

RISK FACTORS

[REDACTED] in our H Shares involves significant risks. You should carefully consider all of the information set out in this document, including the risks and uncertainties described below, before making an [REDACTED] in our H Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] of our H Shares could decline due to any of these risks, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

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, which 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 OUR BUSINESS AND INDUSTRY

Risks Relating to Development of our Products and Product Candidates

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

Our business substantially depends on the successful development, obtaining and maintaining the necessary regulatory approvals and commercialization of our current and future product candidates. As of the Latest Practicable Date, we had commercialized our independently developed RC120. As of the Latest Practicable Date, we also had surgical robot and consumable product candidates under different stages of preclinical and clinical development or registration. See “Business — Our Product Portfolio” for more details. We have invested a significant portion of our time and financial resources towards the development and commercialization of our products and product candidates. We incurred R&D costs of RMB23.9 million, RMB18.9 million, RMB9.2 million and RMB9.1 million in 2023, 2024, and the six months ended June 30, 2024 and 2025, respectively. We incurred loss and total comprehensive loss of RMB34.2 million, RMB37.0 million, RMB19.1 million and RMB18.1 million in 2023, 2024, and the six months ended June 30, 2024 and 2025, respectively. Whether we can generate profit from our operating activities largely depends on the successful commercialization of RC120 and our R&D with respect to more indications, models and functions.

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The success of our products and product candidates will depend on several factors, including but not limited to:

- successful enrollment of trial participants in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data resulting from our clinical evaluations and preclinical studies;
- obtaining and maintaining the necessary regulatory approvals, commercialization authorizations and successfully launching our product candidates effectively in target markets, if and when approved, in a timely manner;
- 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;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret and/or other intellectual property rights of third parties;
- appropriately pricing and timely collecting payments from customers;
- enhancing our marketing and distribution capabilities in an efficient and cost effective manner;
- market and pricing competition with other medical products;
- keeping up with industry and technology developments; and
- continued acceptable safety profile and efficacy of our products and product candidates following regulatory approval, if and when received.

If we are not successful in one or more of these factors in a timely manner, or at all, we could experience significant delays or be unable to obtain the necessary approval for and/or to successfully expand commercialized indications of our percutaneous puncture surgical robot, which may have a materially adverse effect on our business and may result in us not being able to generate sufficient revenue and cash flow to continue our research, development and general business operations.

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The percutaneous puncture surgical robot industry and the field of medical artificial intelligence and medical robot is developing rapidly. If we are not able to develop and release new products that are competitive in the market, or develop successful enhancements or indication expansions of RC120 or any future products in a timely manner, or at all, our products may become obsolete and our business, operating results and financial condition could be materially and adversely affected.

Percutaneous puncture surgical robot industry is new and rapidly evolving, and it is uncertain whether it will achieve and sustain high levels of demand and market adoption. Particularly, the deep integration of AI with medical imaging technologies has become a significant market trend. Our future financial performance will depend on growth in this market and on our ability to adapt to emerging demands of our customers. It is difficult to predict the future growth rate and size of our target markets. The percutaneous puncture surgical robot industry is characterized by rapid technological change, frequent new product introductions and enhancements, application of AI technologies, changing customer demands, and evolving industry standards. Social trends and political policies in this industry may further evolve, which could lead to changes in need for our products, introduction of new AI-assisted functions, and the need for us to adapt our business model and our product pipelines. Our future success therefore will depend on our ability to accurately forecast the industry trends and continuously identify, develop and market more advanced products in a timely manner that addresses unmet clinical needs. Product designs can change with market conditions, as well as demand and preferences of hospitals and medical professionals. We cannot assure you that we will be able to successfully identify new technological opportunities, enhance or adapt to new AI technologies and methodologies, develop new products, or improve or expand the indication coverage of our existing products in a timely manner. Even if we develop new or improve our existing technologies and products, or introducing new AI-assisted functions, our ability to market our products could be limited by the need for regulatory clearance or approval, restrictions imposed on approved indications, entrenched patterns of clinical practice, uncertainty over third-party reimbursement, or other obstacles.

Technological innovations, including the application of AI technologies, often entail great uncertainty. We may not succeed in developing, marketing and delivering in a timely and cost-effective manner enhancements or improvements, especially in relation to AI-assisted functions, to our commercialized products or any new products that respond to continued changes in market demands, new customer requirements or achieve market acceptance. The timetable for the release of new products and enhancements to existing products is difficult to predict due to complexity in product development, and we may not offer new products and updates as rapidly as our users require or expect. Any new products that we develop or acquire may not be introduced in a timely or cost-effective manner, may contain errors or defects, or may not achieve the broad market acceptance necessary to generate significant or any revenue. In addition, technological innovations and the application of AI technologies often require substantial time and investment before we can determine their commercial viability. We devote significant financial and other resources to our R&D activities, while our R&D efforts may not lead to new or improved AI technologies or products that will be commercially successful. Furthermore, we may not have the financial resources necessary to fund future projects. Even if we can successfully develop new products, launched new AI-assisted functions, or improve or expand the indication coverage of existing products, we may not generate revenue to recoup relevant costs, or achieve the desired financial return. These products and relevant technologies may be rendered obsolete or less competitive due to changing customer preferences or the introduction by our competitors of products with newer technologies or features or other factors.

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The introduction of new products by competitors, the development of entirely new AI technologies to replace existing medical product offerings or shifts in healthcare benefits trends could make our products obsolete or materially and adversely affect our business, financial condition and results of operations. We may experience difficulties with software development, R&D in AI technologies, industry standards, design or marketing that could delay or prevent our development, introduction or implementation of new products, indication coverage, additional features or capabilities. If medical services providers do not widely adopt our products, we may not be able to realize a return on our investment. If we do not accurately anticipate patient and physician demands or we are unable to develop, license or acquire new features and capabilities on a timely and cost-effective basis, or if such enhancements do not achieve market acceptance, it could result in adverse publicity, loss of revenue or market acceptance or claims by patients or medical services providers brought against us, each of which could have a material and adverse effect on our reputation, business, results of operations and financial condition.

Clinical development is a lengthy, expensive and uncertain process, and unsuccessful clinical trials or procedures relating to products and indications under development could have a material adverse effect on our prospects, including incurring additional costs, experiencing delays in completing, or ultimately being unable to complete the development and commercialization of our product if clinical evaluations fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities.

We obtained Class III medical device registration certificate for our RC120 in 2024, making it possible for us to commercialize this product in China. As of the Latest Practicable Date, we were in the process of R&D of our product candidates applicable for more indications and with significant upgrades in AI-assisted functions and dynamic respiratory motion compensation function. See “Business — Our Product Portfolio” for more details. We may need to conduct, at our own expense, adequate and well-controlled clinical evaluations to demonstrate the safety and efficacy of our products. There may be more extensive regulatory requirements for the approval, manufacture, and distribution of such products. Complying with additional regulatory requirements for a Class III medical device may increase our R&D, regulatory, manufacturing and distribution costs, delay our R&D and commercialization timelines and have a material adverse effect on our business prospects, results of operations and financial condition.

Successful preclinical studies and early clinical evaluations do not necessarily mean that later clinical evaluations will also result in data that replicate the results of prior evaluations and preclinical studies and ultimately lead to regulatory approval. As of the Latest Practicable Date, we had surgical robot and consumable product candidates under different stages of preclinical and clinical development or registration. See “Business — Our Product Portfolio” for more details. We may experience numerous unexpected events during, or as a result of, clinical evaluations that could delay or prevent our ability to obtain the necessary regulatory approval or commercialize our product candidates, including but not limited to:

- regulators or institutional review boards (“IRBs,” also known as independent ethics committees) may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;

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- unanticipated protracted negotiations or an inability to agree on reasonable contractual terms with prospective CROs and hospitals for the provision of trial centers, which may lead to delayed commencement (if at all) of clinical studies for regulatory approvals;
- failure of our product to demonstrate superior results than competing or alternative products, if applicable;
- clinical trials of our product candidates may fail to demonstrate the primary or secondary endpoints as anticipated, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or subjects may drop out at a higher rate than we anticipate;
- our third-party contractors in connection with our clinical studies may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics; and
- the initial or interim results of the clinical trial may not be predictive of the final results; interim, “topline” and preliminary data from clinical trials of our product candidates under different indications may change as more patient data becomes available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.

There can be no assurance that the ongoing or planned clinical trials will be completed in a timely or cost-effective manner or result in a commercially viable product. If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates, the commercial prospects of that product candidate may be impacted, and our ability to generate revenue from any of those product candidates may be delayed. In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development process and approval process, and jeopardize our ability to commercialize that product candidate. This may have a material adverse effect on business and financial condition. Clinical trials of our product candidates may produce negative or inconclusive results. Our future clinical trial results may not be favorable. Even if our future clinical trial results show favorable efficacy, not all users may benefit. We cannot assure you that our product candidates are able to suit the conditions of each clinical trial participant.

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We may be unable to develop our product candidates or expand indication coverage of existing products as anticipated if the third parties with which we cooperate for clinical trials do not perform in an acceptable manner or if these third parties do not successfully carry out their duties or meet expected deadlines.

We need to cooperate with third parties to assist us in designing, implementing and monitoring our preclinical research and conducting clinical trials. For the clinical trials for RC120, we had cooperated with two hospitals, one CRO and one SMO, to conduct clinical trials in China. If any of these hospitals, CRO and SMO terminates their cooperation with us, the R&D of our product candidates could be substantially delayed. These third parties may not successfully carry out their responsibilities under the cooperation, meet expected deadlines or follow regulatory requirements, including clinical and laboratory guidelines. In addition, we may collaborate with certain third parties to monitor and manage data for some of our clinical programs and control only certain aspects of their activities. If any of such third-party partners do not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. 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 fulfill their obligations under our agreements with them in the manner specified in those agreements, the NMPA and/or other comparable regulatory authorities may not accept the data generated by those studies, which would increase the cost of and the development time for the relevant product candidate. If any of the preclinical studies or clinical trials of our product candidates are affected by any of the above-mentioned reasons, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business and prospects.

In addition, we may engage third-party partners in our R&D process. Our R&D timeline may be delayed if these third parties do not successfully carry out their contractual duties or meet expected deadlines in accordance with regulatory requirements; if there are disagreements between us and such parties; or if such parties are unable to expand capacities. These third parties may also be affected by natural disasters, such as floods or fire, health epidemics, including the COVID-19 pandemic, or geopolitical developments. These third parties could face production issues, such as contamination or regulatory concerns following a regulatory inspection of their facilities. In such instances, we may need to locate an appropriate replacement and establish a contractual relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense and may have a material adverse effect on our business.

The R&D, marketing and sales of our products require us to maintain close relationships with physicians upon whom we rely on to provide considerable knowledge and experience. These physicians may assist us as researchers, marketing consultants, and as public speakers. If we fail to develop, maintain our relationships with them or to continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations.

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If we encounter difficulties in enrolling patients in our clinical trials, our clinical trial 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 enough 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. The timing of our clinical trials depends on our ability to recruit participants to participate and remain in the trials until conclusion, as well as to complete follow-up periods, when required.

Our clinical trials will likely compete with other clinical trials for comparable product candidates. This competition will reduce the number and types of trial participants available to us. For example, some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. In addition, because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of trial participants available for our clinical trials at such clinical trial sites.

Any delays in enrolling trial participants in our planned clinical trials could result in increased costs, or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates or indication expansions of existing products.

If we experience delays in enrolling a sufficient number of participants in our clinical trials to meet relevant regulatory requirements or to generate meaningful statistical data, our clinical trial costs may increase or our clinical trial phases may not be completed on time, which may adversely affect our ability to advance the development of our product candidates and obtain the necessary regulatory approvals in accordance with our current planned timeline.

