Investment in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the "Financial Information" section, before making an* [REDACTED] *in our Shares. Our business, financial conditions and results of operations and growth prospects could be materially and adversely affected by any of these risks and uncertainties. The* [REDACTED] *of our Shares could decline due to any of these risks, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

We believe there are certain risks and uncertainties involved in our business, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to the sales and distribution of our products, (ii) risks relating to the manufacture and supply of our products, (iii) risks relating to the development and commercialization of our products and product candidates, (iv) risks relating to our operations and financing, (v) risks relating to our intellectual property rights, (vi) risks relating to government regulation, (vii) risks relating to doing business in countries and regions in which we operate, and (viii) risks relating to the **[REDACTED]**.

RISKS RELATING TO THE SALES AND DISTRIBUTION OF OUR PRODUCTS

Our success depends on the continued market acceptance and usage of our products. If we fail to achieve or maintain broad market acceptance or usage, our business and results of operations could be materially and adversely affected.

The commercial success of our products depends upon the degree of market acceptance they achieve, particularly among hospitals, physicians and patients. If any of our products fail to gain sufficient market acceptance by hospitals, physicians, patients or third-party payors in the industry, the sales of our products will be adversely affected. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies introduced by our competitors are more favorably received than ours, are more cost-effective or render our products obsolete. Meanwhile, we may also fail to effectively market our product candidates upon commercialization. The degree of market acceptance of our products and product candidates, if approved for commercial use, will depend on a number of factors, including:

- physicians, hospitals and patients considering our products safe and effective;
- the potential and perceived advantages and disadvantages of our products compared to alternative products and treatments;
- the prevalence and severity of any adverse effects of our products;
- the timing of market introduction of our products versus competitive products;
- the pricing of our products as compared to that of alternative devices or treatments;
- our ongoing iterations to upgrade our products to latest clinical practice;
- the availability of sufficient sophisticated physicians who can perform interventional therapies involving our products;

- the availability of adequate coverage and reimbursement by third-party payors and government authorities of our products and procedures involving our products;
- the willingness of patients to pay out-of-pocket in the absence of insurance coverage or reimbursement by third-party payors or government authorities; and
- the effectiveness of our sales and marketing efforts.

We face intense market competition in selling and distributing our products, which may have a material adverse effect on our business and results of operations.

The development and commercialization of medical devices are highly competitive. The global CRM device market is currently dominated by only five multinational companies, namely, Medtronic, Abbott, Boston Scientific, Biotronik and our Company. We also compete with a number of other companies globally which have marketed or are pursuing the development of CRM devices. See "Industry Overview—Overview of the Global CRM Device Market—Competitive Landscape" for details.

Our competitors compete with us in developing advanced technologies, manufacturing high-end medical devices as well as marketing and selling products. Some of our current and potential competitors may have greater resources and better competitive positions in certain markets than we do, which may allow our competitors to respond more effectively than us to new or emerging technologies and changes in market requirements. Our competitors may develop and commercialize products that have greater effectiveness, are less expensive or are more convenient than ours, may undertake more far-reaching and successful product development efforts or marketing campaigns, or may adopt more aggressive pricing policies. In addition, certain competitors could use strong or dominant positions in one or more markets where we operate to gain competitive advantage against us by making acquisitions.

Our inability to compete effectively could reduce our revenue and market share, impair our ability to achieve our target market shares in future periods, cause a decline in our growth rates, and harm our market position. Accordingly, our business, financial condition and results of operations may be materially and adversely affected.

We operate in both mature and developing markets, which impose different risks and challenges to us. We may be unable to maintain or enhance our market share in these markets.

We sell products globally in both mature markets and developing markets. In certain mature markets where we operate, our penetration rate is low and we face significant competition from the existing players. For example, in the United States and Japan, Bluetooth pacemakers are widely available. Our own Bluetooth pacemaker family, such as *Alizea*, *Borea* and *Celea*, sold or expected to be approved for sale in those markets may not be able to compete successfully with existing Bluetooth pacemakers provided by our industry peers.

We also operate in developing markets, such as China, where the industry is rapidly evolving due to economic growth, changes in government policies and funding levels and other factors. In those markets, we face strong competition from our industry peers and need to address the market

conditions that change constantly. We cannot assure you that we will gain market shares in the developing markets.

If we are unable to enhance our penetration in the mature markets or adequately respond to changes in market conditions in a timely manner in the developing markets, it could have a material adverse effect on our business, financial condition and results of operations, which could impede our growth, reduce our revenue and undermine our ability to maintain our market shares or achieve target market shares in future periods. In addition, if we cannot maintain our market position, our reputation and brand may be materially and adversely affected which could adversely affect our relationships with physicians and hospital administrators and our long-term ability to effectively market and sell our products or conduct clinical trials for our new products.

We may not be able to maintain stable relationships with our direct sales customers, and we may not effectively manage and succeed in expanding and deepening market penetration where we predominantly conduct direct sales.

During the Track Record Period, a majority of our revenue was derived from the sales of our products to direct sales customers, which primarily included hospitals and other medical institutions. Our relationships with our direct sales customers largely depend on our ability to provide products that meet their needs. However, there is no assurance that our products will be favorably received at all times. See "—Our success depends on the continued market acceptance and usage of our products. If we fail to achieve or maintain broad market acceptance or usage, our business and results of operations could be materially and adversely affected." If we are unable to maintain stable relationships with our direct sales customers, our sales may be adversely affected and we may be unable to extend our market coverage and deepen our market penetration as contemplated.

Our ability to attract, motivate and retain a sales and marketing team who has expertise and capability to communicate effectively with medical professionals is an important factor for the success of our relationship with our direct sales customers. 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 operations could be materially and adversely affected.

In addition, we have been and plan to continue strengthening our cooperative relationships with our direct sales customers by providing them with technical and product training. However, such promotional activities may not be as effective as we expected, and may be impeded by unanticipated events such as the outbreaks of COVID-19.

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

We sell products through distributors in certain markets, such as China and Japan. The number of our distributors increased steadily during the Track Record Period. However, there is no assurance that we will maintain a sufficient number of competent distributors who will effectively distribute our products. Further, 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 of revenue from losing one or more of our major distributors. In

addition, there is no assurance that we will be able to successfully secure new distributors to capture potential industry growth and broaden our distribution channel. If our distributors do not effectively distribute our products, or we lose any of our distributors, in particular any major distributors, the distribution of our products may be affected, as a result of which our sales volumes and business prospects could be adversely affected.

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

We rely on the distribution agreements and the policies and measures we have in place to manage our distributors. The effective management of our distributors largely depends on their compliance with laws, rules, regulations and our policies. We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors will not breach our agreements and policies. If our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected:

- breaching the distribution agreements or our policies and measures, including by selling products outside their designated territories;
- failing to adequately promote our products;
- failing to provide proper training and after-sales services to our end-users;
- failing to maintain the requisite licenses, permits or approvals or failing to comply with applicable regulatory requirements when selling our products; or
- violating anti-corruption, anti-bribery, sanction, competition or other laws and regulations.

Any violation or alleged violation by our distributors of the distribution agreements, our policies or any applicable laws and regulations could expose us to potential legal liability, affect our reputation or cause a decrease in the market value of our brand and an unfavorable public perception about the quality of our products, which could further lead to a material adverse effect on our business, financial condition, results of operations and prospects.

Our sales may be affected by the level of medical insurance reimbursement available to patients using our products.

Our ability to sell our products depends in part on the possibility and the extent to which medical insurance reimbursement for CRM devices is available to patients in the various jurisdictions where we operate, which is beyond our control. We cannot assure you that all of our products have been or will be covered by medical insurance in each jurisdiction where we operate, or that, for those covered by medical insurance, they will be fully reimbursed in each jurisdiction where we operate. In the absence of medical insurance coverage or full reimbursement for the use of our products, patients may choose alternative treatment methods, and hospitals may recommend alternative treatments, which would reduce demand for our products, and in turn materially and adversely affect our business, financial condition and results of operations.

Our sales and financial performance are subject to seasonal fluctuations.

Sales of certain of our products are subject to seasonality. In particular, our product sales in Europe from which we generate a significant portion of revenue are relatively lower during the summer, especially August, primarily due to the traditional summer vacation widely adopted across Europe, during which time many people take vacations and certain medical activities, including the implantation of CRM devices, slow down, leading to a temporary decrease in the demand for our CRM devices. On the other hand, some components of our costs and expenses such as rental expenses and staff costs are relatively fixed in nature and not affected by seasonality. As a result, our financial performance in the second half of our financial year may be worse than the first half.

RISKS RELATING TO THE MANUFACTURE AND SUPPLY OF OUR PRODUCTS

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

Our products may cause undesirable or unintended severe adverse events as a result of a number of factors, many of which are out of our control. These factors include potential complications not revealed in clinical trials, unusual but severe complications and adverse events in isolated cases, defective products not detected by our quality control system and misuses of our products. Our products may also be perceived to cause adverse events when a conclusive determination as to the cause of the adverse events is not obtained or is unobtainable.

In addition, our products may be perceived to cause severe adverse events if one or more regulators, including the local competent authorities of EU member states, the NMPA, the MHLW or the FDA, determine that other companies' products containing the same or similar key parts or using the same delivery technologies as those of our own products cause or are perceived to have caused severe adverse events.

If our products cause, or are perceived to cause, severe adverse events, we may face a number of consequences, including:

- a severe decrease in the demand for, and sales of, the relevant products;
- the recall or withdrawal of the relevant products;
- revocation of regulatory approvals for the relevant products or the relevant production facilities;
- damage to the brand of our products and the reputation of our Company;
- failure to enter or expulsion from medical insurance coverage for the relevant products; and/or
- exposure to lawsuits and regulatory investigation relating to the relevant products that result in liabilities, fines or penalties.

As a result of these consequences, our sales, profitability and prospects could be materially and adversely affected.

