cause shareholding dilution to our existing Shareholders, and have an adverse effect on our financial performance. Exercise of the awards granted will increase the number of our outstanding Shares, which may adversely affect the [REDACTED] of our Shares.

We have adopted the Pre-[REDACTED] Employee Incentive Scheme in 2020 which was amended and replaced on January 20, 2026. See “Appendix IV — Statutory and General Information — Pre-[REDACTED] Employee Incentive Scheme.” In 2024, 2025 and for the six months ended June 30, 2025 and 2026, we recorded share-based payment expenses of RMB1.5 million, RMB1.4 million, RMB0.7 million and RMB1.4 million, respectively, related to awards granted under the Pre-[REDACTED] Employee Incentive Scheme.

We believe the granting of share-based awards is of significant importance to our ability to attract and retain key personnel and employees. As a result, we will continue to grant share-based compensation to employees in the future, which may further increase our expenses associated with share-based compensation, cause shareholding dilution to our Shareholders, and adversely affect the [REDACTED] of our Shares, and in turn materially and adversely affect our business, financial condition, and results of operations.

Fluctuations in exchange rates may result in foreign currency exchange losses and may have a material adverse effect on your [REDACTED].

If any portion of our revenue, expenses or cash flows is denominated in currencies other than RMB, our operating results and financial condition may be adversely affected by fluctuations in foreign currency exchange rates. In addition, the translation into RMB of revenues, expenses, assets and liabilities denominated in foreign currencies will be affected by changes in foreign currency exchange rates. As we expect our sales to overseas market will expand in the future, we may be exposed to foreign exchange risks for transactions settled in U.S. dollars or currencies other than RMB. Our net income and cash flows may be negatively affected by changes in foreign currency

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exchange rates. In 2024, 2025 and for the six months ended June 30, 2025 and 2026, we recorded net exchange gains of RMB27 thousand, and net exchange losses of RMB75 thousand, RMB3 thousand and RMB207 thousand, respectively.

We have historically received government grants and subsidies operation and we may not receive such grants or subsidies in the future.

We have historically received government grants which mainly represent unconditional government subsidies to encourage the operations of certain subsidiaries of us. In 2024, 2025 and for the six months ended June 30, 2025 and 2026, we recognized government grants as other income of RMB3.0 million, RMB5.3 million, RMB0.3 million and RMB3.6 million, respectively. For further details of our government grants, see “Financial Information.” We cannot assure you of the continued availability of the government grants and other favorable policies currently enjoyed by us. Any reduction or elimination of such government grants and other policies would materially adversely affect our business, financial condition, results of operations and prospects.

We may not be able to fulfill our obligation in respect of contract liabilities which could adversely affect our financial condition, results of operations and prospects.

As of December 31, 2024, 2025 and June 30, 2026, we had contract liabilities of RMB1.2 million, RMB5.2 million and RMB3.5 million, respectively, mainly arisen from the advance payments made by customers for our commercialized products. If we have any difficulties or fail to perform our obligations under our contracts, our relationships with our customer will be adversely affected and we will be unable to recognize such contract liabilities as revenue, exposing us to the risk of shortfalls in liquidity, which may have a material adverse effect on our operational performance and prospects. See “Financial Information — Net Current (Liabilities)/Assets — Contract Liabilities.”

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

As of June 30, 2026, we had intangible assets of RMB0.9 million. Our determination on whether intangible assets are impaired requires an estimation on recoverable amount of the intangible assets, which is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, the carrying amount of the intangible assets may exceed its recoverable amount, our intangible assets may be impaired. Any significant impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations.

For more information regarding our impairment policy in relation to intangible assets, please refer to Note 18 of Appendix I to this document.

RISKS RELATING TO DOING BUSINESS IN THE JURISDICTION WHERE WE OPERATE

We operate within a complex and evolving medical device regulatory landscape across various jurisdictions and regulatory regimes, which may impede or delay the approval and commercialization of our products.

Our products, marketing, sales and development activities and manufacturing processes are subject to extensive and dynamic regulation by the regulatory authorities of the jurisdictions in which we operate. The regulatory framework of the medical device industry in the PRC addresses various aspects of a medical company’s operations, including approval, production, licensing, certification requirements and procedures, periodic renewal and reassessment processes, registration of new medical devices, quality control, pricing and distribution of medical devices and environmental protection. On December 26, 2016, the Notice on Opinions on the Implementation of the “Two Invoice System” in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)的通知》) was jointly issued by the Medical Reform Office of the State Council (國務院醫改辦) and other seven ministries and commissions. On July 19, 2019, the General Office of the State Council issued the Notice on Printing and Distributing the Reform Plan for the Management of High-value Medical Consumables (國務院辦公廳關於印發治理高值醫用耗材改革方案的通知), which encourages local governments to adopt the “Two Invoice System” on a case-by-case basis in order to reduce the circulation of high-value medical consumables and promote the transparency of purchase and sales.