Risks Relating to Commercialization of Our Product Candidates

We have relatively limited experience in commercialization of percutaneous puncture surgical robots. If we are unable to develop and successfully maintain adequate sales and commercial distribution capabilities, our business and results of operations could be adversely affected.

We have relatively limited experience in launching, commercialization and marketing of percutaneous puncture surgical robot products. We started to commercialize our RC120 in 2024 when we obtained medical device registration certificate for this product. We primarily rely on our sales and marketing team and third-party distributors to market and promote our brand and products. During the Track Record Period, we also enhanced our marketing capabilities by appointing some external sales and marketing personnel through labor outsourcing. We incurred selling and distribution expenses of RMB2.9 million, RMB5.3 million, RMB1.9 million and RMB3.8 million in 2023, 2024 and the six months ended June 30, 2024 and 2025,

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respectively. The success of our marketing efforts depends on our ability to maintain and expand our relationships with qualified distributors, and our ability to attract, motivate and retain qualified and professional sales personnel who have, among other things, sufficient expertise in medical imaging and clinical trials and knowledge, and are able to communicate effectively with medical professionals. Competition for experienced sales and marketing personnel is intense. However, we would have little or no control over the selling and distribution efforts of third-party distributors. There can be no assurance that we will be able to develop and successfully maintain our sales and commercial distribution capabilities or establish or maintain relationships with hospitals, physicians, and other third parties to successfully commercialize our products. If we are unable to maintain and expand our relationships with qualified third-party distributors, or to attract, motivate and retain a sufficient number of qualified personnel to support our selling and distribution efforts, sales volumes or margin of our products may be adversely affected and we may be unable to extend our market coverage and deepen our market penetration as contemplated.

In addition, we plan to continue to strengthen our cooperative relationship with hospitals and physicians to enhance our product awareness in the market. However, such promotional activities may not be as effective as we expected, or may be impeded by unanticipated events, which may cause a decline in our sales revenue, and have a material adverse effect on our business, financial condition and results of operations.

Our self-developed methodologies and other relevant technologies are complex and may contain errors, may not operate properly or may not be superior to our competitors, which could adversely affect our business, financial condition and results of operation.

Our self-developed methodologies, AI technologies, and other relevant technologies are crucial to our puncture surgery navigation and positioning system. Due to the complexity of our methodologies and AI technologies, we cannot guarantee that the relevant technologies can always function in a proper manner or do not contain errors or deficiencies. Any error or deficiency contained therein, whether we can identify during product development may lead to inaccurate testing results generated by our products, or in worst case scenario, severe adverse events of our products, which could have a material and adverse effect on our business, financial condition and results of operations.

The use of percutaneous puncture surgical robot is relatively new. Failure to achieve broad market acceptance of RC120, to substitute the traditional CT-guided percutaneous puncturing, or to maintain good reputation among physicians, healthcare service institutions, patients and other customers, could have a material adverse impact on our business, results of operations and prospects.

If our RC120 and any future approved product candidates, including the introduction of new AI-assisted functions, fail to gain sufficient market acceptance by hospitals, physicians or patients, among others, the sales of RC120 may be adversely affected. In addition, hospitals, physicians and patients may prefer other novel products to ours. If our products do not achieve

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an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our products and product candidates, if approved for commercial sales, will depend on a number of factors, including:

- the clinical indications for which our products and product candidates are approved;
- perception by physicians, patients and hospitals of our products and product candidates as safe and effective, and physicians’ willingness to recommend our products;
- the actual and perceived advantages of our products and product candidates over alternative products;
- the prevalence and severity of any adverse effects or complications;
- the timing of market introduction of our products and product candidates as well as competitive products;
- the cost of our products in relation to alternatives;
- the availability of adequate coverage, reimbursement and pricing by government authorities or third-party payors;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by government authorities or third-party payors;
- the effectiveness of our sales and marketing efforts; and
- the operation smoothness of our percutaneous puncture surgical robot.

If any products that we commercialize fail to achieve market acceptance or if we fail to maintain good relationships with customers or potential customers, we will not be able to generate significant revenue. Even if our RC120 achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies introduced are more favorably accepted by the market, more cost effective or render our products obsolete. In addition, the operations of our percutaneous puncture surgical robot and other product candidates may encounter technical obstacles, and it is possible that we may discover additional technical glitches that prevent percutaneous puncture surgical robot from operating properly. If our percutaneous puncture surgical robot does not function reliably or fails to achieve expectations of our customers in terms of performance, we may be required to divert resources allocated for other business purposes to address these issues, may suffer reputational harm, lose or fail to grow our customer base, and may be subject to liability claims.

We believe that enhancing and maintaining awareness of our “Simple Touch (睿觸)” brand is critical to achieving widespread acceptance of our products, gaining trust for our various products and related support services, strengthening our relationships with our existing

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customers and attracting new ones. Successful promotion of our brand depends largely on the quality of our products and product candidates and the effectiveness of our branding and marketing efforts. We expect that our branding and marketing efforts will require us to incur significant expenses and devote substantial resources. We cannot assure you that our sales and marketing efforts will be successful. Brand promotion activities may not lead to increased revenue in the near term, and, even if they do, any revenue increases may not offset the expenses we incur to promote our brand. Our failure to establish and promote our brand and any damage to our reputation will hinder our growth. In addition, our reputation may be undermined as a result of any negative publicity about us or our industry in general.

There is no guarantee that we will effectively manage and succeed in achieving and expanding hospital penetration.

Our business operation significantly depends on our ability to successfully expand and deepen hospital penetration of our products. Hospitals usually organize public tenders for procurement of medical devices. The procedures of such public tenders may vary in different regions and among different hospitals, and there could be uncertainties with respect to the timing of such procedures. We expect to expand into hospitals that either have existing percutaneous puncture capabilities or the potential to perform percutaneous puncture surgeries. However, we may not be able to do so if we cannot penetrate into hospitals effectively, and our sales volume and business prospects could be materially and adversely affected.

The success of our hospital penetration strategy also depends on our ability to attract, motivate and retain our sales and marketing team who have expertise and capability to communicate effectively with medical professionals. If we are unable to attract, motivate and retain a sufficient number of qualified sales personnel to support our hospital penetration strategy, we may not be able to extend our hospital coverage and deepen our market penetration as contemplated, and our business operations and results of operation could be materially and adversely affected.

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

Government agencies, professional associations, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' products and pipeline products. Any such guidelines, recommendations or studies that reflect negatively on our products could result in current or potential decline in the sales of, and revenue from one or more of our products. For example, the government may issue guidelines with respect to the prices of surgical robot or other AI-assisted medical devices. Such guidelines may affect the sales and use of our products and further affect our financial conditions. Furthermore, our future success depends in part on our and our business partners' ability to educate medical services providers and patients about our products, and these education efforts could be rendered ineffective by, among other things, third parties' guidelines, recommendations or studies.

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Commercialization of our products may be affected by the possibility of inclusion in the medical insurance reimbursement list.

Our ability to commercialize our products will depend in part on the possibility and the extent to which medical insurance reimbursement for surgical robot will be available to patients, which is out of our control. China has a complex medical insurance system that is undergoing reform. As of the Latest Practicable Date, robot-assisted percutaneous puncture surgeries had not been covered by the national medical insurance reimbursement list. This may affect the patients’ choice to use a surgical robot in surgery given the high price of surgical robot caused by its consumable parts and components.

As of the Latest Practicable Date, we had not had any communication or correspondence with the relevant authorities with respect to enrolling our RC120 in the national medical insurance reimbursement list. Even if we seek to enroll our products in reimbursement lists in the future, we cannot be sure whether reimbursement will be available for any of our product and product candidates and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact on the demand for, or the price of, any product for which we obtain regulatory approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product that we successfully develop.

In the absence of sufficient medical insurance coverage for the use of RC120, patients may choose alternative surgical or therapeutic methods, and hospitals may recommend such alternative methods, which would reduce demand for RC120 which could in turn materially and adversely affect our business, financial condition and results of operation.

Our commercialization efforts to date have focused mainly on China. Our ability to enter other foreign markets will depend, among other things, on our ability to navigate various regulatory regimes with which we do not have experience, which could delay or prevent the growth of our operations outside of China.

To date, our commercialization efforts have focused primarily on China. Expanding our business to attract customers in other countries and regions is an element of our long-term business strategy. Our ability to continue to expand our business and to attract talented employees and customers in various international markets will require considerable management attention and resources and is subject to particular challenges of supporting a rapidly growing business in an environment of multiple languages, cultures, customs, legal systems, alternative dispute resolution systems, regulatory systems and commercial infrastructures. Entering new international markets will be expensive, our ability to successfully gain market acceptance in any particular market is uncertain and the distraction of our management team could harm our business, financial condition and results of operation.

Sales outside of China are subject to foreign regulatory requirements that vary widely from country to country. In addition, while the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that

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we obtain the marketing authorization of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or marketing authorizations, can be expensive and time-consuming, and we may not receive regulatory authorizations, clearances or approvals in each country in which we may plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or marketing authorizations, if required by other countries, may be longer than that required for NMPA clearance, authorization, or approval, and requirements for such registrations and marketing authorizations may significantly differ from NMPA requirements. If we modify our products, we may need to apply for additional regulatory authorizations before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we may no longer be able to sell the applicable product in that country. A failure or delay in obtaining registration or marketing authorization in one country may have a negative effect on the regulatory process in others.

Doing business internationally also involves a number of additional risks, including data security risks, intellectual property protection, financial risks, and other force majeure factors. These risks and uncertainties may impact our ability to enter foreign markets, which could delay or prevent the growth of our operations overseas, and have a material adverse effect on our business, prospects, results of operations and financial condition.

The actual market size of our products and product candidates may be smaller than we anticipate, which could render them ultimately unprofitable even if commercialized.

Our spending on our product portfolio may not yield any additional commercially viable products, since the actual market size for them may be smaller than we anticipate. For example, the percutaneous puncture surgical robot market in China is emerging and our RC120 and other product candidates are considered as relatively novel. In addition, there may be other available diagnosis or treatment methods for our target market, and other players developing similar technologies in the target markets that may be more competitive than us, which may further limit the market opportunities of our products. As such, the target markets for our products and product candidates may not consist of as many market opportunities as we expect, which could have a material adverse effect on the profitability of our product candidates even if commercialized.

We may fail to effectively manage our network of distributors. Actions taken by our distributors could materially and adversely affect our business, prospects and reputation.

We will rely on third-party distributors to distribute our commercialized products. See “Business — Sales and Marketing” for more details. Our ability to maintain and grow our business will depend on our ability to maintain effective distribution channels that ensure timely distribution of our products to relevant markets where we generate market demand through our sales and marketing activities. However, we do not have complete control over our distributors, who may fail to distribute our products in the manner we contemplate. If any price controls or other factors substantially reduce the margins of our distributors through the resale

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of our products to hospitals and medical institutions, our distributors may terminate their cooperations with us. In line with industry practice, we typically enter into agreements with our distributors for a term of one to five years, which requires us to continually renew distribution agreements with our distributors. There is no assurance that our existing distributors will continue to place orders with us at historical levels, or that we will be able to secure comparable levels of business from other distributors to offset any loss resulting from losing one or more of these major distributors. Further, there is no assurance that we will be able to successfully secure new distributors to capture potential market growth and broaden our distribution channels. While we believe alternative distributors are readily available in China, if we lose any of our distributors, in particular any major distributors, the distribution of our products may be interrupted, as a result of which, our sales volumes and business prospects could be adversely affected.