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

Product quality is extremely important due to the serious and costly consequences of a product failure. We have established a comprehensive set of quality control and assurance procedures to monitor our operations to ensure compliance with relevant regulatory requirements and our internal quality requirements. However, we cannot eliminate the risk of product defects or failure. Problems can arise during the manufacturing process for a number of reasons, including:

- manufacturing errors;
- technical or mechanical malfunctions in the manufacture process;
- human error or malfeasance or equipment malfunctions in the quality control process;
- tampering by third parties; and/or
- quality issues with the raw materials we produce or purchase.

If problems are not discovered before the product is released to the market, we may need to recall or withdraw the relevant product, and may also suffer license revocation or regulatory fines and product liability costs.

Furthermore, if contaminants are discovered in our products or in the manufacturing facilities, we may need to close such manufacturing facilities for an extended period of time to investigate and remedy the contamination. In addition, failure to maintain production stability may affect the manufacture and delivery schedule of our products. Disruptions may occur when we install new equipment, replace old equipment or relocate product lines.

If these problems arise or if we otherwise fail to meet our internal quality standards or those of local competent authorities of EU member states or other applicable regulatory bodies, which include detailed record-keeping requirements, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product liability and other costs, product approvals could be delayed, and our business could otherwise be adversely affected.

We may face damage to, destruction of or interruption of production at our facilities, which could interrupt our development plans or commercialization efforts. If we fail to raise our production capacity to meet market demand, our business prospects could be materially and adversely affected.

As of the Latest Practicable Date, we conducted manufacturing activities primarily at our four manufacturing facilities located in Clamart, France; Saluggia, Italy; Santo Domingo, the Dominican Republic; and Shanghai, China. Our facilities may be harmed or rendered inoperable by physical damage from fire, floods, earthquakes, typhoons, tornadoes, power loss, telecommunications failures, break-ins and similar events. Our production cycle may be interrupted due to strikes, work slowdowns or any other deterioration in relations with our employees, as well as shortages of skilled workers. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization.

We may also experience difficulties in increasing production capacity in a timely manner to meet market demand. For example, advances in manufacturing techniques may render our facilities and equipment inadequate or obsolete, and therefore we may also need to develop advanced manufacturing techniques and process controls in order to fully utilize our facilities. If we are unable to do so, we may not be able to supply our products in sufficient quantities to meet future demand, which would limit our development and commercialization activities and our opportunities for growth. Further, manufacturing of our products also depends on the continued service of qualified manufacturing personnel. Competition for qualified manufacturing personnel in the medical device industry is intense and the pool of qualified candidates is limited. There is no assurance that we will not experience difficulties in attracting and retaining qualified manufacturing personnel in the future. If we are unable to maintain a sufficient number of qualified manufacturing personnel to support our products manufacture, production capacity may be adversely affected.

In addition, there can be no assurance that our manufacturing facilities will produce products in sufficient volumes in the event of any significant increase in market demand. In such event, we may have to engage third parties to produce a portion of such products. Consequently, we will be exposed to the risks of increased pricing for our sub-contracted production and that the third parties may not manufacture products meeting our specifications or in sufficient volumes to meet market demand. As a result, our sales volumes and margins for the relevant products could be materially and adversely affected.

We rely on a limited number of suppliers with some of them supplying components specifically designed for our CRM devices, and may not be able to secure a stable supply of qualified raw materials or components at all times or at all.

Our key raw materials for low-voltage CRM devices and high-voltage CRM devices include integrated circuits, electronic components, batteries, shock capacitors and titanium cases, and those for leads include stainless steel machined components, silicone injections and plastic injections. Most of our components need to be custom-made. To ensure the quality of our principal raw materials, we only procure them from select suppliers in different countries and regions that can satisfy our requirements. As of the Latest Practicable Date, we had 123 suppliers in France, Italy, the United States and other countries and regions. However, we cannot assure you that we will be able to secure a stable supply of qualified raw materials at all times. If any of our suppliers terminate their cooperation relationship with us, we may not be able to secure alternative qualified suppliers in a timely manner and that may materially and adversely affect our business and results of operations.

Further, geopolitical and trade tensions, such as tariff controls, in the countries and regions where our suppliers are located could adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components to us. If our suppliers' ability to provide materials and components to us is materially affected and we cannot secure alternative suppliers in a timely manner, the loss of such suppliers could interrupt our ordinary course of business, which may cause a material adverse effect on our business, financial conditions and results of operations.

In addition, if any of our suppliers, especially those who provide components specifically designed for our CRM devices, lose qualification or eligibility for any reason including failure to comply with regulatory requirements, or if we encounter lengthy custom clearance procedures to import certain of our raw materials, we may experience delays in the supply of our raw materials. If our inventory of the

relevant raw material does not sufficiently cover the deficiency over the relevant time period, our manufacturing process may be interrupted.

Changes in the availability, delivery time or prices of raw materials and volatility in energy prices could have an adverse effect on our business and results of operations.

Our manufacturing processes require substantial amounts of raw materials and components. We typically procure our principal raw materials through third-party suppliers. The price and delivery time of our principal raw materials experienced volatility during the Track Record Period and may be subject to changes in the future. The prices of our raw materials may be affected by a number of factors, including market supply and demand, the environmental and regulatory requirements in their exporting and importing countries, wars and military conflicts, economic sanctions, natural disasters such as fires, outbreak of epidemics or diseases such as COVID-19 and the local and global economic conditions, among others. A significant increase in the cost of raw materials may increase our costs and negatively affect our profit margins and, more generally, our business, financial conditions, results of operations and prospects. Further, the delivery time of certain electronic components of our CRM products increased during the Track Record Period due to a global electronic component shortage. The global electronic component shortage was caused by a combination of factors, including COVID-19 lockdown measures, the Russo-Ukrainian war, among others. There is no assurance that we will not experience material delays in delivery of our raw materials in the future. If we are unable to maintain a sufficient stock of the relevant electronic components at a reasonable cost, our production volume may be affected and that may materially and adversely affect our business and results of operations.

In addition, the production and distribution of our products require material amounts of energy. Energy prices experienced significant volatility in the recent past and may continue to be subject to changes in the future. For example, the electricity and gas prices in Europe soared after the European Union, the United Kingdom and other jurisdictions imposed economic sanctions on Russia as a result of the Russo-Ukrainian war, and may rise again in the future. High energy prices over an extended period of time, as well as changes in energy taxation and regulation in certain geographies, may adversely affect on our operating income and could potentially challenge our profitability in certain markets.

We may be subject to product liability lawsuits that could cause us to incur substantial liability.

We face an inherent risk of product liability as a result of the commercialization of our products and the clinical testing and any future commercialization of our product candidates in the countries and regions where we operate. For example, we may be sued if our products or product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Such product liability claims, if any, may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the medical device product, negligence, strict liability or a breach of warranties. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liability or be required to limit commercialization of our products and product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in decreased demand for our products and loss of revenue, initiation of investigations by regulators, product recalls or withdrawals

and damage to our reputation, among others. As a result, our business, financial condition and results of operations may be materially and adversely affected.

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

To operate our business successfully and meet our customers' demands and expectations, we must maintain a certain level of inventory for our products to ensure immediate delivery when required. Furthermore, we are required to maintain an appropriate level of inventory of our raw materials to support our R&D and manufacturing activities. We maintain our inventory levels based on our internal forecasts which are inherently uncertain and we generally keep higher inventory level if we anticipate there will be any interruption to our supply chain. However, if our forecast demand is lower than actual demand, we may not be able to maintain an adequate inventory level of our products or manufacture our products in a timely manner, and may lose sales and market share to our competitors. On the other hand, we may be exposed to increased inventory risks due to accumulated excess inventory of our products or raw materials. Excess inventory levels may increase our inventory holding costs or risk of inventory obsolescence or write-offs.

During the Track Record Period, our facilities generally maintained a utilization rate of around 70.0%. See "Business—Manufacturing—Production Capacity, Production Volume and Utilization Rates of Our Manufacturing Facilities." We cannot assure you that our utilization rate will stay at or above the optimal level at all times. If our utilization rate stays below the optimal level for a protracted time, we may incur excess costs in the maintenance and repair as well as depreciation of idle equipment, which may significantly increase our total costs and affect our business, financial condition and results of operations.

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

If we do not introduce new products in a timely manner, our products may become obsolete and our business and results of operations may suffer.

The CRM device industry is characterized by technological changes, frequent new product introductions and evolving industry standards. Our ability to generate revenue depends on the successful introduction of new products and new generations of products. Without the timely introduction of new and improved products, our products could become technologically obsolete or more susceptible to competition and our revenue and operating results would suffer. Even if we develop new or improved products, our ability to market them could be limited by the need for regulatory clearance, restrictions imposed on approved indications, entrenched patterns of clinical practice, uncertainty over third-party reimbursement, or other factors.

In 2020, 2021 and 2022, we incurred R&D costs of US$56.4 million, US$63.7 million and US$59.3 million, respectively. The success of our new products and product candidates depends on several factors, including but not limited to:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals;
- establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- 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 that we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- successfully launching our product candidates, if and when approved;
- obtaining favorable governmental and private medical reimbursement for our products, if and when approved;
- competition with other CRM products; and
- continued acceptable safety profile following regulatory approval.

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

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

The research and development process of our products and product candidates, including product design, preclinical development and clinical trials, is expensive and can take many years to complete, and outcomes are inherently uncertain. In particular, failure of clinical trials may occur at any time during the research and development process. The results of preclinical research and early clinical trials of our products candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials.

In addition, there can be significant variance in safety and/or efficacy results between different trials of the same and similar product candidates due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including differences in physical conditions, and dropout rates among clinical trial participants.

We engage third parties to conduct certain aspects of our clinical trials. If we do not maintain our relationships with these third parties, or if these third parties do not successfully carry out their contractual duties or meet our expectations, we may not be able to obtain regulatory approval for or successfully commercialize our products and our business could be substantially harmed.

As is common practice in our industry, we have engaged and plan to continue to engage third parties, including academic institutions, hospitals, clinics, physicians and CROs, to assist us in implementing and monitoring our preclinical research and conducting clinical trials. If we are unable to maintain or enter into agreements with these third parties on terms favorable to us, or if any such engagement with us is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate, and the development of the product candidates covered by those agreements could be substantially delayed.