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The status of the implementation of Two Invoice System for medical devices differs across provinces in China, and the nationwide implementation of Two Invoice System for medical devices shall be determined in accordance with the relevant laws and regulations in effect at that time. If the products offered by us are included in the Two Invoice System, we or our distributors may be required to adjust selling channels, which may adversely affect our product sales.

The international medical device industries are subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new devices and products. In recent years, the regulatory framework in countries where we operate regarding the medical device industry and pharmaceutical industry has undergone changes and we expect that they will continue to undergo additional changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development of our products and solutions and reduce the benefits we believe are available to us from operating globally.

Changes in geopolitical relationships, barriers to trade or escalation of trade disputes, including the imposition of trade restrictions and sanctions, could negatively affect demand for our products and services, and consequently could have a material adverse effect to our business, financial condition and results of operation.

Our global operations are subject to the risk of deterioration in the political and economic relations among countries and sanctions and export controls administered by the government authorities in the countries in which we operate, and other geopolitical challenges. We cannot predict whether the countries in which we operate, or may operate in the future, would become subject to new or additional trade restrictions and sanctions, including the type or effect of such restrictions and sanctions imposed by the United States or other governments. We cannot assure you that we, our research partners, our suppliers and customers, or the global value chains we serve will not be impacted in the future. Any impacts may result in our customers seeking other suppliers for the products and services that we offer, and we may be unable to recapture and/or replace such customers. We may also have to adjust or even terminate our collaborations with our research and other business partners, which could disrupt our research and development and commercialization strategies. Further, any increased customs restrictions and tariffs or quotas, or the imposition of additional duties and other charges on imports and exports could change the way we and our customers conduct business, increase our costs, or impede the timely delivery of our products. This could have a negative effect on our business, financial condition, results of operations and prospects.

In particular, the United States government imposed economic and trade sanctions directly or indirectly affecting certain foreign technology companies. The United States has increased export controls restrictions through the Export Administration Regulations (the “**EAR**”), administered by the Bureau of Industry and Security of the United States Department of Commerce, which includes a list of foreign persons on which certain trade restrictions are imposed, including businesses, research institutions, government and private organizations, individuals and other types of legal persons (the “**Entity List**”), some of which are based in China. Where a foreign person is included on the Entity List, the export, re-export and/or transfer (in-country) of items which are subject to the EAR generally is prohibited unless specified license requirements are met. If certain of our customers, suppliers and research partners are listed on the Entity List and subject to restrictions from sourcing or selling technologies, software, or products from/to us, there is no guarantee that we will be able to obtain as well as extend and maintain the requisite regulatory licenses, permits and approvals in relation to our transactions with these customers, suppliers and research partners, or that such licenses, permits and approvals will cover all our existing and potential transactions with such customers, suppliers and research partners. As relevant policies are rapidly evolving, it may be difficult to evaluate their potential future impacts. The aforementioned restrictions, and similar or more expansive restrictions or sanctions, including sanctions currently imposed or that may be imposed in the future, may materially and adversely affect our customers’, suppliers’ and research partners’ ability to acquire or use technologies, systems, products or materials critical to their operations, which in turn may adversely affect our business, results of operations and financial condition.

The United States government’s attitude towards Chinese service providers in pharmaceutical and biotechnology industries may directly or indirectly affect our business operations. Recent legislative and political developments in the United States reflect intensifying scrutiny of PRC-linked biotechnology companies. In particular, the United States government’s attitude towards Chinese service providers in pharmaceutical and biotechnology industries may directly or indirectly affect our business operations. The United States has recently passed legislation, namely the BIOSECURE Act (the “**BIOSECURE Act**”), to prohibit U.S. federal executive agencies from procuring or obtaining any biotechnology equipment or service produced or provided by a