Risks Relating to Extensive Government Regulation

All material aspects of the R&D and commercialization of our percutaneous puncture surgical robot are heavily regulated.

Our R&D and commercialization activities are regulated in great depth and detail. We intend to focus our activities on the major markets of China, as well as overseas markets such as the United States, the Europe and Southeast Asia. These jurisdictions typically have strict regulations on medical devices, and in doing so they employ broadly similar regulatory strategies, including regulation of product development, approval, manufacturing, sales and marketing and distribution of medical devices. However, there are differences in the regulatory regimes in different jurisdictions, which makes regulatory compliance more complex and costly for companies like ours that plan to commercialize our products in each of these jurisdictions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations require substantial time and financial resources. The NMPA, FDA, CE or other comparable regulatory authorities may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a product candidate with an indication that is not desirable for the successful commercialization of that candidate. Legislative and regulatory proposals may also, from time to time, be made to expand existing requirements.

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The regulatory approval processes of the NMPA, its local counterparts and the comparable regulatory authorities in other jurisdictions are lengthy, time-consuming and inherently unpredictable. Any denial or delay of such approvals would hinder the development and commercialization of our percutaneous puncture surgical robot products and any other product candidates, and could adversely affect our ability to generate revenue, as well as our business and operating results.

The process to develop and obtain regulatory approval for and commercialize medical device product candidates is long, complex and costly. In China, before obtaining regulatory approvals for the commercial sale of our products for a specific indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, to the satisfaction of the NMPA or its local counterparts, that the product is safe and effective for use for that indication. We are also required to report any serious or potentially serious incidents involving our products to the NMPA or its local counterparts. We cannot be certain that any submissions will be accepted for filing and review by the NMPA or its local counterparts, and the review timeline may be subject to uncertainty.

Our product candidates could fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to various factors, including disagreements with regulatory authorities;
- failure to demonstrate that a product candidate is safe and effective;
- failure to deliver clinical trial results that meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- regulatory authority’s disagreement with our interpretation of data from preclinical studies or clinical trials;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;
- regulatory requests for additional analysis, reports, data, nonclinical studies and clinical trials, or questions regarding our interpretation of data and results and the emergence of new information regarding our product candidates;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and/or

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- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

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 jurisdictions. However, regulatory requirements can vary widely from jurisdiction to jurisdiction. Obtaining regulatory approval in one jurisdiction does not mean that 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 its local counterparts), 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 overseas markets in compliance with different regulatory processes. The introduction of our product candidates in these markets could be delayed or prevented, as we may not obtain relevant regulatory approvals on a timely basis, or at all.

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

Even if our product candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be provided to users, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following an approval for commercial sale of our product candidates, certain changes, such as changes in design, may be required by the NMPA and/or comparable regulatory authorities. Regulatory approvals for any of our product candidates may also be withdrawn.

If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Furthermore, we may not be able to generate sufficient revenue and cash flows or obtain sufficient funding to continue the development of any other product candidates in the future.

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Our percutaneous puncture surgical robots as applied under existing and expanded indications will continue to remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our percutaneous puncture surgical robot product or product candidates.

Our RC120 and any additional product candidates that are approved by the regulators are and will be subject to ongoing regulatory requirements with respect to advertising, promotion, sampling, record-keeping, post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China and/or other jurisdictions where we may market or sell our products. We are and will be subject to continual review and inspections by the regulators to assess our compliance with applicable laws, requirements, and adherence to commitments we made in any application materials with the NMPA or other comparable regulatory authorities. Accordingly, we must continue to devote time, money and effort to all areas of regulatory compliance.

If problems occur after our products reach the market, the NMPA or other comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval. Later discovery of previously unknown problems with our products or product candidates may result in requirements to conduct post-market studies or clinical studies to assess new safety risks or the imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or commercialization of our products, withdrawal of the products from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending indications or applications or supplements to approved indications or applications filed by us or suspension or reduce the scope of previously issued medical device registration certificate;
- product seizure or detention, or refusal to permit the import or export of our products and product candidates; and/or
- injunctions or the imposition of civil, administrative or criminal penalties.

We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in all relevant jurisdictions. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

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Adverse events caused by our products and product candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial scope of an approved label, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events caused by our products and pipeline products, including but not limited to safety issues and other serious adverse events, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA or other comparable regulatory authority, or could result in limitations or withdrawal following approvals. For example, in the event that results of our trials reveal a high and unacceptable severity or prevalence of adverse events, our trials may be suspended or terminated by the NMPA, or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our pipeline products.

Any adverse events reported in our clinical trials will affect patient recruitment or the ability of enrolled subjects to complete the trial, and any result in potential product liability claims. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly. In this document and from time to time, we disclose clinical results for our products and products candidates, including the occurrence of adverse events and serious adverse events. Each such document speaks only as of the date of the data cutoff used in such document, and we undertake no duty to update such information unless required by applicable law. For details of the adverse events of our products as observed during clinical trials as of the date of this document, see “Business — Our Product Portfolio — Percutaneous Puncture Surgical Robots — RC120 Puncture Surgical Robot - Our Core Product — Summary of clinical trial results.”

Additionally, if our pipeline products receive regulatory approval, and undesirable safety issues caused by such pipeline products are identified after such approval, a number of potentially significant negative consequences could follow, including, among others:

- we may be required to suspend marketing or remove relevant products from the marketplace;
- regulatory authorities may withdraw approvals of the product;
- we may be required to change the way our products are distributed or administered, or conduct additional clinical trials;
- we may be required to develop risk evaluation and mitigation measures for the product or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;
- we may be subject to regulatory investigations and government enforcement action;

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- a severe decrease in the demand for, and sales of, relevant products;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may be damaged.

Any of these events could prevent us from achieving or maintaining market acceptance of the relevant pipeline products, and could significantly harm our business, results of operations and prospects.

If we, or parties on whom we rely, fail to obtain, maintain or renew necessary permits, licenses, approvals, qualifications and certifications required for the development, production, sale or distribution of our approved or pipeline products, our ability to conduct our business could be materially impaired.

We are required to obtain, maintain and renew various permits, licenses, approvals, qualifications and certifications to develop, produce, promote and sell our products, including but not limited to, the Registration Certificate for Medical Device (醫療器械註冊證) and the Medical Device Production License (醫療器械生產許可證). Furthermore, third parties, such as research institutions, distributors and suppliers whom we may rely on to develop, produce, promote, sell and distribute our products, may be subject to similar requirements. We and our third-party business partners may be also subject to regular inspections, examinations, inquiries or audits by regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of relevant permits, licenses, approvals, qualifications and certifications. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses, approvals, qualifications and certifications may change from time to time, and there can be no assurance that we or our third-party business partners will be able to meet new criteria that may be imposed to obtain or renew necessary permits, licenses and certificates. Many of such permits, licenses, approvals, qualifications and certifications are material to the operation of our business, and if we or our third-party business partners fail to maintain or renew any material permits, licenses, approvals, qualifications and certifications, our ability to conduct business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or our third-party business partners to obtain any additional permits, licenses, approvals, qualifications and certifications that were previously not required to operate our business, there can be no assurance that we or our third-party business partners will successfully obtain such permits, licenses, approvals, qualifications and certifications in a timely manner or at all.

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Recently enacted and future legislations may increase the difficulty and cost for obtaining regulatory approval for, or successfully commercializing, our existing and new products under expanded indications, or any other product candidates, and could therefore adversely affect our business.

In China and some other jurisdictions, a number of legislative and regulatory changes and proposed changes regarding healthcare could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our products and any product candidates for which we obtain regulatory approval. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to commercialize our products, generate revenue, or attain profitability.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for medical devices. We cannot be sure whether additional legislative changes will be enacted, or whether NMPA, FDA or other comparable regulatory agencies’ regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. For example, according to the Regulations on the Supervision and Administration of Medical Devices (2024 Revision) (《醫療器械監督管理條例(2024修訂)》) effective on January 20, 2025, medical device companies are required to establish a quality management system and monitor and evaluate post-approval risks and adverse events caused by the products. In addition, laws and regulations in China, including those regulating intelligent medical devices, may be amended from time to time. Changes in these areas could impose more stringent requirements on us and increase our compliance and other operating costs, and we may not be able to achieve or sustain profitability.

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

We may receive, store, process, transmit and maintain certain medical data in our clinical trials and in the ordinary course of our business based on legitimate needs and in compliance with applicable laws and regulations. As such, we are subject to relevant local, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officers and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

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While we have adopted security policies and measures to protect our proprietary data and patients’ privacy, privacy leakage incidents might not be avoided due to hacking activities, human error, employee misconduct or negligence or system breakdown. We also cooperate with third parties such as hospitals, CRO, SMO and other relevant services providers for our clinical trials and operations. Any leakage or abuse of patient data by our third-party business partners may be perceived by the patients as a result of our failure. Furthermore, we cannot be sure whether additional legislative changes on data security and privacy will be enacted or whether relevant guidance or interpretations will be changed. Any changes in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Risks Relating to Our Intellectual Property Rights

We could be unsuccessful in obtaining or maintaining adequate intellectual property rights protection for our products, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us and our ability to successfully commercialize our products and product candidates may be adversely affected.

Our commercial success will depend, in large part, on our ability to obtain, maintain and enforce our intellectual property rights, including patent rights to protect our proprietary technology, products and pipeline products. We seek to protect our technology, products and pipeline products that we consider commercially important by filing patent applications in China and other jurisdictions. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not

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later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our pipeline products, or otherwise provide us with any competitive advantages. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Patents may be invalidated and patent applications may not be granted for various reasons, including known or unknown prior deficiencies in the patent application or the lack of novelty of the underlying invention or technology. We may also fail to identify patentable aspects of our R&D output in time to obtain patent protection. Moreover, the patent position of medical devices companies is generally uncertain because it involves complex legal and factual considerations. Patent applications we filed may not be successful in the end. As such, we do not know the degree of future protection that we will have on our products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our pipeline products could have a material adverse impact on our business.

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

The issuance of a patent is not conclusive as to its inventor, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in China and other countries. Moreover, we may have to participate in interference proceedings declared by relevant intellectual property authorities to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and pipeline products. Such proceedings also may result in substantial costs and require significant time from our management and R&D personnel, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or pipeline products will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

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Given the amount of time required for the development, testing and regulatory review of new pipeline products, patents protecting such pipeline products might expire before or shortly after such pipeline products are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not be able to prevent unauthorized use of our intellectual property, which could harm our business and competitive position.

We may not be able to prevent others from unauthorized use of our intellectual property, which could harm our business and competitive position. We rely on a combination of patent, trade secret (including those in our know-how), and other intellectual property rights and/or licenses, as well as employee and third-party nondisclosure agreements to establish and protect our rights in our technology and intellectual property.

Our patent or trademark applications may not be granted, any patents or trademark registrations that may be issued to us may not sufficiently protect our intellectual property and any of our issued patents, trademark registrations or other intellectual property rights may be challenged by third parties. Any of these situations may result in limitations on the scope of our intellectual property or restrictions on our use of our intellectual property or may adversely affect the conduct of our business. Despite our efforts to protect our intellectual property rights, third parties may attempt to copy or otherwise obtain and use our intellectual property or seek court declarations that they do not infringe upon our intellectual property rights. Monitoring unauthorized use of our intellectual property is difficult and costly, and the steps we have taken or will take to prevent misappropriation may not be successful. From time to time, we may have to resort to litigation to enforce our intellectual property rights, which could result in substantial costs and diversion of our resources.