In addition, by engaging third parties in conducting clinical trials, we have less control over the quality, time and cost of the studies and the process of recruiting trial subjects than if we conduct these trials wholly by ourselves. There is no guarantee that these third parties may devote adequate time and resources to our studies or perform as required under their contractual obligations, meet our expectations including prescribed deadlines, or act in accordance with regulatory requirements, including clinical, laboratory and manufacturing guidelines. Our reliance on these third parties may result in delays in completing, or failing to complete, these studies if they fail to perform satisfactorily. If these third parties fail to meet expected deadlines, fail to timely transfer to us any regulatory information, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality and/or accuracy of their activities and/or the data they obtain, clinical trials of our product candidates may be extended, delayed or terminated, or data generated by those studies may be rejected or not accepted by the applicable regulatory authorities, 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 is affected by any of the above-mentioned reasons, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business and prospects.

Our product candidates may cause undesirable adverse events which could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

If, prior to regulatory approval, our product candidates cause undesirable adverse events, including but not limited to safety issues and other serious adverse events, that 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 relevant regulatory authorities.

Additionally, if our product candidates receive regulatory approval, and undesirable safety issues caused by such product candidates 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 and 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;
- a severe decrease in the demand for, and sales of, the 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 particular product candidate, and could significantly harm our business, results of operations and prospects.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trials until their conclusion. We may experience difficulties in relation to patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to engage CROs with the appropriate competence and experience;
- the patients' perceptions as to the potential advantages and risks of the product candidates being studied in relation to other available products, product candidates or non-invasive therapies;
- our ability to obtain and maintain patient consents; and

- the risk that patients enrolled in clinical trials may drop out or fail to return for post treatment follow-up at a higher rate than anticipated.

Our clinical trials will likely compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Furthermore, because the number of qualified clinical investigators and clinical trial sites is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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

To obtain regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including but not limited to:

- regulators, institutional review boards or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- our inability to reach agreements on acceptable terms with prospective CROs and hospitals as trial centers, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and hospitals as trial centers;

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; and

- 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 or a finding that participants are being exposed to unacceptable health risks.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be delayed in obtaining regulatory

approval for our product candidates; (ii) not obtain regulatory approval at all; (iii) obtain approval for indications that are not as broad as intended; (iv) have the product removed from the market after obtaining regulatory approval; (v) be subject to additional post-marketing testing requirements; (vi) be subject to restrictions on how the product is distributed or used; or (vii) be unable to obtain reimbursement for use of the product.

If we experience delays in the completion of, or have to terminate, a clinical trial of any of our product candidates, the commercial prospects of that product candidate will be harmed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and impact our ability to commence product sales and generate related revenue for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly.

We allocate our limited resources to pursue particular product candidates and may fail to capitalize on products or identify opportunities that may later prove to be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources and we currently only focus on certain key products in selected indicated applications. However, our selection of focus on CRM devices may cause us to miss other opportunities in the market. If we are unable to accurately evaluate the commercial potential or target market for our commercialized products, or fail to focus on products candidates or identify appropriate opportunities that may later prove to be more profitable or for which there is a greater likelihood of success, our business operations may suffer, which may have a material adverse effect on our financial conditions.

Guidelines, recommendations and clinical studies published by various organizations could negatively affect our products.

Government agencies, academic institutions, professional societies, practice management groups, private health and science foundations and organizations focused on arrhythmias may publish guidelines, recommendations or clinical studies that may affect our commercialized products or product candidates. Any such guidelines, recommendations or clinical studies that reflect negatively on our commercialized products or product candidates, either directly or relative to our competitive product candidates or alternative treatments, could result in immediate or potential decreased use, sales of, and revenue from one or more of our products and product candidates. Furthermore, our success depends in part on our and our business partners' ability to educate healthcare providers and patients about our commercialized products and product candidates, and these educational efforts could be rendered ineffective by, among other things, third parties' guidelines, recommendations or studies.

RISKS RELATING TO OUR OPERATIONS AND FINANCING

Our historical operating results may not be representative of future performance. We may need to obtain additional financing to fund our operations. If we are unable to timely obtain sufficient financing, we may be unable to complete the development and commercialization of our product candidates.

We cannot assure you that our historical operating results, such as our revenue, gross profit and gross profit margin, are indicative of future performance for various reasons, including uncertainties

of the success of our existing and new products in the market and the regulatory environment, as well as our ability to expand production capacity and improve manufacturing capabilities as planned, and manage our sales network and intense competition.

In addition, we expect to continue to spend substantial amounts on advancing R&D capabilities, further optimizing operational efficiency and expanding production capacity, and launching and commercializing our products which we receive regulatory approvals. Our existing cash and cash equivalents may not be sufficient to enable us to complete all development or commercially launch all of our current product candidates for the anticipated indications and to invest in additional programs. Accordingly, we will require further funding. We cannot assure you that our financial resources will be adequate to support our operations. Our future funding requirements will depend on many factors, including:

- the expenses associated with expanding our sales and distribution network;
- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our products and any existing or future product candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any future collaborations, licensing or other arrangements;
- cash requirements of any future development of other product candidates;
- the cost and timing of any expansion of manufacturing activities; and/or
- our headcount growth and associated costs.

In addition, many aspects of our general business operations have ongoing funding requirement that may increase over time.

We expect that the implementation of our strategies and business plans will require us to rely in part on external financing sources. However, our ability to obtain external financing on commercially reasonable terms will depend on a number of factors, many of which are out of our control, including the economic conditions in our principal markets, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government policies on lending. If we cannot obtain sufficient external financing on commercially acceptable terms to implement our strategies and business plans as currently contemplated, we could be required to revise our strategies and business plans, which could adversely affect our business prospects.

We have had operating and accumulated losses, and we cannot assure you that we will achieve profitability in the future.

In 2020, 2021 and 2022, we incurred loss for the year of US$54.3 million, US$88.1 million and US$106.9 million, respectively, primarily because we incurred significant costs resulting from our

business expansion. In addition, we had a net operating cash outflow of US$60.5 million, US$31.8 million and US$48.4 million in 2020, 2021 and 2022, respectively. We have been growing our business, and as a result our operating expenses increased and outpaced our revenue during the Track Record Period. We cannot assure you that we will be able to generate net operating income or positive cash flow from operating activities in the future. Our ability to achieve and maintain net operating income depends on our ability to grow our business to the point where revenue generated exceeds expenses associated with growing and operating the business.

Even if we are able to grow our business successfully, we may continue to incur losses in the future for a number of reasons, including other risks described in this document, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors.

Our operations and business plans may be adversely affected in the event of resurgence of the COVID-19 pandemic.

The COVID-19 pandemic has resulted in a negative impact on the global economy since 2019. In response to the COVID-19 pandemic, governments across the world imposed travel restrictions and/or lockdown to contain its transmission. While most of the mandatory lockdowns, closure of workplaces and restrictions on mobility and travel in response to the COVID-19 pandemic were lifted around the world in 2022, there is still uncertainty as to the future impact of the virus.

During the Track Record Period and up to the Latest Practicable Date, the COVID-19 pandemic did not have any material adverse effect on our results of operations and financial position. However, if the COVID-19 pandemic becomes more severe and/or new variants of COVID-19 evolve to be more transmissible and virulent than the existing strains, it may lead to further disruption of economic activities. For example, the governments across the world may resume restrictions on traveling and transportation, and our suppliers may be forced to close down due to prolonged disruptions. If that happens, we may experience a material delay or shortage of raw materials. Further, the COVID-19 pandemic may cause early termination of our clinical activities or delay in enrolling patients for our clinical trials, which may in turn slow the process of our R&D activities. In addition, in the event of any new waves of the COVID-19 pandemic, some or all of our employees may be affected and/or quarantined thus causing a shortage of labor and we will be required to disinfect our workplace and our production and processing facilities. As a result, with the potential disruption of various aspects of our business, including R&D activities, manufacturing activities, supply chain and marketing, we cannot assure you that the resurgence of the COVID-19 pandemic will not have a material and adverse effect on our business, financial condition and results of operations.

Our business and results of operations are affected by changes in regional and global economic conditions.

We are a global organization conducting R&D and manufacturing activities on three continents and selling products worldwide. Our business is affected by the global economy and the economic conditions of the countries and regions where we operate. Any adverse economic developments, whether as a result of a global recession or a local recession or economic downturn in one or more of our principal markets, credit and capital markets volatility, an economic or financial crisis, or otherwise, could result in reduced consumption or sales prices of our products, which in turn could result in lower revenue and reduced profit.

Furthermore, the economies of the developing markets in which we operate may be negatively affected by changes in government policies, changes in the relations between countries and changes in law and regulations, among others. Operating in developing markets also involves financial risks such as illiquidity, inflation, devaluation, price volatility, currency convertibility and country default. Our results of operations may be materially and adversely affected if such factors cause interruptions to our operations, increase the costs of operating in those countries or limit our ability to repatriate profits from those countries.

Fluctuations in foreign currency exchange rates may lead to volatility in our results of operations.

We presented our consolidated results in U.S. dollars during the Track Record Period, but we derived a vast majority of our revenue from markets that have non-U.S. dollar functional currencies. In particular, the majority of our revenue was generated from our sales of products in European countries using the euro. Similarly, our cost of sales and various costs and expenses were originally denominated in various local currencies such as the euro but reported in U.S. dollars in our financial statements. Consequently, changes in exchange rates between non-U.S. dollar functional currencies, especially the euro, and the U.S. dollar could affect our consolidated income statement and balance sheet. The effect could be significant and result in great volatility in our results of operations if the relevant exchange rates experience significant fluctuations, as was the case for the Track Record Period. For example, from 2021 to 2022, our revenue from sales of medical devices in Europe, Middle East and Africa (EMEA), China and Japan, reported in U.S. dollar terms, decreased by 8.7%, 2.6% and 12.5%, respectively, whereas excluding the impact of foreign exchange fluctuations such revenue would have increased by 2.5%, 8.4% and 6.2%, respectively. We cannot assure you that the fluctuations in foreign exchange rates will not continue to have an adverse impact on our financial statement presentation in the future.

