

RISK FACTORS

You should carefully consider all of the information in this document, including risks and uncertainties described below, before making an [REDACTED] in our Shares. The following is a description of what we consider to be our material risks. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] of our 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.

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

RISKS RELATING TO THE DEVELOPMENT OF OUR PRODUCTS AND PRODUCT CANDIDATES

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.

Clinical trials are expensive and can take many years to complete, and outcomes are inherently uncertain. 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 product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including differences in physical conditions, and dropout rates among clinical trial participants.

We rely on sales of our commercialized products for revenue. Our business, financial condition and results of operations will be materially and adversely affected if sales of these products decline.

During the Track Record Period, we derived revenue substantially from our hemorrhagic stroke products, cerebral atherosclerotic stenosis products and access products. In 2018, 2019 and 2020 and the eight months ended August 31, 2020 and 2021, sales of these products accounted for approximately 99.3%, 99.5%, 99.3%, 99.4% and 99.8% of our total revenue, respectively. We expect to continue to derive a substantial majority of our revenue from these products in the near future. Due to such concentration, an investment in our Company may entail more risk than investments in companies that offer a wider variety of commercialized products. We cannot assure you that demands for our commercialized products will continue to grow as anticipated. There is also no assurance that we will be able to maintain our sales and profit margins for these products, which may be adversely

RISK FACTORS

affected by factors out of our control, including downward pricing pressure caused by changes in market competition, expiration of patent protection, introduction of substitute products marketed by our competitors, disruptions in manufacturing or sales, issues with respect to product quality or severe adverse events incurred after medical procedures, coverage of medical insurance and disputes over intellectual property or other matters with third parties. If we are unable to maintain the sales volume, pricing level or profit margin of our commercialized products, our business, financial condition and results of operations may be materially and adversely affected.

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

The neuro-interventional medical 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 that already exist. 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 addition, our ability to generate revenue also depends on the successful development of, the ability to obtain the necessary regulatory approvals for, and the successful commercialization of our pipeline products which are still under design and development and other pipeline products we may develop in the future. Clinical development involves lengthy and expensive processes with uncertain outcomes. A failure of one or more of our clinical trials can occur at any stage of testing and clinical trials may experience significant setbacks even after earlier trials have shown promising results. The R&D process is lengthy and entails considerable uncertainty. Products that we are currently developing may not complete the development process or obtain the regulatory or other approvals required to market such products in a timely manner, or at all.

We have invested a significant portion of our efforts and financial resources in the R&D of our pipeline products. For the years ended December 31, 2018, 2019 and 2020 and the eight months ended August 31, 2020 and 2021, we incurred R&D expenditure (including the capitalized R&D expenses) of RMB56.9 million, RMB76.0 million, RMB80.5 million, RMB47.6 million and RMB60.0 million, respectively. The success of our new products and product candidates will depend 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;

RISK FACTORS

- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret 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 interventional procedural 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 revenues and cash flows to continue our operations.

We face substantial competition. Our competitors may have substantially greater resources than we do and may be able to develop more effective products or offer their products at lower prices than we can, which could materially and adversely impact our business, financial condition and results of operations.

The market for neuro-interventional medical devices is intensely competitive and rapidly changing. We face competition from major neuro-interventional medical device producers worldwide. According to CIC, international neuro-interventional medical device companies have a dominant share in the neuro-interventional medical device market in China. A number of companies in the global market are currently selling neuro-interventional medical devices and competing for limited resources on the market. We compete with international neuro-interventional medical device companies in obtaining limited raw materials, recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies necessary for, our programs. Many of our competitors have significantly greater financial resources and expertise in R&D, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the medical device industries may result in even more resources being concentrated among a small number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our business and results of operations will suffer if we fail to compete effectively.

Our competitors may also be applying for marketing approvals in China or other countries for medical device products with the same intended uses as our products and product candidates. The ability of the relevant authorities, such as the NMPA, to concurrently review multiple marketing applications for the same type of innovative medical devices may be limited. When our product and its competing products are subject to the NMPA’s concurrent review, the NMPA’s schedule may be affected, and the registration process of our product may be prolonged. Moreover, our competitors may obtain approval from the NMPA, FDA or other comparable regulatory authorities for their

RISK FACTORS

products more rapidly than we obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and/or slow our regulatory approval.