We may, from time to time, be subject to claims or legal proceedings brought by third parties alleging infringement, misappropriation or other violations of patents, trademarks and/or other intellectual property rights, and may also be involved in lawsuits to protect or enforce our intellectual property. Such matters are inherently uncertain, may be time-consuming and costly, and could result in significant liability, restrict our ability to use certain technologies, and delay the commercialization of our products and product candidates in certain jurisdictions.

We may become party to intellectual property infringement proceedings. Companies, organizations, or individuals, including our competitors, may hold or obtain patents, trademarks or other proprietary or intellectual property rights that would prevent, limit or interfere with our ability to manufacture, use, develop, sell, or market our products or product candidates, which could make it more difficult for us to operate our business. As of the Latest Practicable Date, we did not have registered patents in overseas jurisdictions where we plan to expand our business, which would expose us to elevated risks of intellectual property infringement proceedings in these areas. We may receive communications from holders of

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patents, software copyrights, trademarks, trade secrets or other intellectual property or proprietary rights alleging that we are infringing, misappropriating, diluting or otherwise violating such rights. Such parties may also in the future bring suits against us alleging infringement or other violation of such rights, or otherwise assert their rights and urge us to acquire licenses to their intellectual property. In addition, we may not be aware of existing patents or patent applications that could be pertinent to our business as many patent applications are filed confidentially and are not published until months following the applicable filing date.

In the event that a claim relating to intellectual property is asserted against us or our suppliers or our third-party business partners, or if third parties not affiliated with us hold pending or issued patents that relate to our technology or products, we may need to seek licenses to such intellectual property or seek to challenge those patents. Even if we can obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us. In addition, we may be unable to obtain these licenses on commercially reasonable terms, if at all, and our challenge of third-party patents may be unsuccessful. Litigation or other legal proceedings relating to intellectual property claims, regardless of merit, may cause us to incur significant expenses and could distract our R&D and management personnel from their normal responsibilities. Further, if we are determined to have infringed upon a third party’s intellectual property rights, we may be required to do one or more of the following:

- cease selling, incorporating certain components into, or using products that incorporate or use the intellectual property that we allegedly infringe, misappropriate, dilute or otherwise violate;
- pay substantial royalty or license fees or other damages;
- seek a license from the holder of the infringed intellectual property right, which license may not be available on reasonable terms, or at all;
- redesign or reengineer our technologies, products or product candidates, which may be costly, time-consuming or impossible; or
- establish and maintain alternative branding for our products.

In the event of a successful claim of infringement against us and our failure or inability to obtain a license to the infringed technology or other intellectual property right, our business, prospects, financial condition, results of operations, and cash flows could be materially and adversely affected. In addition, any litigation or claims, whether valid or not, could result in substantial costs, negative publicity and diversion of resources and management attention.

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Competitors may also infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing or misappropriating our intellectual property rights. An adverse result in any litigation proceeding could put our patents, as well as any patents that may be issued in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

Our patent applications may not be ultimately granted.

Patent applications may not be granted for a number of reasons, including known or unknown prior deficiencies in the patent application or the lack of novelty of the underlying invention or technology. As of the Latest Practicable Date, we also had 22 patent applications in China and one application with the World Intellectual Property Organization. There is no assurance that our patent applications will be granted in a timely manner, or at all. Certain of our patent applications remained with an “applied” status. Such patent applications were under substantial review by the CNIPA as of the Latest Practicable Date. As the time required for the substantial review is at the discretion of the CNIPA, we are unable to predict the expected time frame of receiving material updates in relation to the pending patent applications. If any of the patent applications were rejected, we may lack patent protection covering certain key characteristics of our key products.

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

Although various extensions may be available, the life of a patent and the protection it affords are limited. Even if patents covering our services and products are obtained, we may be open to competition from other companies once our patent rights expire. See “Business — Intellectual Property” for more details.

As of the Latest Practicable Date, we had been granted 101 patents in China. Our granted patents have a valid term ranging from 10 to 20 years from the earliest claimed filing date of a non-provisional patent application. As of the Latest Practicable Date, we also had 22 patent applications in China and one application with the World Intellectual Property Organization.

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Upon expiration of our issued patent or patents that may be issued from our pending patent application, and without patent term extensions, we will not be able to assert such patent rights against potential competitors and our business and results of operation may be adversely affected.

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

In addition to our granted patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our products and product candidates. We seek to protect these trade secrets, inventions and discoveries, in part, by entering into non-disclosure and confidentiality agreements or including such undertakings in the agreement with relevant parties that have access to them, such as our employees, cooperated hospitals and other third-party business partners. However, non-disclosure agreements or relevant undertakings may not adequately prevent disclosure 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.

Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. As of the Latest Practicable Date, we were not aware of any material threatened or pending claims related to these matters. However, we cannot assure you that litigation may be necessary to defend against such claims in the future. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

Periodic maintenance fees on any issued patent are due to be paid to relevant patent agencies such as the CNIPA in several stages over the lifetime of the patent. The CNIPA and various governmental patent agencies typically require compliance with a number of procedurals, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events could result in abandonment or lapse of a patent or patent application including failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

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

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Any of the above threats could have material adverse effect on our business.

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

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

Risks Relating to Our General Operations

If there is unsatisfactory performance of or defects in our products, or failure to maintain an effective quality management system, it may harm our reputation, lead to product returns, damage our customer relationships, and may expose us to product liability and other claims, and materially and adversely affect our business, financial condition and results of operations.

We may offer products that are affected by substandard quality or unsatisfactory performance due to design and manufacturing defects. We may also be exposed to potential product liabilities. The consequences of such product defects may be severe and we may be subject to claims for contract breaches or be liable for property damage or even bodily injuries and harms. Furthermore, the causes of product defects may be manifold and sometimes beyond our control. Besides errors in the design, R&D and production of our products, defects may also be caused by defective raw materials delivered by our suppliers. As we do not have direct control over the quality of the materials and intermediate products manufactured or supplied by third parties, we are exposed to a risk relating to the quality of such materials and intermediate products. In addition, we may manufacture certain products pursuant to specifications and quality requirements set by our customers. If our products do not meet the specifications and quality requirements stipulated by our customers, relevant production may be discontinued until the cause of the product defect has been identified and remedied.

Therefore, our failure to maintain consistent quality control throughout our production process may result in substandard quality or unsatisfactory performance of our products, causing a failure to achieve or maintain relevant certifications, significant damage to our market reputation and a decrease in our sales price and volumes. If we deliver any defective products, or if there is a perception that our products are of substandard quality or provide unsatisfactory performance, we may incur substantial costs due to returns or replacements of our products or even recall of our products, significant return or exchange could affect our

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business and financial performance, and our market reputation and sales price and volumes may be also adversely affected. We may also need to upgrade or rectify our production procedures to meet the quality and performance required by our customers. Such upgrade or rectification may be costly and have a material adverse effect on our financial condition and results of operations.

In addition, as our customers may sell our products after further process to their end consumers in respective markets, we may be also exposed to potential product liability claims from end consumers in the relevant jurisdictions in case that any safety damage results from the use of our products even if we have no direct sales to end consumers. There can be no assurance that we will not experience material product liability losses in the future, or that we will be able to defend such claims at a contained level of cost.

If we are unable to retain customers or attract new customers, our business, financial condition and results of operations could be materially and adversely affected.

We are committed to reinforcing relationships with customers while continuously broadening our customer base and enhancing our brand recognition. We have invested in branding, sales and marketing to acquire and retain customers since our inception. We incurred selling and distribution expenses of RMB2.9 million, RMB5.3 million, RMB1.9 million and RMB3.8 million in 2023, 2024 and the six months ended June 30, 2024 and 2025, respectively. There is no guarantee that new customers will stick with us or that the net profits from new customers will cover the expenses of acquiring them. Our customers may decline materially or their demand may fluctuate as a result of many factors, including, among other things, dissatisfaction with the performance, quality or price of our products, negative publicity related to our brands, or alternative products offered by our competitors. If we are unable to retain customers or to acquire new customers in a cost-effective manner, our business, financial conditions and results of operations may be adversely affected.

We may not be able to secure stable supply of raw materials and components with acceptable quality or at acceptable prices, which could adversely affect our operations and financial condition.

We procure raw materials and components such as robotic arms, industrial control machines, circular frame, sensing board, intermediate plate and servo motor necessary for manufacturing our products. The availability and prices of certain raw materials and components are subject to fluctuations and influenced by factors beyond our control, including market conditions, inflation, supply chain shortages, and global demand for such raw materials and components, all of which could adversely affect our business and operating results. Any shortages or delay in the supply of our raw materials could result in occasional price adjustments or cause delays in our production and delivery to customers. We cannot guarantee that we will not in the future experience price fluctuations and supply shortages of raw materials. There is no guarantee that we will be able to find alternate sources of supply in a

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timely manner and at a reasonable price, or at all. If we are unable to keep up with demand for our products due to the failure to obtain raw materials we need, our customers may reduce, delay or cancel their orders and our business could be adversely affected.

Any failure to properly maintain, upgrade, or expand our production capacity may materially and adversely affect our business, financial condition, and results of operations.

We manage manufacturing of our products at our own manufacturing facility in Shanghai, China. There is no guarantee that we can maintain or expand our manufacturing facility in a cost-effective manner or recoup these investments through our production and sales. Any construction delays or budget overruns could adversely affect our financial condition, production capacity, and results of operations.

Our manufacturing premise may expose both employees and visitors to risks related to workplace safety, including damage to, or destruction of, production equipment and facilities, or operational accidents, and could also result in personal injury, casualty, performance delays, monetary losses and legal liability. The conditions within these plants can lead to accidents unless safety protocols are strictly enforced and updated on a regular basis. There can be no assurance that serious accidents or fatalities will not occur in the future. If we fail to prevent serious accidents or fatalities, we will be held liable for damages arising out of or in connection with such incidents or facilities, which could have a material adverse effect on our results of operations, business, financial condition and prospects.

Any disruption to the operation of our manufacturing facility could restrict our ordinary business operations and materially and adversely affect our financial condition and results of operations.

As of the Latest Practicable date, we had one manufacturing facility in Shanghai, China. The operation of our manufacturing facility may be disrupted by physical damage from fires, floods, earthquakes, typhoons, power outages, mechanical breakdowns, telecommunications failures, loss of licenses, certifications and permits, changes in governmental planning for the underlying land, and the regulatory development, many of which are beyond our control. Moreover, any power outage, disruption or shortage in power supply could therefore have a materially adverse impact on our production and employee safety.

We are also subject to risks associated with equipment failures, industrial accidents, fires and explosions. While we believe we have adequate systems of safe production and related trainings, these risks can result in personal injuries and fatalities, damage to or destruction of properties or production facilities, and pollution and other environmental damages. Any of these consequences, if significant, could disrupt the operation of our production bases and result in business interruption and legal liability, and materially and adversely affect our financial condition and results of operations.

RISK FACTORS

Our business depends substantially on the efforts of our key management, key personnel in our R&D team, sales and marketing team, and other qualified personnel, and we may not be able to find suitable replacement in case of loss of service of any of them.

Our future success is significantly dependent upon the continued service of our management, key R&D personnel and highly qualified personnel with specialized skills. Our ability to compete effectively depends on our ability to retain and motivate existing employees and attract new employees. We may need to offer higher compensation and other benefits to attract and retain key personnel and our compensation and benefits payments may increase unexpectedly or at a greater rate than expected. If we lose the services of any member of management, key R&D personnel or highly qualified personnel, we may not be able to locate suitable or qualified replacements in a timely manner at a reasonable cost, or at all. Our failure to attract and retain key management, key R&D personnel or highly qualified personnel and any increase in staffing costs to retain such personnel could have a negative impact on our ability to maintain our competitive position and grow our business and may have a material adverse effect on our financial condition, results of operations and growth prospects.