In addition, we translate statement of profit or loss items into U.S. dollars at the exchange rates approximating the foreign exchange rates on the respective translation dates, and translate statement of financial position items into U.S. dollars at the closing foreign exchange rates at the end of the reporting period. The resulting exchange differences resulted in the recognition of US$0.9 million and US$16.3 million translation of foreign operations losses in other comprehensive income reserves in 2021 and 2022, respectively.

We may encounter difficulties in managing the expansion of our operations successfully.

As our development and commercialization plans and strategies evolve, we may need to recruit a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel globally. As our operations expand, we expect that we will need to manage additional relationships with distributors, suppliers and other third parties. Our expansion will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop and commercialize our products and product candidates and to compete effectively will depend, in part, on our ability to effectively manage our expansion, as it may divert a substantial amount of our management's attention away from day-to-day activities.

If we are not able to effectively manage our growth, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and product candidates and, accordingly, may not achieve our research, development and commercialization goals. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our Company.

We received government grants and subsidies for our R&D activities and benefited from certain preferential tax and financial incentives. We may not receive such grants or subsidies in the future and the preferential tax and financial incentives may expire.

During the Track Record Period, we enjoyed a research tax credit, CIR (*crédit d'impôt recherche*), from the French government to support research and development projects in the amount of US$4.5 million, US$5.0 million and US$3.8 million in 2020, 2021 and 2022, respectively. Our eligibility for such preferential tax treatment is dependent on a variety of factors, including relevant government policies, the assessment of our improvement on existing technologies, the availability of funding at different granting authorities and the R&D progress made by other peer companies. In addition, the policies according to which we historically enjoyed the preferential tax treatment may be halted by the relevant government entities at their sole discretion. There is no assurance that we will continue to receive such tax credit or receive similar level of tax credit, or at all, in the future. In the event that any of the preferential tax treatment currently enjoyed by us is reduced, discontinued or withdrawn by the government authorities, our results of operations and growth prospects may be materially and adversely affected.

Our future success depends on our ability to retain key senior management, key clinical and scientific personnel and a stable skillful manufacturing workforce. If we are unable to recruit, hire and retain qualified personnel, our ability to effectively manage our operations and meet our strategic objectives may be harmed.

We may experience difficulties in attracting and retaining qualified employees. Competition for qualified employees in the medical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of our senior management or key clinical and scientific personnel, or attract and retain experienced senior management or key clinical and scientific personnel in the future. If one or more of our senior management or key clinical and scientific personnel are unable or unwilling to continue in their present positions or joins a competitor or forms a competing company, we may not be able to replace them in a timely manner, or at all, and our product development progress may be disrupted as a result, which will have a material and adverse effect on our business and results of operations. In addition, we will need to hire additional employees as we expand our commercialization and manufacturing teams. We may not be able to attract and retain qualified employees on acceptable terms, or at all. Our business and growth depend on the continued service of our senior management and personnel in our R&D team to develop product candidates and

our sales and marketing team to promote our products. Although we have formal employment agreements with our employees, these agreements do not prevent them from terminating their employment with us at any time.

The fair-value changes of our financial liabilities due to the issuance of Convertible Bonds are subject to uncertainties in accounting estimation.

In October 2022, we issued Convertible Bonds with an aggregated principal amount of US$130.0 million, which we designated as financial liabilities at fair value through profit or loss in our financial statements for the year ended December 31, 2022. We incurred a fair value loss on the Convertible Bonds of US$5.6 million in 2022 due to fair-value changes. The Convertible Bonds are categorized as Level 3 financial liabilities. The Convertible Bond's estimated changes in fair values involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. Please also see Note 29(d) to the Accountants' Report in Appendix I to this document for more information about the fair value measurement of the Level 3 valuations. As such, the financial liabilities valuation has been, and will continue to be, subject to uncertainties in accounting estimation, which may not reflect actual fair value of these financial liabilities and result in significant fluctuations in profit or loss from year to year.

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

We generally grant credit terms between 60 and 90 days to our customers, including direct sales customers and distributors. As of December 31, 2020, 2021 and 2022, we had trade receivables of US$44.3 million, US$43.6 million and US$38.5 million, respectively, which was net of allowance for doubtful debts of US$6.3 million, US$5.7 million and US$4.8 million, respectively. The average turnover days of our trade receivables for 2020, 2021 and 2022 were 96 days, 73 days and 73 days, respectively. If our customers' cash flows, working capital, financial condition or results of operations deteriorate, they may be unable or unwilling to pay trade receivables owed to us promptly, or at all. Any substantial defaults or delays could materially and adversely affect our cash flows, and, if the defaulting party is one of our distributors, we may need to terminate our relationships with distributors in a manner that will impair the effective distribution of our products.

Our failure to honor our obligations in respect of our contract liabilities may lead to our refund obligation, customer dissatisfaction, or even customer disputes with us, which may adversely affect our reputation, business, results of operations and financial condition

As of December 31, 2020, 2021 and 2022, our contract liabilities amounted to US$40.6 million, US$37.9 million and US$33.6 million, respectively. Our contract liabilities represent our unfulfilled performance obligations for post-implantation services when payments from our customers for such services are received in advance. If we fail to fulfill our obligations under our contracts with customers, we may not be able to convert such contract liabilities into revenue, and our customers may also require us to refund their payment we have received, which may adversely affect our cash flow and liquidity condition and our ability to meet our working capital requirements and, in turn, our results of operations and financial condition. In addition, if we fail to fulfill our obligations under our contracts with customers, it may also adversely affect our relationships with such customers, which may in turn affect our reputation and results of operations in the future.

We have entered into collaborations, and may establish or seek collaborations in the future, and we may not timely realize the benefits of such collaborations.

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

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

Our Controlling Shareholders have and may continue to have substantial influence over our Company after the completion of the* [REDACTED]*, and their interests may not be aligned with the interest of our other Shareholders.

Our Controlling Shareholders have substantial influence over our business, including matters relating to our management, policies and decisions regarding acquisitions, mergers, expansion plans, consolidations and sales of all or substantially all of our assets, election of Directors and other significant corporate actions. Immediately after completion of the **[REDACTED]**, assuming none of the Convertible Bonds is converted and the **[REDACTED]** is not exercised, our Controlling Shareholders will hold (including direct and indirect shareholdings) approximately **[REDACTED]**% of the issued share capital in our Company. Our Controlling Shareholders will, through their voting power at Shareholder meetings and their delegates on the Board, have substantial influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional Shares or other equity securities, timing and amount of dividend payments, and our management. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of our Controlling Shareholders may differ from the interests of our other Shareholders. It is possible that our Controlling Shareholders may exercise their substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

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

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products and product candidates and regulatory approvals; and/or
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

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

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. If any verdict or award is rendered against us or if we settle with any third parties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business projects. Ongoing or threatened litigation, legal or contractual disputes, investigations or administrative proceedings may divert our management's attention and consume their time and our other resources. Furthermore, any litigation, legal or contractual disputes, investigations or administrative proceedings which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. In addition, negative publicity arising from litigation, legal or contractual disputes, investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

Our internal IT systems may fail or suffer security breaches.

Our internal IT systems are vulnerable to damage from computer viruses and unauthorized access. If any material system failure or security breach occurs and causes interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our data utilizing on-site systems and outsourced vendors. These data encompass a wide variety of

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

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our Company and our vendors, including personal information of our employees and patients, and other confidential data of our Company. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes are costly and require ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

Our insurance coverage may not completely cover the risks relating to our business and operations.

Our operations are subject to hazards and risks associated with our research and manufacturing operations, which may cause significant harm to persons or damage to property. We maintain insurance policies that are required under the jurisdictions where we operate as well as based on our assessment of our operational needs and industry practice. However, there is no assurance that our insurance policies will cover all the fields we could incur losses. While our insurance policies cover

product liability, we may still be subject to product liability claims which are not covered by insurance. In addition, even though we maintain insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Losses incurred and associated liabilities may have a material adverse effect on our results of operations if such losses or liabilities are not covered by our insurance policies.

Negative publicity and allegations involving us, our Controlling Shareholders, Directors, officers, employees, affiliates and business partners may affect our reputation and, as a result, harm our business, financial condition and operations.

We, our Controlling Shareholders, Directors, officers, employees, affiliates and business partners may be subject to negative publicity in the future. Such negative publicity could affect our reputation. If our employees, distributors, sub-distributors, suppliers or other parties we cooperate with are non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. In addition, any unauthorized use of our brand name by any third parties may also adversely affect the value of our brand, reputation and business. Therefore, we may have to spend substantial time and cost to address negative publicity, allegations and legal actions including litigation to enforce our rights to our brand name, and may not be able to diffuse them to the satisfaction of our investors, customers, hospitals and physicians. Our business, operation results and financial condition may be materially and adversely affected as a result of such damage to our reputation and the diversion of our limited sources.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

Our commercial success will partially depend on our ability to obtain, maintain and enforce our intellectual property rights, including patent rights to protect our proprietary technology, products and product candidates. We seek to protect the technology, products and product candidates that we consider commercially important by filing patent applications in Western Europe and other commercially important countries and regions, as well as relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost 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 later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our product candidates, or otherwise provide us with any competitive advantage. 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 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. 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 have applied for may not be granted 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 product candidates may have an 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 employees, consultants, advisers 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.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices of the countries and regions we file in, such as Western Europe, China, Japan and the United States. Moreover, we may have to participate in interference proceedings declared by intellectual property offices of such countries and regions to determine priority of invention or in post-grant challenge proceedings that challenge the patentability of our patents. 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 scope of the patent protection of our technology, products and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. Consequently, we do not know which aspects of our technologies, products or product candidates may not be protectable or remain protected by valid and enforceable patents.