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“biotechnology company of concern”, or entering into or renewing a contract, loan, or grant with an entity that uses such biotechnology service or equipment. For details, see “Regulatory Overview — Overview of Laws and Regulations in the United States — Recently Passed Law by the U.S. Government: The BIOSECURE Act. On October 9, 2025, the U.S. Senate passed a revised version of the BIOSECURE Act as an amendment to the National Defense Authorization Act (“NDAA”) for the year of 2026. The final version of the NDAA containing this legislative language was passed by the Senate and House of Representatives and signed into law by President Trump on December 18, 2025. The Act prohibits the U.S. Government from procuring or obtaining biotechnology equipment or services produced or provided by a “biotechnology company of concern” (“BCC”); entering into, extending, or renewing government contracts with an entity that directly or indirectly (e.g., via a subcontractor) uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract. Companies designated as a BCC include those that are identified on the U.S. Department of Defense’s annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. Government also has the ability to designate entities as BCCs through a separate designation process. There is no guarantee that the legislation would not apply to or impact certain biotechnology equipment or services that we procure or use. As a result, any continued use of such biotechnology equipment or services provided or produced could affect our ability to continue our development or the third parties that we may contract with, which may, in turn, affect our business operations. In addition, although the BIOSECURE Act does not affect the FDA’s review of medical device submissions, if we or any of our affiliates were in the future to be designated as a BCC or included on the 1260H List, U.S. federal executive agencies, federal contractors and recipients of federal loans and grants could be prohibited from procuring or using our products, which could materially limit our ability to commercialize iNowill in the United States even if FDA approval is obtained. As of the Latest Practicable Date, neither we nor any of our affiliates had been designated as a BCC or included on the 1260H List. More broadly, heightened political and public scrutiny in the United States of PRC-based medical device and biotechnology companies may adversely affect the willingness of U.S. hospitals, group purchasing organizations, distributors and clinicians to adopt our products, and may result in additional legislation, procurement restrictions, tariffs or other measures targeting products or companies with PRC connections. Moreover, the implementing regulations and guidance under the BIOSECURE Act, the process and criteria for designating entities as BCCs, and the scope of “biotechnology equipment or services” covered by the Act remain subject to further development and change, and the scope and impact of the Act could be broader or more restrictive than we currently anticipate. Consequently, we may need to re-evaluate or adjust our established supply chains now that the BIOSECURE Act has become law. The need to re-evaluate our supply chain contracts may impose additional costs and operational complexities on our business, including, among other things, an examination and potential modification to existing personnel and expertise, and examination of our existing contracts, and a re-assessment of our current suppliers in order to identify possible alternative sources of supply. We may not be able to identify alternative sources of supply with competitive prices and terms and satisfactory quality in a timely manner, and any disruption to our established supply chains may lead to delays in procurement, production, and delivery, all of which could have a material adverse effect to our business, financial condition and results of operations.

Compliance with applicable cybersecurity, data security and personal information protection laws and regulations could require additional expenditures and consequently affect our business, financial conditions and operating results.

We are subject to various PRC cybersecurity, data security and personal information protection laws and regulations, including but not limited to the PRC Civil Code (《中華人民共和國民法典》), the PRC Cybersecurity Law (《中華人民共和國網絡安全法》) (the “**Cybersecurity Law**”), the PRC Data Security Law (《中華人民共和國數據安全法》) (the “**Data Security Law**”) and the PRC Personal Information Protection Law (《中華人民共和國個人信息保護法》) (the “**Personal Information Protection Law**”). See “Regulatory Overview — Laws and Regulations Relating to Cyber Security and Data Protection” for details. Furthermore, on February 24, 2023, the CSRC promulgated the Provisions on Strengthening the Confidentiality and Archives Management Work Related to the Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》), which became effective on March 31, 2023. See “Regulatory Overview — Regulations on Securities Issuance and Overseas [REDACTED] and [REDACTED]” for details.

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In addition, our U.S. counterparties may be subject to U.S. laws restricting certain transactions that provide persons connected with the PRC with access to U.S. sensitive personal data. On February 28, 2024, the President of the United States issued Executive Order 14117, and the U.S. Department of Justice’s implementing regulations under 28 C.F.R. Part 202, known as the Data Security Program (the “DSP”), took effect on April 8, 2025. The DSP prohibits or restricts U.S. persons from engaging in certain data brokerage, vendor, employment and investment transactions that would give a “country of concern” (which includes the PRC) or a “covered person” access to bulk U.S. sensitive personal data, including personal health data above specified volume thresholds. Because we are organized under the laws of the PRC and have our principal place of business in the PRC, we constitute a “covered person” for the purposes of the DSP, as do our PRC subsidiaries and PRC-resident employees, and U.S. persons are accordingly prohibited from, or restricted in, engaging in covered data transactions with us. The DSP contains exemptions for certain transactions involving data that are ordinarily incident to FDA-regulated clinical investigations and certain transactions involving regulatory approval and post-marketing surveillance data, subject to the conditions specified in the applicable regulations; the availability of any such exemption depends on the particular facts and circumstances of the relevant data transaction.