Our key management, key R&D personnel and highly qualified personnel are subject to confidentiality terms. However, we cannot assure you that such terms or arrangements can be fully and legally enforced. If any of our management, key R&D personnel or highly qualified personnel joins or establishes a competing business, we may lose some of our customers, which may have a material adverse effect on our business.

We may not be successful in executing our business plans and strategies effectively or at all, and our business, financial condition and results of operations could be materially and adversely affected.

Our business plans and strategies are based on our assumptions of future events which may entail certain risks and are inherently subject to uncertainties. These assumptions may not be correct, which could affect the commercial viability of our business plans and strategies. As such, there can be no assurance that our business plans and strategies will be implemented successfully as scheduled or at all.

If we fail to implement our business plans and strategies effectively and efficiently, we may be unable to expand our operations, grow our business, take advantage of market opportunities as expected or remain competitive in the industry. Furthermore, even if we implement our business plans and strategies effectively and efficiently, there may be other unexpected events or factors beyond our control that may prevent us from achieving desirable and profitable results, such as the changes in local laws and regulations and governmental policies, the availability of skilled professionals and changes in consumer demand. Moreover, our business plans and strategies may increase our operating costs, such as higher staff costs, and increases in our cash outflows for operating and investing activities. Accordingly, if our business plans and strategies cannot be successfully implemented, or if they do not yield ideal results, we may have significant difficulties in recovering our costs and therefore experience a material adverse impact on our business, financial condition and results of operations.

RISK FACTORS

We may not be able to successfully expand our business into new markets or manage our international expansion plans effectively.

We intend to grow by expanding our business, increasing market penetration of our existing product, and developing new AI-assisted functions and dynamic respiratory motion compensation function and expanding indications and models. The management of our growth may place significant demands on our managerial, administrative, operational, financial, and other resources. Moreover, our growth depends on our ability to maintain stable production capacity and offer reliable products to our customers. Our efforts to grow our business may be more costly than we expect, and we may not be able to increase our revenue enough to offset our increased operating expenses. We may incur significant losses in the future for a number of reasons, including the other risks described herein, and unforeseen expenses, difficulties, complications, delays, and other unknown events. If we are unable to achieve and sustain profitability, our business may be harmed. If we fail to achieve the necessary level of efficiency as we grow, our growth rate may decline, [REDACTED] perceptions of our business and prospects may be adversely affected, and the [REDACTED] of our Shares could decline.

Our business and prospects depend on our ability to build our brand and reputation, which could be harmed by negative publicity regarding us, our Directors, employees, branding, products, suppliers, customers or other third parties. Any negative publicity, whether warranted or not, could adversely affect our business.

We need to maintain and enhance our brand identity while increasing market awareness of the reputation of our business and products. The successful promotion of our brand will depend on our efforts to achieve widespread acceptance of our products, attract and retain customers, maintain our current market leadership, and successfully differentiate our offerings from those of competitors. These efforts require substantial capital expenditures, and we anticipate expenses will increase as our market becomes more competitive and as we expand into new markets. Furthermore, these investments in brand promotion and thought leadership may not yield increased revenue. To the extent they do, the resulting revenue still may not be enough to offset the increased expenses we incur.

In addition, adverse publicity, with or without merits, relating to events or activities attributed to us, our management, Directors, employees, shareholders, business partners or their affiliates, industry, or products similar to ours, may tarnish our reputation and reduce the value of our brands. For instance, unfounded and adversarial statements or opinions could be misleading and harm our business and reputation. Given the delicate and complex nature of the industry that we operate in, we are vulnerable to such statements or opinions. If we fail to respond to such statements or opinions in a proper manner, our business reputation, financial condition and results of operations may be adversely affected. Moreover, our brand value depends on our ability to provide products that meet industry standards in our markets. Damage to our reputation and loss of brand equity may reduce demand for our products, have an adverse effect on our future financial results, or reduce the [REDACTED] of our Shares. Damage may also require additional resources to rebuild our reputation and restore the value of the brands. If we are unable to successfully enhance and protect our reputation, our business operations, results of operations, and financial condition could be materially and adversely affected.

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We depend on information technology and other infrastructure that are exposed to certain risks, including cyber security risks.

We rely on a variety of information technologies and automated operating systems to manage or support our operations. The proper functioning of these systems is critical to the efficient operation and management of our business. In addition, these systems may require modifications or upgrades as a result of technological changes or growth in our business. These changes may be costly and disruptive to our operations and could impose substantial demands on management time. Our systems and those of third-party providers may be vulnerable to damage or disruption caused by circumstances beyond our control, such as catastrophic events, power outages, natural disasters, computer system or network failures, viruses or malware, physical or electronic break-ins, unauthorized access, cyber-attacks and thefts. We cannot assure you that the measures and steps we take to secure our systems and electronic information are adequate. Any significant disruption to our systems could result in unauthorized disclosure of confidential information and adversely affect our business and operating results.

We may in the future be, subject to legal and regulatory proceedings and/or investigations in the ordinary course of our business.

From time to time, we may face litigation, regulatory proceedings and government investigations which may be brought against us by customers, patients, competitors, governmental entities conducting civil, regulatory or criminal investigations, or other parties. These claims could be asserted under a variety of laws, including but not limited to product liability laws, customer protection laws, intellectual property laws, labor and employment laws, securities laws, tort laws, contract laws, property laws, and employee benefit laws. There is no guarantee of our success in defending against these legal and regulatory proceedings or investigations or in asserting our rights under applicable laws.

Even if we succeed in our defense or asserting our rights, the process can be expensive, time-consuming, and may not yield the desired outcome. Legal and regulatory proceedings can also expose us to negative publicity, substantial financial damages, legal defense expenses, injunctive orders, and criminal, civil and administrative fines and penalties.

Our insurance coverage strategy may not be adequate to protect us from all business risks and cover all of our potential losses.

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs. During the Track Record Period and as of the Latest Practicable Date, we made contributions to the social insurance and housing provident funds for our employees in accordance with relevant PRC laws and regulations in all material respects. We have elected not to maintain certain types of insurances such as business interruption insurance, product liability insurance and keyman insurance at current stage. Our insurance coverage strategy may not protect us from all business risks. If we were to incur substantial losses and liabilities stemming from uninsured occurrences such as business disruptions, litigation, or natural disasters, we could face significant costs and resource diversion, which could have a material adverse effect on our business, results of operations, financial conditions and prospects. We may be required to bear our losses to the extent that our insurance coverage is insufficient.

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We may face penalties for the non-registration of our lease agreements in China.

Pursuant to applicable PRC laws and regulations, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, we had one lease agreement that had not been filed with the governmental authorities. We cannot assure you that we will not be subject to any penalties arising from the non-registration of lease agreements in the future. Our PRC Legal Advisors are of the view that the non-registration of lease agreements will not affect the validity of the lease agreements, but the failure to file and obtain property lease agreement filing certificates, as required under PRC laws, may subject us to a fine ranging from RMB1,000 to RMB10,000 for each agreement not filed.

Our risk management and internal control systems may not be adequate or effective.

We are dedicated to the establishment and maintenance of robust risk management and internal control systems. We have adopted and continually improve our internal control mechanisms to ensure the compliance of our business operations. Furthermore, we conduct periodic review of the implementation of our risk management policies and internal control measures to ensure their effectiveness and sufficiency. While we seek to improve our risk management and internal control systems on a continuous basis, we cannot assure you that these systems are sufficiently effective in ensuring, among other things, accurate reporting of our financial results and the prevention of fraud. See “Business — Risk Management and Internal Control” for more details. Since these systems depend on implementation by our employees, and even though we provide relevant internal training in this regard, we cannot assure you that our employees are sufficiently or fully trained to implement these systems, or that their implementation will be free from human error or mistakes. If we fail to timely update, implement and modify, or fail to deploy sufficient human resources to maintain our risk management policies and procedures, our business, financial condition, results of operations and prospects could be materially and adversely affected.

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

Healthcare service providers, physicians and other medical professionals play a primary role in the recommendation and application of any products for which we obtain regulatory approval. As we have obtained and will continue to seek regulatory approval for our products and product candidates from the NMPA and other competitive regulatory authorities, which products are then marketed in the PRC or such other jurisdictions, our operations are subject to various applicable anti-kickback statutes, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China as well as in other jurisdictions, including, without limitation, the Criminal Law of the PRC (《中華人民共和國刑法》), Regulations on the Supervision and Administration of Medical Devices

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(《醫療器械監督管理條例》) and the Administrative Measures for the Registration and Recordation of Medical Devices (《醫療器械註冊與備案管理辦法》). These laws may impact, among other things, our R&D activities, applications and proposed sales, marketing and education programs. Violations of fraud and abuse laws may be punishable by criminal and/or administration penalties and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC government.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices (including the sales and marketing of medical devices to third parties such as distributors and hospitals) may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable 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 are subject to equivalents of each of the healthcare laws described above in other jurisdictions, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. There are ambiguities as to what is required to comply with these requirements, and if we fail to comply with an applicable law requirement, we could be subject to penalties.

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

We may be subject to anti-corruption, anti-bribery, anti-money laundering, financial and economic sanctions, and similar laws and regulations, and noncompliance with such laws and regulations can subject us to administrative, civil, and criminal penalties, collateral consequences, remedial measures, and legal expenses, all of which could adversely affect our business, prospects, results of operations, financial condition, and cash flows.

We may be subject to anti-corruption, anti-bribery, anti-money laundering, financial and economic sanctions, and similar laws and regulations in jurisdictions where we conduct activities. A violation of relevant laws or regulations could adversely affect our business, prospects, results of operations, financial condition, and cash flows. We are in the process of implementing policies and procedures designed to ensure compliance by us and our Directors,

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officers, employees, distributors, representatives, consultants, agents, and business partners with applicable anti-corruption, anti-bribery, anti-money laundering, financial and economic sanctions, and similar laws and regulations. However, our policies and procedures may not be sufficient and our Directors, officers, employees, representatives, consultants, agents, and business partners could engage in improper conduct for which we may be held responsible.

Non-compliance with anti-corruption, anti-bribery, anti-money laundering, or financial and economic sanctions laws and regulations could subject us to whistleblower complaints, adverse media coverage, investigations, and severe administrative, civil and criminal sanctions, collateral consequences, remedial measures, and legal expenses, all of which could materially and adversely affect our business, prospects, results of operations, financial condition, and cash flows.

Certain countries or organizations, including the U.S., the European Union, the United Nation, the United Kingdom, and Australia, have, through executive order, legislations or other government means, implemented measures that impose economic sanctions against certain countries, regions or targeted industry sectors, groups of companies or persons, and/or organizations within such countries and regions. Sanctions laws and regulations are continually evolving, with new individuals and entities regularly being added to the list of sanctioned persons. Moreover, new requirements or restrictions may come into effect, potentially intensifying scrutiny on our business, particularly concerning our international expansion plans, or resulting in one or more of our business activities being deemed to have violated sanctions. Our business and reputation could be adversely affected if the authorities of relevant jurisdictions were to determine that any of our future activities constitutes a violation of the sanctions they impose.

Any misconduct by our employees or by business partners and/or their employees could potentially expose us to significant legal liabilities, reputational harm, and other damage that may adversely affect our business.

We rely on our employees to maintain and operate our business and have implemented an internal code of conduct to guide the actions of our employees. However, we do not have control over the actions of our employees, and any misbehavior of our employees could materially and adversely affect our reputation and business. We also rely on our business partners such as suppliers for raw materials, human resources services providers and clinical trial cooperating partners for our business operations. Although we have implemented measures to select business partners, we may not be able to successfully monitor, maintain and improve the quality of their products and services. In the event of any unsatisfactory performance by our business partners and/or their employees, our business, prospects, results of operations, financial condition, and cash flows may be materially and adversely affected.