Furthermore, the life of a patent and the protection it affords is limited. We may face competition for any approved product candidates even if we successfully obtain patent protection once the patent life has expired for the patented aspect(s) of the product. The issued patents for our products and product candidates are expected to expire on various dates. Upon the expiration of our issued patents, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. 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.

We may not be able to protect our intellectual property rights.

As of December 31, 2022, we had 1,017 patents and 166 pending patent applications. All of the material patents that we owned or applied for are self-developed. Filing, prosecuting, maintaining and

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

In addition, as of December 31, 2022, we had 136 trademarks and 3 trademark applications pending. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names and may not be able to build name recognition in our markets of interest, which may materially and adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks that infringe, dilute or otherwise violate our trademark rights, our business could be adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in countries where the legal framework for IP rights is developing. The legal system in these countries could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights in these countries. Proceedings to enforce our intellectual property and proprietary rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our products and product candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, external advisers, consultants, advisers and other third parties. We also enter into employment or consulting agreements with our employees and consultants that include undertakings regarding assignment of inventions and discoveries. However, any of these parties may breach such agreements and disclose

our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim against a party that has 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 are lawfully obtained or independently developed by a competitor, we may not be able to prevent them from using that technology or information to compete with us and our competitive position may be harmed.

We may be subject to claims that we or our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. 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 and consultants involved in the development of intellectual property to execute agreements assigning such intellectual property 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 management and scientific personnel.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and may delay us from developing or commercializing our product candidates. Our patent rights relating to our products and product candidates may be found invalid or unenforceable if challenged.

Competitors may infringe on our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Third parties may also raise similar claims before administrative bodies in the jurisdictions where we operate, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our products or product candidates. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, in the case of willful infringement, pay royalties or redesign our infringing product candidates, which may be impossible or require

substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may be subject to injunctive or other equitable relief and need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Any such license might not be available on reasonable terms, or at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the **[REDACTED]** of our Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If third parties successfully claim that we infringe upon their intellectual property rights, or if they engage us in expensive litigation, we may incur liabilities and financial consequences and may have to redesign or discontinue selling the affected products.

Companies operating in our industry routinely seek patent protection for their products, and many of our principal competitors have large patent portfolios. Similar to companies in other industries, medical device companies are known to use intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves the analysis of complex legal and factual issues, the determination of which is often plagued by uncertainty. We may face the risk of allegations that we have infringed on third parties' intellectual property rights in the countries and regions where we operate. In addition, a number of our employees have previously worked for one or more of our competitors. There can be no assurance that such employees have not used, or will not use in the future, their previous employers' proprietary know-how or trade secrets in their work for us which could result in litigation against us. Prior to developing major new products, we seek to evaluate existing relevant third-party intellectual property rights. However, our competitors may also have filed for patent protection which is not as yet a matter of public knowledge at the time of our evaluation, or claim trademark rights that have not been revealed through our searches of relevant public records. Therefore, our efforts to identify prior art and to limit the risk of infringing on third parties' intellectual property rights may not always be successful. Moreover, in the event that our competitors initiate malicious lawsuits or wrongful legal procedures, defending these claims, regardless of their merit, would involve substantial litigation expense and may be a substantial diversion of resources from our business. Any claims of patent or other intellectual property infringement, even those without merit, could:

- be expensive and time-consuming to defend;
- result in us being required to pay significant damages to third parties;

- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, if feasible;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management; or
- result in hospitals and physicians terminating, deferring or limiting their purchase of the affected products until resolution of the litigation.

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

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

Changes in either the patent laws or their interpretation in the jurisdictions where we operate may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any future granted patents will provide sufficient protection from competitors. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance.

RISKS RELATING TO GOVERNMENT REGULATION

The research, development and commercialization of our products are heavily regulated in all material aspects and, given our worldwide geographical presence, compliance with different regulations in the various jurisdictions where we operate is time-consuming and costly.

All jurisdictions in which we conduct our research, development and commercialization activities regulate these activities in great depth and detail. These geopolitical areas all have comprehensive regulation 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 regions, which make regulatory compliance more complex and costly for companies like us that plan to operate in each of these regions.

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

We are exposed to regulatory risks associated with operating in highly regulated markets across the world, including Western Europe, United States, China and Japan, among others.

The medical devices that we manufacture and market are subject to regulation by numerous regulatory bodies worldwide, including the local competent authorities of EU member states, the NMPA, the MHLW, the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations through regulatory approval, license renewal and compliance monitoring, governing various areas of business operation, including development, testing, manufacturing, labeling, marketing and distribution. Medical devices are also generally subject to varying levels of regulatory control based on risk level of the device.

Regulatory approval

Before we can launch or maintain new products on the market, we are required to obtain approvals or certifications from the governments, competent authorities or bodies of every country where we operate, such as the local competent authorities of EU member states, the NMPA, the MHLW and the FDA. The process of obtaining approvals from the regulatory agencies is typically lengthy and expensive, and could involve rigorous preclinical and clinical testing. Further, the approvals are not guaranteed. There is no assurance that all of our new products will be timely approved by the relevant regulatory agencies for entering into the market or that the approvals will not be significantly qualified.

Renewal of licenses

Most regulatory bodies in countries where we operate require that product approvals be renewed or recertified on a regular basis, generally every four to five years. The renewal or recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct and document appropriate testing for continued compliance. Where renewal or recertification applications are required, the relevant applications may need to be submitted and approved in order for us to continue selling our recertification products in those countries. We cannot assure that we will timely obtain the required renewal or recertification approvals or that the renewal approvals will not be significantly qualified.

Compliance monitoring

The competent local authorities of EU member states and other regulatory agencies worldwide actively monitor compliance with local laws and regulations through review and inspection of design and manufacturing practices, recordkeeping, reporting of adverse events, labeling and promotional practices.

For example, in the European Union, the competent authorities of each EU member state are required to perform appropriate checks on the conformity characteristics and performance of devices, including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk where they deem it necessary to do so for public interests. Similarly, in China, according to the Measures for Supervision and Administration of Medical Device Production (《醫療器械生產監督管理辦法》), if the local medical device administration finds that the relevant manufacturer fails to timely adopt measures to eliminate hidden risk of product quality in the production process, the medical product administration may issue a warning, request an accountability interview or order rectification within a limited period of time, among others. For medical devices that have caused harm to any human body or may endanger human health, the relevant medical product administration may take emergency control measures to suspend production, import, operation or use of the relevant devices or release a safety warning.

In countries such as Japan and the United States, relevant authorities such as the MHLW and the FDA can ban certain medical devices, detain or seize adulterated or misbranded medical devices, order repair, replacement, refund or recall of these devices and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. Any adverse regulatory action, depending on its magnitude, may restrict a company from effectively marketing and selling its products, may limit a company's ability to obtain future premarket clearances or approvals and could result in a substantial modification to our business practices and operations.

Further, in the Dominican Republic, the Dominican Ministry of Health surveils and oversees the commercial activities related to these regulated activities. It has the authority to suspend or revoke the authorizations and grant permits due to serious sanitary infringements, such as confirmed quality deficiencies on the product that could result in undisclosed side effects. See "Regulatory Overview—Governmental Regulations Applicable to Our Products—Laws and Regulations Specific to Medical Devices" for details about medical device regulation in our principal markets.

We may not be able to obtain, or experience delays in obtaining, required regulatory approvals.

Obtaining regulatory approvals is a lengthy, expensive and uncertain process, and approvals may not be obtained. When we submit a filing application to the regulatory authorities, the regulatory authorities will decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the regulatory authorities. In addition, the time required to obtain approval from the regulatory authorities is unpredictable but typically takes years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. It is possible that none of our existing product candidates or any product candidates we may develop, in-license or acquire and seek to develop in the future will ever obtain such approval.

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

- failure to begin or complete clinical trials;
- failure to demonstrate that a product candidate is safe and effective;
- failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- encountering data integrity issues related to our clinical trials;
- encountering regulatory authority's disagreement with our interpretation of data from preclinical studies or clinical trials;
- the finding of deficiencies related to the manufacturing processes or facilities from regulatory authorities;
- 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; and
- regulatory requests for additional analysis, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our product candidates or other products.

Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products. Obtaining regulatory approval in one country does not necessarily mean that regulatory approval will be obtained in any other country. For example, certain jurisdictions may have more stringent requirements on clinical trials and clinical data than those of the local competent authorities of EU member states or the NMPA. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval in such emerging countries could require additional nonclinical studies or clinical trials, if required by the local authorities, which could be costly and time-consuming. For these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. If we are unable to obtain regulatory approval for our products 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 products will be materially and adversely affected.

Recently enacted and future legislation and regulations may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect their prices.

In the countries and regions where we operate, 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. In recent years, there have been and will likely continue to be efforts to enact administrative or legislative changes to healthcare laws and policies, including measures which may result in more rigorous coverage criteria and downward pressure on the price that we receive for any approved product. For example, the countries and regions where we operate may be affected by economic pressure to contain healthcare costs, which can lead to more rigorous evidence requirements and lower reimbursement rates for either our products directly or procedures in which our products are used. Governments and third-party payors may also institute changes in healthcare delivery systems that may reduce funding for services or encourage greater scrutiny of healthcare costs. Such cost containment measures or other healthcare reforms may ultimately reduce selling prices of our products and/or reduce the number of procedures in which our products are implanted, which may adversely impact our net sales, market share and operating profits from our international operations.

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 the regulations, guidance or interpretations related to the local competent authorities of EU member states or other regulatory approvals necessary for our operations, will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. For example, in the European Union, the MDR amended the previous regulatory regime for medical devices by introducing new classification rules, new provisions on the clinical evaluation and clinical investigations, and provided additional post-market surveillance obligations which significantly increase the regulatory burden for manufacturers of medical devices.