If we encounter difficulties in enrolling patients in 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 size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to engage CROs/SMOs with the appropriate competence and experience;
- the patients' perceptions as to the potential advantages and risks of the pipeline products being studied in relation to other available products, pipeline products or non-surgical 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 being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of 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

RISK FACTORS

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 revenues for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly.

We allocate our limited resources to pursue particular pipeline products 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 selective indicated applications. However, our selection of focus on neuro-interventional medical 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

RISK FACTORS

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.

RISKS RELATING TO COMMERCIALIZATION AND DISTRIBUTION OF OUR PRODUCTS

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

Our business operation significantly depends on our ability to successfully expand and deepen hospital penetration of our products. Hospitals usually organize public tenders for procurement of medical devices. The procedures of such public tenders may vary in different regions and among different hospitals, and there could be uncertainties with respect to the timing of such procedures. As of the Latest Practicable Date, we had penetrated approximately 2,200 hospitals, among which over 1,300 are Class III hospitals. We expect to expand into other hospitals that either have existing neuro-interventional procedures capabilities or the potential to perform neuro-interventional procedures. However, we may not be able to do so if we cannot penetrate into hospitals effectively, and our sales volume and business prospects could be materially and adversely affected.

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

Failure to achieve broad market acceptance could have a material adverse impact on our business and results of operations.

The commercial success of our current and future products depends upon the degree of market acceptance they achieve, particularly among physicians, patients and hospitals. Neuro-interventional procedures are recently developed and introduced to the market. We believe that physicians may not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer-reviewed journal articles, that the use of our products provide a safe and effective alternative to existing non-interventional treatments for the conditions we are seeking to address. Meanwhile, physicians and patients may prefer traditional open neurosurgery intravenous thrombolysis over the use of neuro-interventional medical devices, given its established market acceptance, comparatively lower cost and available coverage by governmental and private medical insurance. Consequently, if we fail to demonstrate safety and efficacy that is comparable to non-interventional treatments available on the market, or if published peer-reviewed journal articles, recommendations or studies reflect negatively on neuro-interventional procedures, market demand of neuro-interventional procedures might shift away and adoption rates of our products may decline significantly.

In addition, physicians face a learning process to become proficient in the use of our products, which may take longer than expected and therefore affect our ability to market our products. If our

RISK FACTORS

products or product candidates, upon commercialization, fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the industry, the sales of our products will be adversely affected. If our products and product candidates, upon commercialization, do not achieve an adequate level of acceptance, we may not generate significant product sales revenues.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost-effective or render our products obsolete.

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 various diseases 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 revenues 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 education efforts could be rendered ineffective by, among other things, third parties’ guidelines, recommendations or studies.

The neuro-interventional medical device industry in China is rapidly evolving, and we may be unable to maintain or enhance our market share in this industry for a variety of reasons.

The neuro-interventional medical device industry in China is rapidly evolving due to economic growth in China, changes in government policies and funding levels, increasing competition and other factors discussed in this document. To maintain and enhance our market share in this highly competitive and changing environment, we need to adopt advanced solutions from time to time depending on market conditions. In addition, neuro-interventional medical device companies had developed various types of products for neurovascular diseases. We cannot assure you that we will continuously maintain and enhance our market share.

Our inability to adequately respond to changes in market conditions in a timely manner 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 current market share or achieve targeted market share in future periods. In addition, if we cannot maintain our market position, our reputation and brand name 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.

RISK FACTORS

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 rely on third-party distributors to distribute our commercialized products, and certain of our distributors engage sub-distributors to on-sell such products. See “Business—Sales, Distribution and Marketing—Our Sales and Distribution Model” for details. Our ability to maintain and grow our business will depend on our ability to maintain effective distribution channels that ensure timely distribution of our products to the relevant markets where we generate market demand through our sales and marketing activities. However, we do not have complete control over our distributors, who may fail to distribute our products in the manner we contemplate. If PRC price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our products to hospitals and medical institutions, our distributors may terminate their relationships with us.