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Our business operations are subject to risks relating to potential accidents arising from our manufacturing process, as well as from any failure to comply with applicable safety measures and procedures.

Our business is subject to certain laws and regulations relating to occupational health and safety matters. Under these laws and regulations, we are required to maintain safe production conditions and protect the occupational health of our employees. While we have conducted periodic inspections of our operating facilities and carried out equipment maintenance to ensure that our operations are in compliance with applicable laws and regulations, we cannot assure you that we will not experience any material accidents or worker injuries in the course of our business activities in the future. Although we made contributions to the social insurance for our employees in accordance with relevant PRC laws and regulations, this may not provide full coverage against all potential liabilities in relation to injuries to our employees.

We are subject to risks associated with international trade policies, geopolitics and trade protection measures, and our business, financial condition and results of operations could be adversely affected.

Our operations may also be negatively affected by any deterioration in the political and economic relations among countries and sanctions and export controls administered by the governmental authorities in the countries in which we operate or distribute our products, and other geopolitical challenges, including, but not limited to, economic and labor conditions, increased duties, taxes and other costs as well as political instability. Furthermore, concerns over inflation, energy costs, geopolitical friction, capital market volatility and liquidity issues may create difficult operating conditions in the future. The tension in international trade and rising political tension may affect our or our customers’ business operations and results of operations.

The international trade policies and trade protection measures are likely subject to frequent changes, and their interpretation and enforcement involve substantial uncertainties, which may be heightened by national security concerns or driven by political and/or other factors that are beyond our control. These may materially and adversely affect us and our key suppliers’ and other business partners’ abilities to obtain technologies, systems, devices or components that may be critical to our R&D, product offerings and business operations. For example, recent changes in U.S. trade policies have created significant uncertainty for global trade. Beginning in February 2025, the United States imposed a series of escalating tariffs on imports from certain countries, including Canada, Mexico, and China. If any new tariffs, legislation and/or regulations are implemented by the U.S. or other jurisdictions in the future, or if existing trade agreements are renegotiated, such changes could adversely affect our business, financial condition and results of operations. It may also be difficult or costly to comply with such legislation and regulations, and would subject us to regulatory investigations, fines, penalties or other actions and reputational harm.

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We are subject to various environmental, occupational health and safety laws and regulations, which may result in potential costs for compliance, as well as monetary damage, fines, liabilities, and reputational harm in the event of non-compliance.

We are subject to environmental, occupational health and safety laws and regulations related to the manufacturing of our products. Changes in these laws or other new environmental and safety laws and regulations may require us to change our operations, potentially resulting in a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. These laws can give rise to liability for administrative oversight costs, cleanup costs, property damage, bodily injury, fines and penalties. Violations of these laws and regulations could result in substantial fines and penalties, third-party damages, suspension of production, remedial actions or a cessation of our operations. Contamination at properties we own or operate, or properties to which we send hazardous substances, may result in liability for us under environmental laws and regulations.

In addition, from time to time, Chinese government issues new regulations, which may require additional actions on our part to comply. If our plant or any of other future constructions fail to comply with applicable regulations, we could be subject to substantial liability for clean-up efforts, personal injury or fines or be forced to close or temporarily cease the operations of our plants or other relevant constructions, any of which could have a material adverse effect on our business, prospects, financial condition and results of operation.

Our operations are also subject to workplace safety laws and regulations, which require compliance with various workplace safety requirements, including environmental safety. These laws and regulations can give rise to liability for oversight costs, compliance costs, bodily injury (including workers’ compensation), fines, and penalties. Additionally, non-compliance could result in delay or suspension of production or cessation of operations. The costs required to comply with workplace safety laws can be significant, and non-compliance could adversely affect our production or other operations, which could have a material adverse effect on our business, prospects, results of operations, financial condition, and cash flows.

Moreover, there is a growing global focus on the environmental practices of manufacturers. Additionally, more stringent social responsibility laws and regulations may be adopted in the future, which may result in an increase in our cost of compliance. Compliance with such regulations is considered costly industrywide. As we expand into new markets, we will become subject to additional environmental and safety laws and regulations. We may incur additional costs to ensure compliance with such laws and regulations.

We face risks related to health epidemics, natural disaster, terrorist activities, political unrest, financial or economic crisis and other force majeure events, which could significantly disrupt our operations.

Our business could be adversely affected by the effects of health epidemics. In recent years, there have been outbreaks of COVID-19 pandemic globally. In response to COVID-19 pandemic, various nations have adopted, among other measures, restrictions on mobility and travel, cancelation of public activities and temporary suspension on public transportation

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which may lead to delays or disruption in our operations, including but not limited to, business activities and R&D activities. The recurrence of an outbreak of COVID-19 and other health epidemics could restrict the level of economic activities generally and/or slow down or disrupt our business activities, which could in turn adversely affect our business, prospects, results of operations, financial condition, and cash flows.

In addition to the impact of health pandemics as described above, our business could be materially and adversely affected by natural disasters, such as snowstorms, earthquakes, fires or floods, or other events, such as wars, acts of terrorism, environmental accidents, power shortage or communication interruptions. The occurrence of such a disaster or prolonged outbreak of an epidemic illness or other adverse public health developments in the countries and regions where we have operations could materially disrupt our business and operations. Such events could also significantly affect our industries and cause a temporary closure of the facilities we use for our operations, which would severely disrupt our operations and have a material and adverse effect on our business, results of operations, financial conditions and prospects.

Any financial or economic crisis, or perceived threat of such a crisis, including a significant decrease in consumer confidence, may materially and adversely affect our business, financial condition and results of operations. With a deteriorating worldwide economy, consumer spendings and consumption of non-essential items may diminish, which in turn will affect the demand for our sales and marketing services. It is unclear whether these challenges will be contained and what effects they each may have. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies that have been adopted by the central banks and financial authorities of some of the economies where we operate our businesses, include China. To the extent any fluctuations in the global economy significantly and adversely affect consumers’ demand for our products, our business, results of operations, financial conditions and prospects may be materially and adversely affected.

RISKS RELATING TO OUR FINANCIAL POSITION

We are basically a pre-revenue medical device company. We have incurred significant net losses since inception, and anticipate that we will continue to incur operating losses for the foreseeable future and may never become profitable. As a result, you may lose all or part of your [REDACTED] in us given the high risks involved in our business and associated with the medical devices industry.

We are basically a pre-revenue medical device company and only received our first approval for RC120 in 2024. [REDACTED] in the development of innovative medical devices such as our surgical robots are highly speculative. It entails substantial upfront capital expenditure and significant risks that a pipeline product may fail to gain regulatory approval or become commercially viable. As a result, you may lose all or part of your [REDACTED] in us given the high risks involved in our business and associated with surgical robots market. We did not generate any revenue from our approved product or the pipeline products we are developing, and we will continue to incur significant R&D and other expenses related to our ongoing operations. Our ability to generate revenue will depend primarily on the success of the

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clinical trials, regulatory approval and commercialization of our RC120 and other product candidates, which is subject to significant uncertainty. Even if we successfully complete clinical trials and obtain regulatory approval to market our products, our future revenue will depend upon other factors such as the market size for the proposed applications of our approved product or pipeline products, and our ability to achieve sufficient market acceptance.

We have incurred significant expenses, especially R&D expenses for RC120 and other product candidates, in the past. We may continue to incur net losses in the near future, and the losses may increase as we further our R&D efforts, continue the development of, seek regulatory approvals for, and commercialize our products. The size of our future net losses will depend, in part, on the number, scope and complexity of our product development programs and the associated costs of those programs, and the cost of commercializing any approved products and our ability to generate revenues. We may never become profitable. Even if we achieve profitability in the future, we may not be able to maintain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our R&D efforts, expand our business and/or continue our operations. Failure to become and remain profitable may adversely affect the [REDACTED] of our H Shares and our ability to raise capital. A decline in the [REDACTED] of our H Shares could cause potential [REDACTED] to lose all or part of their [REDACTED] in our business.

We may need significant additional financing to fund operations, capital expenditures, and the development and commercialization of our products and product candidates. If we cannot secure such financing, our business, financial condition, and results of operations could be materially harmed.

We recorded net cash outflows during the Track Record Period. We anticipate funding our capital expenditures with our existing cash balances and net [REDACTED] from the [REDACTED]. However, in the event of adverse market conditions in the future or changes in our growth plan, operational process, technologies, prices of machinery and equipment or interest rates, our actual expenditures may exceed our planned expenditures and we may not have sufficient sources of liquidity to affect our current operational plan and would need to secure additional financing from external sources. There can be no assurance that external sources of liquidity will be available to fund our ongoing operations or our product development. The failure to obtain financing would hinder our ability to make continued investments in product development or carry out our business strategy, which could materially and adversely affect our business, results of operations and financial condition.

We have been and intend to continue investing significantly in R&D activities, which may adversely affect our profitability and operating cash flow and may not generate the results we expect to achieve.

During the Track Record Period, we continued to invest in R&D for products. In 2023, 2024 and the six months ended June 30, 2024 and 2025, our R&D costs were RMB23.9 million, RMB18.9 million, RMB9.2 million and RMB9.1 million, respectively. We may continue investing significant resources in R&D in order to develop more product candidates with

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desirable performance, AI-assisted functions and pricing and remain competitive in the rapidly evolving industry. However, R&D activities are inherently uncertain, generally lasting for a long time and requiring substantial R&D costs. Our R&D activities and investments made during design phase cannot guarantee revenue generation, and we may not be able to recover costs incurred. We cannot assure you that our R&D projects will be successful or completed within the anticipated time frame and budget, or that our innovative products and AI-assisted functions will have commercial success. If we fail to successfully develop innovative products and technologies, optimize our existing products and technologies, or competitively price our new products, our business, results of operations and financial performance will be materially and adversely affected.

In addition, our existing or potential competitors may develop products which are similar or superior to our products with more competitive prices. Due to uncertainties in the time frame for developing new products and the duration of the market window for these products, we may have to abandon ongoing developments that are no longer commercially viable, even after having invested significant resources in their R&D. If we fail in our product R&D efforts, our business, prospects, financial condition and results of operations may be materially and adversely affected.

Fluctuations in exchange rates could have a material adverse effect on our business, prospects, results of operations, and financial condition.

The Renminbi has fluctuated against foreign currencies, sometimes significantly and unpredictably. The value of Renminbi against foreign currencies is affected by changes in China’s political and economic conditions and by China’s foreign exchange policies, among other things. It is difficult to predict how market forces or PRC or the foreign government policies may impact the exchange rate between Renminbi and foreign currencies in the future. Any significant appreciation or depreciation of Renminbi may materially and adversely affect our revenues, earnings and financial position, and the value of, and any dividends payable on, our H Shares in foreign currency. For example, to the extent that we need to convert Hong Kong dollars we receive from the [REDACTED] into Renminbi to pay our operating expenses, appreciation of Renminbi against the Hong Kong dollars would have an adverse effect on the Renminbi amount we would receive from the conversion. Conversely, a significant depreciation of Renminbi against Hong Kong dollars may significantly reduce Hong Kong dollars equivalent of our earnings, which in turn could adversely affect the [REDACTED] of our H Shares.

During the Track Record Period, our revenue and expenses were denominated in Renminbi. However, we plan to explore new sales markets outside of China. Also, we held certain U.S. dollars during the Track Record Period. Any significant appreciation or depreciation of Renminbi may materially and adversely affect our business plans, revenues, earnings and financial position. Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. The availability and effectiveness of hedging transactions may be limited and we may not be able to adequately hedge our exposure or at all. As a result, fluctuations in exchange rates may have a material adverse effect on your [REDACTED].