For instance, under Italian law, an annual budget has been established at the national and regional level for purchasing medical devices by public hospitals and entities. In 2015, Italy enacted a clawback law that, if the purchase amount exceeds the relevant public expenditure ceiling, medical device companies selling those relevant products to public hospitals and entities are required to bear part of the relevant costs and pay back an amount of money proportional to the sales made to the various regions and autonomous provinces in which the expenditure ceiling was exceeded. In 2022, the Italian government issued invoices retrospectively for the years between 2015 and 2018, and as of December 31, 2022, it had not yet issued invoices for the years between 2019 and 2022 as the clawback law for the years through 2019 and 2022 had not been enforced. As such, we have assessed our potential exposure and recorded provisions accordingly. Our total reserve for the Italian clawback was US$7.2 million as of December 31, 2022, of which US$1.5 million (representing the clawback for 2022) was deducted from our revenue in 2022 and the remaining US$5.7 million (representing the clawback for the years between 2015 and 2021) was recorded in other operating costs in 2022. The Italian clawback law may continue to adversely impact our revenue and operating profits in the future. See "Regulatory Overview—Compliance Monitoring—Italy" and "Financial Information—Description of Certain Items in the Consolidated Statements of Profit or Loss—Other Operating Costs" for details.

Similarly, in China, the revised Regulations on the Supervision and Administration of Medical Devices (修訂後的《醫療器械監督管理條例》) came into effect on June 1, 2021 and the revised Administrative Measures for the Registration and Recordation of Medical Devices (修訂後的《醫療器械注冊與備案管理辦法》) came into effect on October 1, 2021, the requirements of clinical trials, sales and regulation of medical devices have changed in some aspects. For details, see "Regulatory Overview—Laws and Regulations Specific to Medical Devices—China—Classified Supervision over Medical Devices." The impact of these more specific requirements and whether they will adversely affect the registration of our products with the NMPA are yet to be observed. If we or parties on whom we rely fail to maintain the necessary licenses for the development, production, sales and distribution of our products, our ability to conduct our business could be materially impaired.

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 patients who use our products and other personal or sensitive information.

We have access to certain data of medical institutions and individual patients from our clinical trials and our remote monitoring for after-sale product performance. As such, we are subject to the 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. 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.

In EU member states, we are subject to the GDPR, which regulates the collection, use, disclosure, transfer and all other processing of personal data of identified or identifiable individuals located in the European Economic Area, including the European Union. See "Regulatory Overview—General Data Protection Regulation" for details. In France, with regards to data protection, in addition to the GDPR, clinic trial sponsors are also subject to a specific legal framework. In particular, in order to conduct clinical trials and studies, sponsors need to make a declaration of conformity before the French data protection authority, namely the National Commission on Informatics and Liberty (*Commission nationale de l'informatique et des libertés*, the "CNIL"). If any such provisions are not complied with, the sponsor must seek an authorization from the CNIL to carry out the trial/study. Some of these methodology of references restrict the transfer of personal data, such as the data related to patients' identities, to areas outside the EU. Similarly, in Italy, clinical trial sponsors and operators are required to comply with the provisions of applicable data protection laws and regulations, including the GDPR, the Italian Data Protection Code (Legislative Decree No. 196/2003) and applicable guidelines issued by the Italian Data Protection Authority, including Guidelines for Data Processing within the Framework of Clinical Drug Trials. Such data protection regime imposes obligations to inform patients and subjects enrolled in clinical trials about the purposes and modalities of the data processing as well as to obtain their prior consents. In Spain, as we sell implantable CRM devices, we have access to personally identifiable data recorded on the implantation cards that we must provide for each medical device that is implanted in a Spanish healthcare center. In this regard, we shall process said health data in compliance with the stringent requirements set forth in the GDPR and the implementing Spanish legislation. Any non-compliance with the law and regulations in any of the above areas or countries may result in administrative sanctions as well as criminal or civil liability.

Certain laws and regulations may also affect the collection and transfer of personal data in China, including the Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》), the Personal Information Protection Law of the People's Republic of China (《中華人民共和國個人信息保護法》), the Biosecurity Law of the People's Republic of China (《中華人民共和國生物安全法》) and the Regulation of the People's Republic of China on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》).

In the Dominican Republic, Dominican Data Protection Law, No. 172-13, classifies personal health data as highly sensitive information, which may only be collected or stored by third parties upon free and conscious consent of its owners. Otherwise, such data may only be collected and treated by third parties based on general interest grounds. Sensitive information may be used for statistic or scientific purposes if disaggregated. Besides these general rules, there are no special provisions that concern clinical trials or other medical or scientific studies.

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.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects' private or medical records without their consent, they will be held liable for damage caused thereby. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. 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 including hospitals, CROs and other third-party contractor and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure.

It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our clinical trial practices, potentially resulting in confiscation of relevant data and administrative fines. 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 change 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 could 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.

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

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.

We are required to comply with a comprehensive set of national and European laws and regulations concerning anti-bribery and corruption. In France, we are subject to the French Anti-gift law, French Sunshine Act and Sapin 2 Law. According to the applicable Italian laws, companies that carry out activities in Italy, including foreign companies, are subject to the applicability of Legislative Decree 231/2001. In Spain, we are subject to the Royal Legislative Decree 1/2015 and the Royal Decree 1591/2009.

The laws in Western Europe may impact, among other things, our research and development 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 governments of the relevant countries.

In China, we are subject to the Criminal Law of the PRC （《中華人民共和國刑法》）, the Law of the People's Republic of China Against Unfair Competition (《中華人民共和國反不正當競爭法》), Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and the Administrative Measures for the Registration and Recordation of Medical Devices (《醫療器械注冊與備案管理辦法》).

In Japan, we are also subject to the Unfair Competition Prevention Act (Act No 47 of 1993) and the Penal Code (Act No 45 of 1907) that prohibits the offering of a bribe to domestic public officials and persons to be appointed public officers, as well as the acceptance of the bribe by the aforementioned persons.

In the Dominican Republic, under Dominican Health Law, the commercialization of a medical device in poor condition, with defects or without a proper label that identifies its nature or characteristics, is considered a criminal offense that can be punished with 15 days to a year in prison, and administrative fines.

We may also be subject to the Foreign Corrupt Practices Act of the United States and the Bribery Act of the United Kingdom. Under the Foreign Corrupt Practices Act, it is unlawful for a foreign company to cause, directly or through agents, an act in furtherance of such corrupt payment to take place within the territory of the United States. Under the Bribery Act, a foreign company which carries on any part of its business in the UK could be prosecuted for failure to prevent bribery even where the bribery takes place wholly outside the UK and the benefit or advantage to the company is intended to accrue outside the UK. See "Regulatory Overview—Anti-Bribery and Corruption" for details about anti-bribery and corruption law in our principal markets.

In certain jurisdictions where we operate, the government has not provided definitive guidance on the applicability of fraud and abuse laws to our business. The interpretation of these laws may also be subject to change. As a result, our business practices may from time to time be found to be not in compliance 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.

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

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

Although we maintain employment injury insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain

insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Centralized procurement programs in China may adversely affect our products' prices and reduce our profitability.

In 2019, China started to initiate pilot programs of centralized procurement in an effort to regulate the prices of medical devices through group procurement at the provincial level. Pursuant to a series of official documents and communications (such as the National Medical Insurance Plan under the 14th Five-Year Plan promulgated in September 2021), the implementation of centralized procurement may be expected to be further expanded. As of the Latest Practicable Date, according to Frost & Sullivan, (i) our China-made and imported pacemakers were subject to centralized procurement in most provinces in China, (ii) our *Beflex* lead was subject to centralized procurement in the Anhui, Guangdong, Jiangxi, Hubei and Guizhou provinces, and (iii) our recently approved ICD device, *Platinium*, would be subject to centralized procurement in Guangdong, Jiangxi, Hubei and Guizhou provinces, but had not been sold in China as of the Latest Practicable Date. See "Business—Recent Evolvements in the PRC Regulatory Environment—Centralized Procurement." We cannot be sure whether our other products will also be covered in the future. If our products are covered by centralized procurement in the future, the price of our products in the relevant provinces may decrease, which could harm our results of operations.

RISKS RELATING TO DOING BUSINESS IN COUNTRIES AND REGIONS IN WHICH WE OPERATE

Changes in the political, social and economic policies and conditions of the countries and regions where we operate may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

As we operate in multiple countries and regions around the world, our operations are subject to a number of market, business and financial risks and uncertainties, including those related to geopolitical and economic instability, foreign currency exchange and interest rate fluctuations, competitive product offerings, local changes in healthcare financing and payment systems and healthcare delivery systems, local product preferences and requirements, including preferences for local manufacturers, workforce instability, weaker intellectual property protection in certain countries and longer accounts receivable cycles. Such risks and uncertainties may adversely impact our ability to implement our growth strategy in these markets and, as a result, our sales growth, market share and operating profits from our international operations may be adversely affected.

Changes to and uncertainties in laws and regulations applicable to our business operations, including those related to environmental protection, occupational health and safety, labor rights, social security, anti-corruption, anti-money laundering, export control and economic sanctions, may negatively affect our results of operations.

We are subject to various and burdensome laws and regulations which mainly relate to environmental protection, occupational health and safety, labor rights, social security, organizational and management control and tax positions and interpretations. In addition, we are also required to comply with applicable anti-corruption, anti-money laundering, export control and economic sanctions laws and regulations. In particular, because we are a global organization doing business in many countries around the world, we cannot assure you that our business will be free of sanction risks in the countries subject to sanctions by the U.S., EU, United Nations or any other governments or organizations who impose sanctions on an extraterritorial basis. Further, as many sanction programs are constantly evolving, new requirements or restrictions could come into effect, which requires us to constantly update our sanctions compliance analyses on a global basis. Any violation of applicable anti-corruption, anti-money laundering, sanctions or other laws or regulations could result in governmental or regulatory investigations, civil or criminal fines or other sanctions, whistleblower complaints and adverse publicity, which could have an adverse effect on our reputation, business, operating results and prospects. Responding to any enforcement action may also result in a significant diversion of management's attention and significant defense costs and other professional fees.