As a result, U.S. hospitals, clinical research sites, contract research organizations, patient registries, data vendors, cloud service providers, distributors and other U.S. persons with which we deal or may deal may decline to contract with us, may impose data localization, access-restriction, audit and termination terms that increase our costs and limit our ability to use data generated in the United States, or may require that our U.S. activities be conducted without remote access from the PRC. Our currently contemplated PMA application for the neonatal PPHN indication is expected to rely principally on published literature, non-U.S. real-world evidence and registry data and device nonclinical testing, and we do not currently expect the DSP to materially affect that application. However, any clinical trials we conduct in the United States for PH, ARDS or COPD, any U.S. post-market study or registry, the collection of device usage data from U.S. hospitals through connected features of our products, and the employment of personnel in the United States will need to be structured to comply with the DSP, which may increase our costs, delay our U.S. development and commercialization activities, limit the data available to us, or cause prospective partners, investigators or customers to decline to work with us. Violations of the DSP by our counterparties may expose them to substantial civil and criminal penalties, which may further reduce their willingness to engage with us, and the DSP and related U.S. measures may be expanded in scope, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes and developments in the enforcement of cybersecurity, data security and personal information protection laws and regulations present challenges in ensuring comprehensive compliance and increase our operational costs, as we must allocate time and resources to address various compliance requirements. Given the evolving legal and regulatory landscape, no assurance can be given as to the effectiveness of these policies and measures adopted by us or our suppliers or other business partners. Any non-compliance or perceived non-compliance by our business partners with any applicable cybersecurity, data security or personal information protection regulations may result in negative publicity against us, as well as legal proceedings or regulatory actions. Such outcomes could lead to the imposition of fines, revocation of licenses, suspension of relevant operations or other legal or administrative penalties, which may damage our reputation, deter existing and potential customers and expose us to fines and damages. Consequently, these matters could have a material and adverse effect on our business, financial conditions and operating results.

There might be uncertainties in effecting service of legal process and enforcing judgments against us and our management.

All our assets and the majority of our Directors and senior management are located in the PRC. As a result, it may not be possible to effect service of process within certain jurisdictions outside the PRC upon us or most of our Directors and senior management. Pursuant to Arrangements for Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Cases between Courts of the Chinese Mainland and Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) effective on January 29, 2024, promulgated by the Supreme People’s Court, a party with an enforceable final court judgment rendered by the competent People’s Court of the PRC or the High Court of Hong Kong with respect to any civil and commercial cases excluding certain types of which, may apply for recognition and enforcement of the judgment in the relevant Intermediate People’s Court of the PRC or the High court of Hong Kong. The recognition and enforcement of such judgment in a PRC court is subject to the conditions and procedures under the New Arrangement.

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We are a PRC enterprise and we are subject to PRC tax on our income, and the dividends payable to [REDACTED] and [REDACTED] on the sale of our H Shares by our [REDACTED] are subject to PRC tax. Under the Enterprise Income Tax (the “EIT”) Law of the PRC (the “EIT Law”), our offshore subsidiaries may therefore be subject to PRC income tax on their worldwide taxable income.

Under applicable PRC tax laws, a PRC-established company is generally subject to a tax of 25% on its global income. However, we have been recognized as a “High and New Technology Enterprise” and currently entitled to a preferential enterprise income tax rate of 15% till November 2026. In addition, 5 of our subsidiaries were subject to “small and thin-profit enterprises” and have benefit from a preferential tax rate of 20% under the EIT Law during the Track Record Period. There is no guarantee that we will maintain such preferential tax treatment in the future. If our preferential tax treatments are revoked, become unavailable or if the calculation of our tax liability is successfully challenged by the PRC tax authorities, the discontinuation of any of the various types of preferential tax treatment we enjoy could materially and adversely affect our results of operations.