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We may be exposed to credit risk from our customers, and any failure to collect our trade receivables in a timely manner may adversely affect our financial condition and results of operations.

Although we will make efforts to assess the creditworthiness of our customers and require them to make certain advance payments to us before our delivery of goods, there can be no assurance that the collection of amounts due from our customers will be timely. Various factors beyond our control, such as economic downturns and customer insolvency, may hinder or prevent us from collecting our trade and other receivables in a timely manner or at all. Failure to effectively manage the credit risk associated with our trade receivables and collect payments in a timely manner would have material and adverse effects on our business, prospects, financial condition, results of operations, and cash flows.

Failure to maintain optimal inventory levels could increase our inventory holding costs or negatively impact our sales.

Our inventories are raw materials and finished goods. As of December 31, 2023 and 2024 and June 30, 2025, we had inventories of RMB0.4 million, RMB1.3 million and RMB1.9 million, respectively. Our business model requires us to manage our inventories efficiently.

We depend on our demand forecasts to make purchase decisions for raw materials and to pace our production progress to manage our inventories. Such demand, however, can change significantly from time to time and we may not always be able to accurately make predictions. Demand may be affected by general market conditions, end market conditions, new product launches, pricing and discounts, and not all of them are within our control. In addition, as we develop and market a new product, we may not be successful in accurately forecasting market demand and establishing stable and favorable supplier relationships. The procurement of certain types of raw materials may require certain lead time and prepayment and they may not be returnable. Furthermore, as we plan to continue expanding our product offerings, we expect to include a wider variety of raw materials, which will make it more challenging for us to manage our inventory and logistics effectively.

We cannot guarantee that our inventory levels will be able to swiftly meet the demands of customers, which may adversely affect our revenue. We also cannot guarantee that all of our inventories can be sold or utilized within a reasonable period of time. If we mismanage our inventory, we may be subject to increased inventory storage costs, a heightened risk of inventory obsolescence, a decline in inventory value and write-down of inventories. Any of the above may materially and adversely affect our results of operations and financial condition. If we underestimate demand for our products, or if our suppliers fail to supply in a timely manner, we may experience inventory shortages, which might result in diminished customer base and loss of revenue, any of which could harm our business, financial condition and results of operations.

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We have granted, and may continue to grant additional share incentives, which may result in dilution to the shareholding of existing shareholders.

We have established incentive platforms for the purpose of granting share-based compensation awards to qualified individuals, primarily comprising our employees, to incentivize their performance and align their interests with ours. See “History, Development and Corporate Structure — Employee Incentive Platforms” for more details. We recorded equity-settled share award arrangements of RMB3.5 million, RMB12.0 million, RMB7.2 million and RMB5.3 million in 2023, 2024 and for the six months ended June 30, 2024 and 2025, respectively. We believe the granting of share-based compensation is important to attract and retain key personnel and employees, and we will continue to grant share-based compensation to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations, and the shareholding of existing shareholders may experience further dilution.

Future tax payments or the discontinuation of any of the preferential tax treatments currently available to use could reduce our profitability.

In each taxable period during the Track Record Period, we recorded a net loss and did not incur any income tax. We may be subject to PRC corporate income tax in the future, which could reduce our profitability. In addition, we are qualified for certain preferential tax treatment policies in the PRC. For example, we were entitled to the tax preference in relation to our R&D activities in accordance with a preferential tax treatment policy. We cannot assure you that we will continue to enjoy such preferential tax treatment at historical levels, or at all. In the event that any of the preferential tax treatment we currently enjoy is reduced, discontinued or withdrawn by the government authorities, our results of operations and growth prospects may be materially and adversely affected.

If we do not continue to receive government subsidies, our results of operations may be adversely affected.

During the Track Record Period, we received certain government grants, primarily representing subsidies granted by the PRC local government authorities as incentives for our operating activities. Any delay or uncertainty in collection or the discontinuation of these governmental subsidies could adversely affect our business, cash flows, financial condition, profitability, prospects and results of operations.

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RISKS RELATING TO OUR DOING BUSINESS IN CHINA

Changes in the economic, political and legal conditions, as well as the interpretation and implementation of the relevant laws, regulations and government policies, may affect our business, prospects, results of operations, financial condition, and cash flows.

Due to our extensive operations in the PRC, our business, financial condition, results of operations and prospects are inherently influenced by economic and legal developments within the PRC. Laws, rules and regulations in relation to economic matters are promulgated from time to time, including those related to such as foreign investment, corporate organization and governance, commerce, taxation, finance, foreign exchange and trade.

Furthermore, the interpretation and application of the laws and regulations governing our industries also undergo continuous evolution and revision. These dynamic changes in the legal landscape have the potential to significantly impact our operations and business environment.

We may be subject to additional regulatory requirements under new laws and regulations on overseas offerings and listings issued by PRC government authorities.

On July 6, 2021, the relevant PRC government authorities issued the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》). These opinions emphasize the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and propose to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies.

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “Trial Measures”) along with five relevant guidelines, which became effective on March 31, 2023. The Trial Measures require, among others, that PRC domestic companies that seek to initially offer and list securities in overseas markets, either directly or indirectly, shall file the required documents with the CSRC within three business days after its application for overseas listing is submitted. We will file with CSRC within a specific time limit as required by the Trial Measures. However, we cannot assure you that we could complete such filing in a timely manner or at all, the failure of which may restrict our ability to complete the proposed [REDACTED] and have a material and adverse effect on our business, prospects, results of operations, financial condition, and cash flows.

On February 24, 2023, the CSRC, the Ministry of Finance of the PRC, the National Administration of State Secrets Protection of China, and the National Archives Administration of China published the Provisions on Strengthening Confidentiality and Archives Administration of 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》) (the “Archives Rules”), which came into effect on March 31, 2023. The Archives Rules require that, in relation to the overseas securities offering and listing activities of domestic enterprises, either in direct

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or indirect form, such domestic enterprises, as well as securities companies and securities service institutions providing relevant securities services, are required to strictly comply with relevant requirements on confidentiality and archives management, establish a sound confidentiality and archives system, and take necessary measures to implement their confidentiality and archives management responsibilities. The interpretation and implementation of the Archives Rules may keep evolving, failure to comply with which may materially affect our business, prospects, results of operations, financial condition, and cash flows. See “Regulatory Overview — Regulations Relating to Securities and Overseas Securities Offering.”

Given that the Trial Measures and the Archives Rules were recently promulgated, their interpretation, application, and enforcement are still evolving and subject to change. We are closely monitoring how they will affect our operations and our future financing activities.

We may be subject to the approval, filing or other requirements of the CSRC or other PRC governmental authorities in connection with future capital raising activities.

We cannot assure you that any new rules or regulations promulgated in the future will not impose additional requirements or restrictions on us or our financing activities. If it is determined in the future that approval from or filing with the CSRC or other regulatory authorities or other procedures are required, we may fail to obtain such approval, perform such filing procedures or meet such other requirements in a timely manner or at all. We may face sanctions by the CSRC or other PRC regulatory authorities for failure to seek CSRC approval or other government authorization, or perform filing procedures, for this [REDACTED] or our future financing activities, and these regulatory authorities may impose fines and penalties on us, limit our operating activities in the PRC, limit our ability to pay dividends outside the PRC, delay or restrict the repatriation of the [REDACTED] from the [REDACTED] into the PRC or take other actions to restrict our financing activities, which could have a material and adverse effect on our business, prospects, results of operations, financial condition, and cash flows.

Changes in international trade policies, and in relationships between the PRC and other countries, may adversely impact our business and operating results.

We will actively pursue expansion into international markets. Specifically, we plan to sell our products in new geographic regions and establish cooperations with local and international entities.

Unfavorable government policies related to international trade, including capital controls or tariffs, or adverse shifts in diplomatic relations between China and foreign countries or regions, have the potential to impact the sales of our products, in international markets. These factors may also affect our ability to recruit engineers and other R&D personnel and influence the import or export of raw materials essential to our international expansion efforts. The implementation of new tariffs, changes in legislation and regulations, or the renegotiation of existing trade agreements could result in a material adverse effect on our business, prospects, results of operations, financial condition, and cash flows.

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We are subject to the currency exchange regulatory system.

The conversion of Renminbi is subject to applicable laws and regulations in the PRC. It cannot be guaranteed that under a certain exchange rate, we will have sufficient foreign exchange to meet our foreign exchange requirements. Under the current PRC foreign exchange regulatory system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from the SAFE, but we are required to present documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business.

Under existing foreign exchange regulations, following the completion of the [REDACTED], we will be able to pay dividends in foreign currencies without prior approval from the SAFE by complying with certain procedural requirements. However, there is no assurance that these foreign exchange policies regarding payment of dividends in foreign currencies will continue in the future. In addition, any insufficiency of foreign exchange may restrict our ability to pay dividends to shareholders or to satisfy any other foreign exchange requirements, capitalize our capital expenditure plans, and even our business, prospects, results of operations, financial condition, and cash flows may be adversely affected.

Certain PRC regulations may make it more difficult for us to pursue growth through acquisitions.

The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. Such regulation requires, among other things, that the MOFCOM be notified in advance of any change of control transaction in which a foreign investor acquires control of a PRC domestic enterprise and involves any of the following circumstances: (i) any important industry is concerned; (ii) such transaction involves factors that have or may have an impact on the national economic security; or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. We do not expect that the [REDACTED] will trigger MOFCOM pre-notification under each of the above-mentioned circumstances or any review by other PRC government authorities. Moreover, the PRC Anti-Monopoly Law (《中華人民共和國反壟斷法》), and the Regulations on Filing Threshold for Concentration of Undertakings (《國務院關於經營者集中申報標準的規定》) require that transactions which are deemed concentrations and involve parties with specified turnover thresholds must be cleared by the State Administration for Market Regulation of the PRC, or the SAMR, the successive authority of MOFCOM, before they can be completed. In addition, Rules of the Ministry of Commerce on Implementation of Security Review System of Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《商務部實施外國投資者併購境內企業安全審查制度的規定》) that became effective in September 2011 and Measures for the Security Review of Foreign Investment (《外商投資安全審查辦法》) that became effective in January 2021

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require acquisitions by foreign investors of PRC companies engaged in military related or certain other industries that are crucial to national defense and security be subject to security review before consummation of any such acquisition.

If we, in the future, plan to pursue potential strategic acquisitions that are complementary to our business and operations, complying with the requirements of these regulations to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval or clearance from MOFCOM and the NDRC and their respective local counterparts, may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain our market share. It is unclear whether our business would be deemed to be in an industry that raises national defense and security or national security concerns. Recently, the SAMR imposed administrative penalties on a number of anti-monopoly cases in the internet industry, and the regulatory environment of anti-monopoly is tightening.

Our operations are subject to PRC tax laws and regulations.

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. The PRC tax laws and regulations might be subject to interpretations and adjustments by relevant authorities from time to time. Although we believe that in the past, we have acted in compliance with the requirements under the relevant PRC tax laws and regulations in all material aspects and established effective internal control measures in relation to accounting regularities, we cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or actions that could materially and adversely affect our business, prospects, results of operations, financial condition, and cash flows.

Holders of H Shares may be subject to PRC income taxes.

Holders of H Shares, being non-PRC resident individuals or non-PRC resident enterprises, whose names appear on the register of members of H Shares of our Company, are subject to PRC income tax in accordance with the applicable tax laws and regulations, on dividends received from us and gains realized through the sale or transfer by other means of H shares by such shareholders.