The permits and licenses required to carry out our business may be subject to periodic renewal, modification, suspension or revocation by the relevant authorities. In the event of expansion of our business, we may also be required to obtain additional permits and licenses. Any failure by us to obtain, keep current, comply with or modify on a timely basis all of the permits and licenses that we need to carry out our business, or any suspension or revocation of such permits and licenses, could have a material adverse effect on our business, results of operations and financial condition.

Environmental Protection Laws and Regulations in Western Europe

We are subject to laws and regulations relating to the use, disposal and remediation of hazardous substances in Western European countries, including France, Italy and Spain. See "Regulatory Overview—Environmental Protection" for details. We will continue to face ongoing costs and liabilities in connection with environmental laws and regulations. Moreover, if any violation of environmental protection laws and regulations rises to the level of criminal violation, the judicial authorities in France and Italy could order the seizure or shutdown of the sites linked to such violations, which could force us to interrupt our production process. In Spain, regardless of whether the action constitutes a criminal or administrative infringement, authorities could also order the temporary or definitive seizure or shutdown of the sites linked to such violation if there is a serious danger or harm to the health of people or to the environment. In addition, any new laws and regulations regarding increased fuel economy requirements, reduced greenhouse gas or pollutant emissions that may be promulgated in the future, or any changes in existing laws and regulations, may expose us to significant costs.

Occupational Health and Safety Laws and Regulations in Western Europe

We are required to comply with a comprehensive set of national and European laws and regulations concerning the protection of occupational health and safety and the prevention of industrial accidents in Western European countries, including France, Italy and Spain. For example, in France, if a court finds that an accident or a disease that happened to our employees was work-related, that may effect the work-related accident and disease contribution rate paid by our Company. There may also be additional liability on us if a court finds that, as an employer, we have committed inexcusable fault (*faute inexcusable de l'employeur*) which led to the work-related accident or disease of our employee. The occurrence of such accidents or diseases could expose us to significant litigation, enforcement actions, legal sanctions (including but not limited to fines, suspensions of our production activities and limitations on our commercial activities), reputational harm, management distraction and, potentially, corporate criminal liabilities.

Labor Laws in Japan

Our relationships with our employees in Japan are governed by various Japanese labor laws. These laws include minimum wage requirements, employer contributions to social security, unemployment insurance and workers' accident compensation insurance, and other wage and benefit requirements. Significant additional government regulations and new laws or other labor law changes could have a material adverse effect on our business, financial condition and results of operations. Additionally, if our employees unionize, it could also have a material adverse effect on our business, financial condition and results of operations.

In the ordinary course of our business, we may also be subject to employee claims against us based on alleged discrimination, harassment, wrongful termination or violation of labor laws, among other things. These claims may divert our financial and management resources that would otherwise be used to benefit our operations. The ongoing expense of any resulting lawsuits and any substantial settlement payment or damage award against us could have a material adverse effect on our business, financial condition and results of operations, and on our brand image and employee recruitment as well.

We may be subject to natural disaster, acts of war or terrorism or other factors beyond our control.

Natural disasters, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. For example, the Russo-Ukraine conflict and resulting sanctions and export restrictions are adversely impacting global energy prices and supply, particularly for crude oil and natural gas, as well as creating barriers to doing business in Russia. These sanctions or forthcoming sanctions upon taking effect could have negative impact on the general economic conditions in Europe and globally, which may in turn affect our business and results of operations.

There are uncertainties regarding the interpretation and enforcement of laws, rules and regulations in certain countries such as China.

China is one of our principal markets, and our operations in China are governed by PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value. Since 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past three decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the non-binding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis, or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

Governmental control of currency conversion, and restrictions on the remittance of renminbi into and out of China, may adversely affect the value of your investment.

The renminbi is not currently a freely convertible currency, as the PRC government imposes controls on the convertibility of renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. China is one of our principal markets and we have established a subsidiary in China, MicroPort CRM Shanghai. Our PRC subsidiary will need to convert renminbi into foreign currencies for the payment of dividends, if any. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under China's current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from China's State Administration of Foreign Exchange (the "SAFE"). Approval from appropriate government authorities is required where renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The PRC government may also at its discretion restrict access in the future to foreign currencies for current account transactions. Since 2015, in response to China's declining foreign

currency reserves, the PRC government has placed increasingly stringent restrictions on the convertibility of the renminbi into foreign currencies. Further, there is no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of renminbi into or out of China. As such, we may be required to make additional efforts and satisfy additional requirements in order to comply with the necessary regulatory requirements.

Furthermore, a PRC enterprise is permitted to declare and repatriate dividends on profits after tax based on PRC Accounting rules provided that the losses of such enterprise have been remedied and amounts for mandated reserves have been deducted. The mandated reserves include (i) statutory common reserve funds, which is 10% of after-tax profits of each company (totaling up to 50% of the registered capital of each such company), and (ii) discretionary common reserve funds.

These reserve funds, if put aside discretionally by a shareholder meeting or compulsorily by law, cannot be repatriated even if an enterprise has no losses or likely prospects of losses, or even if the reserve funds are not needed for their prescribed purposes. These reserves could potentially create a significant pool of trapped cash that cannot be used to pay dividends. If there are insufficient retained profits after tax after deducting these reserves, the amount of dividends that our PRC subsidiary can declare will be limited, which may adversely affect our business, financial conditions and results of operations.

Changes in international trade policies and trade barriers, or the escalation of trade tensions, may have an adverse effect on our business.

Our operations may be negatively affected by international trade policies and trade barriers administered by the government authorities in the countries in which we operate, including, but not limited to, sanctions and export controls, economic and labor conditions, increased duties, taxes and other costs and political instability. Margins on sales of our products and services in certain countries and on sales of products that include components obtained from certain foreign suppliers could be materially and adversely affected by international trade regulations, including duties, tariffs and antidumping penalties. For example, the U.S. government imposed economic and trade sanctions directly or indirectly affecting China-based companies. For details, see "—The political relationships between China and other countries may affect our business operations." Such laws and regulations are likely subject to frequent changes, and their interpretation and enforcement involves substantial uncertainties, which may be heightened by national security concerns or driven by political and/or other factors that are out of our control. Therefore such restrictions, and similar or more expansive restrictions that may be imposed by the jurisdictions where we operate in the future, may be difficult or costly to comply with and may materially and adversely affect our abilities to acquire technologies, systems, devices or components that may be critical to our technology infrastructure, service offerings and business operations.

The political relationships between China and other countries may affect our business operations.

In 2020, 2021 and 2022, revenue from our sales in China accounted for 4.4%, 5.9% and 6.2% of our total revenue, respectively. During the Track Record Period, some of our products sold in China were manufactured in our manufacturing facilities in Europe and the Dominican Republic and imported to China, and some were manufactured in our manufacturing facility in Shanghai whose raw materials and components were largely imported from foreign countries and regions. Therefore, our

business is subject to constantly changing international economic, regulatory, social and political conditions. Tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects.

For example, our manufacturing facility in Shanghai relies on certain suppliers located in the United States. In the event that China and/or the United States impose import tariffs, trade restrictions or other trade barriers affecting the importation of such components or raw materials, we may not be able to obtain a steady supply of necessary components or raw materials at competitive prices, and our business and operations may be adversely affected. Since 2018, there have been ongoing trade tensions between the United States and China. There remains much uncertainty as to how the trade tensions between the United States and China will progress. If the trade tensions continue or escalate, our revenue from our sales and profitability in China may be materially and adversely affected, which may in turn affect our Company's business, results of operations and financial condition.

In addition, China's political relationships with certain foreign countries and regions may affect the prospects of our relationships with third parties. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions.

RISKS RELATING TO THE [REDACTED]

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

Prior to the **[REDACTED]**, there was no public market for our Shares. There can be no guarantee that an active trading market for our Shares will develop or be sustained after the completion of the **[REDACTED]**. The **[REDACTED]** will be determined by negotiations between us and the **[REDACTED]** and the **[REDACTED]** (for themselves and on behalf of the **[REDACTED]**), which may not be indicative of the price at which our Shares will be traded following completion of the **[REDACTED]**. The market price of our Shares may drop below the **[REDACTED]** at any time after completion of the **[REDACTED]**.

In addition, the trading price of our Shares may be volatile and could fluctuate widely in response to factors beyond our control, including general market conditions of the securities markets in Hong Kong, France, the United States and elsewhere in the world. In particular, the performance and fluctuation of the market prices of other companies that have listed their securities in Hong Kong may affect the volatility in the price of and trading volumes for our Shares, and the price of our Shares may not reflect our actual results of operations.

***There will be a gap of several days between* [REDACTED] *and* [REDACTED] *of our Shares, and the* [REDACTED] *of our Shares when* [REDACTED] *begins could be lower than the* [REDACTED].**

The **[REDACTED]** of our Shares is expected to be determined on the **[REDACTED]**. However, our Shares will not commence **[REDACTED]** on the Hong Kong Stock Exchange until they are delivered, which is expected to be no more than five Hong Kong business days after the **[REDACTED]**

[REDACTED]. As a result, **[REDACTED]** may not be able to sell or **[REDACTED]** our Shares during that period. Accordingly, holders of our Shares are subject to the risk that the price of our Shares could fall before **[REDACTED]** begins as a result of unfavorable market conditions, or other adverse developments that could occur between the time of sale and the time **[REDACTED]** begins.

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

Our management may use the net **[REDACTED]** received by our Company from the **[REDACTED]** in ways that you may not agree with or that do not yield a favorable return to our Shareholders. By investing in our Shares, you are entrusting your funds to our management, upon whose judgment you must depend, for the specific uses we will make of the net **[REDACTED]** received by our Company from this **[REDACTED]**. For more information, see "Future Plans and **[REDACTED]**."

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

Our ability to declare future dividends will depend on the availability of dividends, if any, received from our operating subsidiaries. Under applicable laws and the constitutional documents of our operating subsidiaries, the payment of dividends may be subject to certain limitations. The calculation of certain of our operating subsidiaries' profit under applicable accounting standards differs in certain respects from the calculation under HKFRS. As a result, our operating subsidiaries may not be able to pay a dividend in a given year even if they have profit as determined under HKFRS. Accordingly, since we derive all of our earnings and cash flows from dividends paid by our operating subsidiaries, we may not have sufficient distributable profit to pay dividends to our Shareholders.