Under applicable PRC tax laws, regulations and statutory documents, non-PRC resident individuals and enterprises are subject to different tax obligations with respect to dividends received from us or gains realized upon the sale or other disposition of our H Shares. Non-PRC individuals are generally subject to PRC individual income tax under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) with respect to PRC source income or gains at a rate of 20% unless specifically exempted by the tax authority of the State Council or reduced or eliminated by an applicable tax treaty. We are required to withhold related tax from dividend payments. Pursuant to applicable regulations, domestic non-foreign — invested enterprises issuing shares in Hong Kong may generally, when distributing dividends, withhold individual income tax at the rate of 10%. However, withholding tax on distributions paid by us to non-PRC individuals may be imposed at other rates pursuant to applicable tax treaties (and up to 20% if no tax treaty is applicable) if the identity of the individual holder of H shares and the tax rate applicable thereto are known to us. Whether gains realized upon disposition of H shares by non-PRC individuals are subject to PRC individual income tax will be determined by the then effective laws and regulations.

Non-PRC resident enterprises that do not have establishments or premises in the PRC, or that have establishments or premises in the PRC but their income is not related to such establishments or premises are subject to PRC EIT at the rate of 10% on dividends received from PRC companies and gains realized upon disposition of equity interests in the PRC companies pursuant to the EIT Law and other applicable PRC tax regulations and statutory documents, which may be reduced or eliminated under special arrangements or applicable treaties between the PRC and the jurisdiction where the nonresident enterprise resides. Pursuant to applicable regulations, we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including [REDACTED]). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be subject to the PRC tax authorities’ verification. As of the Latest Practicable Date, there were no specific rules on how to levy tax on gains realized by nonresident enterprise holders of H shares through the sale or transfer by other means of H shares.

The PRC tax treatment of gains derived by holders of our H Shares from dispositions of H Shares will be determined in accordance with the laws and regulations in effect then. If any such tax is collected, the value of our H Shares may be materially and adversely affected.

Under the EIT Law, an enterprise established outside the PRC with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it is treated in a manner similar to a Chinese enterprise for EIT Law purposes. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties” of the enterprise. In addition, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies (the “Circular 82”) specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal, and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. State Administration of Taxation of the PRC (the “SAT”) has subsequently provided further guidance on the implementation of Circular 82.

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As substantially all of the operational management of our Company is currently based in the PRC, our offshore subsidiaries (such as our subsidiaries established in Hong Kong and the United States) may be deemed to be “PRC resident enterprises” for the purpose of the EIT Law. If our offshore subsidiaries are deemed PRC resident enterprises, they could be subject to the EIT at 25% on our global income, except that the dividends we receive from our PRC subsidiaries may be exempt from the EIT to the extent such dividend income constitutes “dividends received by a PRC resident enterprise from its directly invested entity that is also a PRC resident enterprise.” It is, however, unclear what type of enterprise would be deemed a “PRC resident enterprise” for such purposes. The EIT on our subsidiaries’ global income could significantly increase our tax burden and adversely affect our cash flows and profitability.

Payment of dividends is subject to restrictions under PRC law and regulations.

Under PRC law and regulations, we may only pay dividends out of distributable profits. Distributable profits are our after-tax profits, less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make. As a result, we may not have sufficient or any distributable profit to enable us to make dividend distributions to our Shareholders, including in periods for which our financial statements indicate we are profitable. Any distributable profit not distributed in a given year is retained and available for distribution in subsequent years.

Moreover, as the calculation of distributable profits under PRC GAAP is different from the calculation under IFRS in certain respects, our subsidiaries may not have distributable profits as determined under PRC GAAP, even if they have profits for that year as determined under IFRS, or vice versa. Accordingly, we may not receive sufficient distributions from our subsidiaries for us to pay dividends. Failure by our operating subsidiaries to pay us dividends could adversely impact our ability to make dividend distributions to our Shareholders and our cash flow, including periods in which we are profitable.

Applicable currency exchange requirements may affect our ability to utilize our revenue effectively.

The convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China are in accordance with and subject to the relevant regulatory framework. A substantial portion of our revenue is denominated in RMB. The compliance with applicable conversion and remittance requirements may affect our ability to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations. The RMB is currently convertible under the “current account,” which includes dividends, trade and service-related foreign exchange transactions, but its convertibility under the “capital account” (which includes foreign direct investment and loans) remains subject to regulation. Currently, we and our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the prior approval of SAFE by complying with certain procedural requirements. Since a portion of our revenue is denominated in RMB, any existing and future regulations on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our H Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

RISKS RELATING TO THE [REDACTED]

No [REDACTED] currently exists for our H Shares, and an active [REDACTED] for our H Shares may not develop and the [REDACTED] of our H Shares may decline or become volatile.

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

RISK FACTORS

The [REDACTED] and [REDACTED] of our H Shares may be volatile, which could lead to substantial losses to [REDACTED].