According to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) and the Implementation Regulations for the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), both came into effect on January 1, 2019, the tax applicable to non-PRC resident individuals is proportionate at a rate of 20% for any dividends obtained from within China or gains on transfer of shares and shall be withheld and paid by the withholding agent. Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region (the “Hong Kong SAR”) for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (the “Double Taxation Arrangements”) executed on August 21, 2006, the PRC Government may levy taxes on the dividends paid by

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PRC companies to Hong Kong residents in accordance with the PRC laws, but the levied tax (in the case the beneficial owner of the dividends are not companies directly holding at least 25% of the equity interest in the company paying the dividends) shall not exceed 10% of the total dividends.

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), which was newly revised and implemented on December 29, 2018, and the Implementation Regulations for the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》), which was newly revised and implemented on December 6, 2024, if a non-resident enterprise has no presence or establishment within China, or if it has established a presence or establishment but the income obtained has no actual connection with such presence or establishment, it shall pay an enterprise income tax on its income derived from within China with a reduced rate of 10%. Pursuant to the Double Taxation Arrangements, dividends paid by PRC resident enterprises to Hong Kong residents can be taxed either in Hong Kong or in accordance with the PRC laws. However, if the beneficial owner of the dividends is a Hong Kong resident, the tax charged shall not exceed: (i) 5% of the total amount of dividends if the Hong Kong resident is a company that directly owns at least 25% of the capital of the PRC resident enterprise paying dividends; or (ii) otherwise, 10% of the total amount of dividends.

Considering the foregoing, non-PRC resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers by other means of the H Shares.

While this may also apply to other jurisdictions, there might be difficulties in effecting service of legal process, enforcing foreign judgments against us or our Directors and senior management in the PRC.

We are a company incorporated in China. A majority of our Directors and senior management reside within mainland China, and substantially all of our and their assets are located within the PRC. Therefore, it may be difficult for [REDACTED] to directly effect service of legal process upon us or our Directors and senior management in the PRC.

On July 14, 2006, the Supreme People’s Court of the PRC and the government of Hong Kong SAR entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “Arrangement”), which was taken into effect on August 1, 2008.

Pursuant to the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the

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judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a mainland court is expressly selected as the court having sole jurisdiction for the dispute.

On January 18, 2019, the Supreme People’s Court of the PRC and the government of Hong Kong SAR signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “New Arrangement”), which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong SAR and the mainland China. On January 29, 2024, the New Arrangement was declared effective jointly by the Supreme People’s Court of the PRC and the government of Hong Kong SAR, which has replaced the Arrangement. However, the New Arrangement does not apply to certain judgments of civil and commercial matters. Furthermore, there remain uncertainties as to the outcome of any applications to recognize and enforce such judgments and arbitral awards in the PRC.

Although we will be subject to the Hong Kong Listing Rules and the Hong Kong Codes on Takeovers and Mergers and Share Repurchases upon the [REDACTED] of our H Shares on the Stock Exchange, the holders of H Shares will not be able to bring actions on the basis of violations of the Hong Kong Listing Rules and must rely on the Stock Exchange to enforce its rules. The Hong Kong Listing Rules and Hong Kong Codes on Takeovers and Mergers and Share Repurchases do not have the force of law in Hong Kong.

RISKS RELATING TO THE [REDACTED]

We are subject to filings to the CSRC for the [REDACTED] and [REDACTED] of our H Shares on the Stock Exchange.

On July 6, 2021, the relevant PRC government authorities issued Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law (《關於依法從嚴打擊證券違法活動的意見》). These opinions emphasized the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based [REDACTED] companies.

On February 17, 2023, the CSRC promulgated the Overseas Listing Trial Measures and five supporting guidelines, which has become effective on March 31, 2023. The Overseas Listing Trial Measures require, among others, that PRC domestic enterprises that seek to offer and list securities in overseas markets, either directly or indirectly, to file the required documents with the CSRC within three business days after its application for [REDACTED] is submitted. On the same date, the CSRC promulgated the Arrangement for Filing-based Administration. According to the Arrangement for Filing-based Administration, PRC domestic

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enterprises shall not be required to complete the filing procedures if all of the following conditions are met: (i) the application for indirect [REDACTED] or [REDACTED] shall have passed the hearing for a contemplated [REDACTED] and/or [REDACTED] in Hong Kong prior to the effective date of the Overseas Listing Trial Measures; (ii) it is not required to re-perform the overseas regulatory procedures for overseas securities [REDACTED] and [REDACTED]; and (iii) such overseas securities [REDACTED] or [REDACTED] shall be completed before September 30, 2023.

Furthermore, we cannot assure you that any new rules or regulations promulgated in the future will not impose additional requirements or restrictions on us or our financing activities. If it is determined in the future that approval from or filing with the CSRC or other regulatory authorities or other procedures are required, we may fail to obtain such approval, perform such filing procedures or meet such other requirements in a timely manner or at all. We may face sanctions by the CSRC or other PRC regulatory authorities for failure to seek CSRC approval or other government authorization, or perform filing procedures, for this [REDACTED] or our future financing activities, and these regulatory authorities may impose fines and penalties on us, limit our operating activities in the PRC, limit our ability to pay dividends outside of the PRC, delay or restrict the repatriation of the [REDACTED] from the [REDACTED] into the PRC or take other actions to restrict our financing activities, which could have a material adverse effect on our business.

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

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

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

The [REDACTED] and [REDACTED] volume of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the political uncertainties in Hong Kong and 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] volume 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 fluctuations in our revenue, earnings, cash flows, investments, expenditures, regulatory developments, relationships with our suppliers and customers,

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movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies [REDACTED] on the Stock Exchange with significant operations and assets in the PRC have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in price not directly related to our performance but related to the overall political and economic conditions in Hong Kong, the PRC or elsewhere in the world.

Since there will be a gap of several days between the pricing and the [REDACTED] of our H Shares, holders of our H Shares are subject to the risk that the [REDACTED] of our H Shares may fall during the period before the [REDACTED] of our H Shares begin.

The [REDACTED] to the public of our H Shares offered in the [REDACTED] is expected to be determined on the [REDACTED]. However, the H Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be several business days after the [REDACTED]. As a result, [REDACTED] may not be able to sell or otherwise [REDACTED] in the H Shares during that period. Accordingly, Shareholders are subject to the risk that the [REDACTED] of the H Shares when [REDACTED] begins could be lower than the [REDACTED] in the event of adverse market conditions or other adverse developments that may occur between the time of sale and the time [REDACTED] begins.

You will incur immediate and significant dilution if the [REDACTED] of the [REDACTED] is higher than the net tangible asset value per H Share, and may experience further dilution if we issue additional 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. There can be no assurance that if we were to immediately liquidate after the [REDACTED], any assets will be distributed to Shareholders after the creditors' claims. To expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per Share of their Shares if we issue additional Shares in the future at a [REDACTED] which is lower than the net tangible asset value per Share at that time.

Future sales or perceived sales of substantial amounts of our H Shares in the [REDACTED] following the [REDACTED] could have a material adverse effect on the [REDACTED] of our H Shares and our ability to raise additional capital in the future, and may result in dilution of your shareholding.

The [REDACTED] our H Shares could decline as a result of future sales of a substantial number of our H Shares or other securities relating to our H Shares in the [REDACTED], or the issuance of new shares or other securities, or the perception that such sales or issuances may occur. Future sales, or anticipated sales, of substantial amounts of our securities, including any future offerings, could also materially and adversely affect our ability to raise capital at a

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specific time and on terms favorable to us. In addition, our Shareholders may experience dilution of their holdings if we issue more securities in the future. New shares or shares-linked securities issued by us may also confer rights and privileges that take priority over those conferred by the H Shares.

According to the stipulations by the State Council’s securities regulatory authority and the Articles of Association, our Unlisted Shares may be converted into H Shares and such converted H Shares may be [REDACTED] or [REDACTED] on an overseas stock exchange, provided that prior to the conversion and [REDACTED] of such converted shares, the requisite internal approval processes (but without the necessity of Shareholders’ approval by class) have been duly completed and the approval from the relevant PRC regulatory authorities, including the CSRC, have been obtained. In addition, such conversion, [REDACTED] and [REDACTED] must comply with the regulations prescribed by the State Council’s securities regulatory authorities and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. We can apply for the [REDACTED] of all or any portion of our Unlisted Shares on the Stock Exchange as H Shares in advance of any proposed conversion to ensure that the conversion process can be completed promptly upon notice to the Stock Exchange and delivery of shares for entry on the [REDACTED]. This could increase the supply of H Shares in the market, and future sales, or perceived sales, of the converted H Shares may materially and adversely affect the [REDACTED] of H Shares.

The interests of our Controlling Shareholders may not be aligned with the interest of other Shareholders.

Our Controlling Shareholders have substantial influence over our business and operations, including matters relating to management and policies, decisions in relation to acquisitions, expansion plans, business consolidation, the sale of all or substantially all of our assets, nomination of directors, dividends or other distributions, as well as other significant corporate actions. Immediately following the completion of the Shares Subdivision and the [REDACTED] (assuming the [REDACTED] and the [REDACTED] are not exercised), Mr. Liu, Shanghai Ruicong L.P., and Shanghai Ruiru L.P. will collectively hold approximately [52.74]% of our total issued Shares. The concentration of voting power and the substantial influence of our Controlling Shareholders over our Company may discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their Shares as part of a sale of our Company and reduce the [REDACTED] of our H Shares. In addition, the interests of our Controlling Shareholders may differ from the interests of our other Shareholders. Subject to the Listing Rules, our Articles of Association and other applicable laws and regulations, our Controlling Shareholders will continue to have the ability to exercise substantial influence over us and to cause us to enter into transactions or take, or fail to take, actions or make decisions which conflict with the best interests of our other Shareholders.

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

Our management may spend the net [REDACTED] from the [REDACTED] in ways with which you may not agree or which do not yield a favorable return to our shareholders. We plan to use the net [REDACTED] from the [REDACTED] to primarily fund, our ongoing and planned R&D and commercialization of our product candidates, and expansion of our manufacturing capacity. For details, see “Future Plans and Use of [REDACTED] — Use of [REDACTED].”

See “Business — Our Strategies” and “Future Plans and Use of [REDACTED]” for details.

However, our management will have discretion as to the actual application of our net [REDACTED]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net [REDACTED] from this [REDACTED].

There can be no assurance of the accuracy or completeness of certain facts, forecasts and other statistics obtained from various government publications contained in this document.

This document, particularly the section headed “Industry Overview,” contains information and statistics relating to the medical robot industry, surgical robot industry, percutaneous puncture surgical robot industry and other relevant industries. Such information and statistics have been derived from third-party reports, either commissioned by us or publicly accessible and other publicly available sources. The information from official government sources has not been independently verified by us, the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED], or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics being inaccurate or not comparable to statistics produced for other economies. You should therefore not place undue reliance on such information. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

You should read this entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles and/or other media regarding us, our business, our network of medical institutions, our industry or the [REDACTED].

You are strongly advised to read the entire document carefully and are cautioned against placing any reliance on the information in any press article or any other media coverage which contains information not disclosed or not consistent with the information included in this document.

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Prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED]. Our Directors would like to emphasize to prospective [REDACTED] that we do not accept any responsibility for the accuracy or completeness of such information, and such information is not sourced from or authorized by our Directors or our management team. Our Directors make no representation as to the appropriateness, accuracy, completeness and reliability of any information or the fairness or appropriateness of any forecast, view or opinion expressed by the press or other media regarding us or our H Shares. In making decisions as to whether to [REDACTED] in our H Shares, prospective [REDACTED] should rely only on the financial, operational and other information included in this document.