In addition, any future dividend declaration and distribution will be at the discretion of our Directors and will depend on our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors deem relevant. Any declaration and payment as well as the amount of dividends will also be subject to our Articles of Association, including (where required) the approvals from our Shareholders and our Directors. Our Shareholders at a general meeting must approve any declaration of dividends, which must not exceed the amount recommended by our Board. Moreover, our Directors may from time to time pay such interim dividends as our Board considers to be justified by our profits and overall financial requirements, or special dividends of such amounts and on such dates as they think appropriate. As a result, we cannot assure you that we will make any dividend payments on our Shares in the future.

The shareholding percentage of the existing Shareholders will be diluted following the conversion of the Convertible Bonds into our Shares.

In October 2022, our Company issued the Convertible Bonds to R-Bridge Investment Five Pte. Ltd. ("R-Bridge"), MicroPort International HK, ICBC International Investment Management Limited ("ICBCI"), River Lashing Capital Limited ("River Lashing)" and Tetris Investment Holding Limited ("Tetris") in the total amount of US $130.0 million. Under the Convertible Bonds, the holder of the Convertible Bonds shall have the right, but not the obligation, to convert any portion of the Convertible Bonds into such number of shares of our Company pursuant to the terms of the respective Convertible Bonds. Assuming all the Convertible Bonds are fully converted into the Shares at the

conversion price of approximately US$7.67 upon the **[REDACTED]** and that the **[REDACTED]** is not exercised, R-Bridge, MicroPort International HK, ICBCI, RIver Lashing and Tertis are expected to be issued in aggregate **[REDACTED]** Shares, representing approximately **[REDACTED]**% of the enlarged issued Share capital upon the **[REDACTED]**. See "History, Reorganization and Corporate Structure—The Pre-**[REDACTED]** Investments—Issuance of the Convertible Bonds" for details. Therefore, to the extent the Convertible Bonds are partially or all converted, the shareholding percentages of the existing Shareholders in our Company would be diluted.

There may be difficulties in protecting your interests under the laws of the Cayman Islands.

Our corporate affairs are governed by, among other things, our Memorandum of Association and Articles of Association, the Companies Act and common law of the Cayman Islands. The rights of Shareholders to take action against our Directors, actions by minority shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those in other jurisdictions. Such differences may mean that the remedies available to the minority shareholders may be different from those they would have under the laws of other jurisdictions.

Our subsidiaries in certain countries are subject to foreign investment laws and regulations in these countries, pursuant to which we and our investors may be subject to a notification requirement to the relevant regulatory authorities in certain circumstances.

Italy

Under Legislative Decree of March 15, 2012, No. 21, as amended and restated from time to time, most recently on May 20, 2022 (the "Italian Foreign Investments Law"), transactions affecting the ownership structure of Italian companies holding assets or carrying out activities in certain selected sectors of national interest for Italy (the "Italian Relevant Sectors") are subject to certain notification obligations to the Presidency of the Ministers' Council (*Presidenza del Consiglio dei Ministri*), which may block or impose restrictions on such transactions.

As of the date of this document, the share capital of our Company is distributed among its shareholders (the "Existing Shareholders") as described in this document. Further, our Company owns 100% of the corporate capital of MicroPort CRM HK, which, in turn, owns 100% of the corporate capital of MicroPort CRM Netherlands. MicroPort CRM Netherlands owns 100% of the corporate capital of Sorin CRM, which in turn owns 100% of the corporate capital of MicroPort CRM Italy.

MicroPort CRM Italy is engaged in the manufacturing and distribution of medical devices, including (i) critical technologies for the analysis of data and the utilization of biological knowledge for health and for the diagnostic, prognostic, therapeutic and follow-up purposes, as well as (ii) critical bioengineering technologies and nanotechnologies. These activities qualify as an Italian Relevant Sector for the purposes of the Italian Foreign Investments Law.

The **[REDACTED]** is not itself subject to any notification obligations under the Italian Foreign Investments, nor are the Existing Shareholders in respect of their shareholdings in our Company as of the date of this document. However, in light of the existing indirect shareholding structure of MicroPort CRM Italy, if, as a result of a participation in the **[REDACTED]** or, at any time after the **[REDACTED]**, as a result of trading activities, (i) a non-EU investor would come to hold, either directly or indirectly, shares in our Company representing at least 10% of the voting stock or of the corporate capital of our Company (or any of the certain subsequent thresholds), or (ii) a EU or a non-EU investor would come to hold a controlling participation in the share capital of our Company, such investor would be regarded as having acquired a corresponding indirect participation in the corporate capital of MicroPort CRM Italy under Italian Foreign Investments Law. Such indirect acquisition would trigger the obligation of that investor to notify such acquisition (where possible, jointly with MicroPort CRM Italy) to the Italian Presidency of the Ministers' Council under the Italian Foreign Investments Law. Failure to comply with the aforesaid notification obligations would expose the relevant obligor to the application of significant administrative fines.

Furthermore, where the notification is made, there is no certainty that the Italian Presidency of the Ministers' Council would not veto or impose restrictions on the relevant acquisition transaction, in which latter case both the investor and MicroPort CRM Italy would be required to comply with such restrictions, under the penalty, *inter alia*, of being applied administrative fines in case of non-compliance. See "Regulatory Overview—Foreign Investment Laws—Italy" for details.

Occurrence of any of the circumstances described above might have an adverse negative effect on the economic and financial conditions of MicroPort CRM Italy and, indirectly, of our Group as a whole.

Spain

Pursuant to Article 7 bis of the Spanish Law 19/2003, of July 4, on the legal regime of the movement of capital and foreign economic transactions (*Ley 19/2003, de 4 de Julio, sobre régimen jurídico de los movimientos de capitales y de las transacciones económicas con el exterior*), as amended and restated from time to time, most recently on November 18, 2020 (the "Spanish Foreign Investments Law"), certain foreign investments in Spain are subject to certain reporting duties to General Directorate of International Trade and Investments of the Ministry of Industry, Commerce and Tourism.

Under the Spanish Foreign Investment Law, foreign investment transactions which affect the ownership structure of Spanish companies holding assets or carrying out activities in certain selected sectors of the national interest of Spain (the "Spanish Relevant Sectors") are subject to certain reporting duties. MicroPort CRM Spain, the Spanish wholly owned indirect subsidiary of our Company, is engaged in the manufacturing and distribution of medical devices, including (i) critical technologies for the analysis of data and the utilization of biological knowledge for health and for the diagnostic, prognostic, therapy and follow up purposes, as well as (ii) critical bioengineering technologies and nanotechnologies. These activities qualify as a Spanish Relevant Sector for the purposes of the Spanish Foreign Investments Law.

The **[REDACTED]** is not *per se* subject to any notification obligations under the Spanish Foreign Investment Law. However, in light of the existing corporate structure of our Group, if, as a result of a

participation in the **[REDACTED]** or, at any time after the **[REDACTED]**, resulting from trading activities, a non-EU/EFTA investor comes to hold at least 10% of the voting stock or of the corporate capital of our Company as detailed under the standards for notification obligation above, such investor will be deemed to have acquired an indirect participation of at least 10% in the voting stock or corporate capital of MicroPort CRM Spain and, given that MicroPort CRM Spain operates in an Spanish Relevant Sector, such indirect acquisition will trigger the obligation of the relevant investor to notify such acquisition to the Spanish General Directorate of International Trade and Investments under the Spanish Foreign Investments Law and wait to receive the relevant approval.

To trigger the notification obligation, it is necessary that the relevant investor effects a relevant acquisition in MicroPort CRM Spain via our Company or officially undertakes to do so, for example, through an *ad hoc* corporate resolution or agreement. Failure to comply with the notification obligation would expose the relevant investor to the application of administrative fines and other consequences. It is less likely that MicroPort CRM Spain would be subject to the administrative fine and sanctions outlined above, but we cannot disregard such risk, especially if MicroPort CRM Spain is informed that the relevant transaction will or will likely take place.

Furthermore, in case the notification is effected, there is no certainty that the General Directorate of International Trade and Investments or the Council of Ministers, as the case may be, will not exercise the special powers provided for by the Spanish Foreign Investments Law and it may either (i) impose special conditions on the acquisition or (ii) veto the acquisition. In the case under (i), MicroPort CRM Spain and/or its direct sole shareholder would be obliged to comply with such special conditions, if any, and, in case of non-compliance, they would be exposed to administrative fines and sanction. See "Regulatory Overview—Foreign Investment Laws—Spain" for details.

Occurrence of any of the circumstances described above might have an adverse effect on the economic and financial conditions of MicroPort CRM Spain and, indirectly, our Group as a whole.

Facts, forecasts and statistics in this document relating to the medical device industry may not be fully reliable. We cannot guarantee the accuracy of facts, forecasts and other statistics obtained from official governmental sources or other sources contained in this document.

Facts, forecasts and statistics in this document relating to the CRM device industry are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Joint Sponsors, the **[REDACTED]**, the **[REDACTED]**, the **[REDACTED]** nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the industry statistics in this document may be inaccurate and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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

This document contains certain forward-looking statements and information relating to us that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words "aim," "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "going forward," "intend," "ought to," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "will," "would," and similar expressions, as they relate to our Group or our management, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, business operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. Subject to the ongoing disclosure obligations of the Listing Rules or other requirements of the Stock Exchange, we do not intend publicly to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events or otherwise. Investors should not place undue reliance on such forward-looking statements and information.

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

Prior to the publication of this document, there may be press, media and research analyst coverage regarding us and the **[REDACTED]**, which may contain, among other things, certain financial information, projections, valuations and other forward- looking information about us and the **[REDACTED]**. We have not authorized the disclosure of any such information in the press, media or research analyst coverage and do not accept responsibility for the accuracy or completeness of such press articles, other media coverage or research analyst reports. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.