The [REDACTED] and [REDACTED] 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 [REDACTED] of the shares of other companies engaging in similar business may affect the [REDACTED] and [REDACTED] of our H Shares. In addition to market and industry factors, the [REDACTED] and [REDACTED] 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, 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. Moreover, shares of other companies listed on the Hong Kong Stock Exchange with significant operations and assets in China have experienced [REDACTED] volatility in the past, and our H Shares may be subject to changes in [REDACTED] not directly related to our performance.

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

Prior to the [REDACTED], there has not been a [REDACTED] 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 [REDACTED] of our H 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 [REDACTED] or the perception that these sales may occur could significantly decrease the prevailing [REDACTED] 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 [REDACTED] or sale of additional share capital or share capital-linked securities by our Company in future [REDACTED]. 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].

Future [REDACTED] in China or conversion of our Unlisted Shares into H Shares, could have a material and adverse effect on the prevailing [REDACTED] of our H Shares and our ability to raise additional equity capital in the future, or may result in dilution of your [REDACTED].

We are currently applying for all of the Company's Unlisted Shares to be converted into H Shares after the completion of the [REDACTED]. According to the PRC Company Law, the Unlisted Shares issued by the Company prior to the [REDACTED] are restricted from [REDACTED] within one year from the [REDACTED]. Such restriction from trading will limit the number of H Shares to be [REDACTED] on the market, which will in turn adversely affect the [REDACTED] of the H Shares during such restriction period. If our application for the [REDACTED] of our relevant Unlisted Shares on the Hong Kong Stock Exchange after the completion of the [REDACTED] is successful, any future sales (after the expiration of the restrictions set out above) of Unlisted Shares by relevant Shareholders in the [REDACTED] may affect the [REDACTED] of our H Shares. Moreover, if we issue Unlisted Shares in the future and convert a substantial amount of Unlisted Shares into H shares to be [REDACTED] and [REDACTED] in the future on the Hong Kong Stock Exchange, it may further increase the [REDACTED] of the H shares in the [REDACTED], which may adversely affect the [REDACTED] of the H shares.

As the [REDACTED] of our [REDACTED] is higher than our net tangible book value per share, [REDACTED] of our H Shares in the [REDACTED] may experience immediate dilution upon such [REDACTED]. [REDACTED] of H Shares may also experience further dilution in [REDACTED] if we issue additional H Shares in the future.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] net tangible asset value, and our [REDACTED] Shareholders will receive an increase in the [REDACTED] adjusted consolidated net tangible assets per share of their H Shares. To expand our business, we may consider [REDACTED] and [REDACTED] additional Shares in the future. [REDACTED] of the [REDACTED] may 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.

RISK FACTORS

Our Single Largest Group of Shareholders have had and will continue to have substantial influence over the outcome of shareholder actions in our Company.

As of the Latest Practicable Date, our Single Largest Group of Shareholders controlled approximately 34.61% of our issued Shares. Immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), our Single Largest Group of Shareholders will control approximately [REDACTED]% of our issued Shares. As a result, our Single Largest Group of Shareholders will have significant influence over our business, including decisions regarding mergers, consolidations, liquidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions, and may take actions that are not in the best interest of us or our other Shareholders. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could have the effect of depriving our other Shareholders of the opportunity to receive a premium for their shares as part of a sale of our Company and may reduce the price of the H Shares. This concentrated control will limit your ability to influence corporate matters and could discourage others from pursuing any potential merger, takeover or other change of control transactions that other holders of our ordinary shares may view as beneficial.

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

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

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 results of 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 [REDACTED] on your [REDACTED] in our H Shares will likely depend entirely upon any future [REDACTED] appreciation of our H Shares. There is no guarantee that our H Shares will appreciate [REDACTED] after the [REDACTED] or even maintain the [REDACTED] at which you [REDACTED] the H Shares. You may not realize a [REDACTED] on your [REDACTED] in our H Shares and you may even lose your entire [REDACTED] in our H Shares.

Facts, forecasts and statistics in this document relating to our industry that were obtained from official government publications may not be fully reliable.

Facts, forecasts and statistics in this document relating to the cardiopulmonary diagnostic and therapeutic devices market are obtained from sources including official government publications. However, we cannot guarantee the quality or reliability of such official government publications. Neither we, the [REDACTED], the Sole Sponsor, the [REDACTED] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from the official government publications. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics 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 obtained from the official government publications. 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.

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

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