As of the Latest Practicable Date, we had established an extensive distribution network. During the Track Record Period, the numbers of our distributors fluctuated from time to time. As of December 31, 2018, 2019, 2020 and August 31, 2021, we had a total of 89, 79, 60 and 17 distributors, respectively. The number of our distributors decreased during the Track Record Period primarily because (i) certain regional distributors chose to become sub-distributors of other larger, national distributors to leverage such national distributors’ stronger customer bases, capital resource and logistic capacity; and (ii) our distribution agreements with certain distributors expired and we decided not to renew such distribution agreements due to commercial reasons. For the year ended December 31, 2018, 2019, 2020 and the eight months ended August 30, 2021, the aggregate sales to our five largest distributors were RMB106.9 million, RMB155.2 million, RMB218.5 million and RMB228.7 million, respectively, representing 86.2%, 84.5%, 98.4% and 96.3% of our revenue, respectively. Sales to our largest distributor for the same periods was RMB79.3 million, RMB122.4 million, RMB129.9 million and RMB80.4 million, respectively, representing 63.9%, 66.6% , 58.5% and 33.8% of our revenue, respectively. In line with industry practice, we typically enter into agreements with our distributors for a term of one year, which requires us to continually renew distribution agreements with our distributors. There is no assurance that our existing distributors will continue to place orders with us at historical levels, or that we will be able to secure comparable levels of business from other distributors to offset any loss of revenue from losing one or more of these major distributors. Further, there is no assurance that we will be able to successfully secure new distributors to capture the potential industry growth and broaden our distribution channel. While we believe alternative distributors are readily available in China, if we lose any of our distributors, in particular any major distributors, the distribution of our products may be interrupted, as a result of which, our sales volumes and business prospects could be adversely affected.

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, including their compliance with laws, rules, regulations and our policies. See “Business—Sales, Distribution and Marketing—Sales to Distributors—Selection and Management of Distributors.” We also adopt robust measures and selection criteria to manage the anti-bribery and anti-corruption risks involved with our distributors. For details, see “Business—Sales, Distribution

RISK FACTORS

and Marketing—Sales to Distributors—Selection and Management of Distributors” and “Business—Risk Management and Internal Control.” We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors would 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 failure to comply with applicable regulatory requirements when selling our products; or
- violating anti-corruption, anti-bribery, competition or other laws and regulations of China or other jurisdictions.

Any violation or alleged violation by our distributors of the distribution agreements, our policies or any applicable laws and regulations could result in the erosion of our goodwill, a decrease in the market value of our brand and an unfavorable public perception about the quality of our products, resulting in a material adverse effect on our business, financial condition, results of operations and prospects.

Downward change in pricing of our products caused by changes in market competition may have a material adverse effect on our business and results of operations.

During the Track Record Period, all of our products were sold through distributors. We primarily operate a multi-layer distribution system, where a majority of our products are sold from distributors to sub-distributors, and such sub-distributors on-sell our products to hospitals through their own sales and distribution networks; and a relatively smaller proportion of our products are sold from our distributors directly to hospitals. We take into account a number of factors in determining our prices, such as prices of competing products and the manufacturing costs and differences in features between our products and competing products in determining the price of our products sold to distributors. For details, see “Business—Sales, Distribution and Marketing—Sales to Distributors—Pricing.” Hospitals may gain more bargaining power depending on the availability of alternative products, demands of patients and the preference of physicians. If hospitals lower retail prices of our products and therefore reduce the profitability of our distributors, our distributors may have less incentive to purchase and promote our products, and we may need to lower the order price we set for our distributors.

As of the Latest Practicable Date, there was no price guidance set on neuro-interventional medical devices by the PRC government. If the PRC government issues price guidance for neuro-interventional medical devices, the price of our products and therefore our business and results of operations may be negatively affected.

RISK FACTORS

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

Our ability to sell our products will depend in part on the possibility and the extent to which medical insurance reimbursement for neuro-interventional medical devices will be available to patients, which is out of our control. In the absence of medical insurance coverage 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 our sales which could in turn materially and adversely affect our business, financial condition and results of operations. As of the Latest Practicable Date, neuro-interventional medical devices had not been covered by the PRC national medical insurance reimbursement list. This may affect the patients’ willingness to use a neuro-interventional medical device in surgery given its high price caused by its consumable parts and components.

China has a complex medical insurance system that is undergoing reform. According to CIC, the Consultation Draft on Interim Measures for Management of Medical Consumables Under Basic Medical Insurance Scheme (《基本醫療保險醫用耗材管理暫行辦法(徵求意見稿)》) issued by the NHSA in June 2020 and the Consultation Draft on Interim Measures for Management of payments of Medical Consumables Under Basic Medical Insurance Scheme 《基本醫療保險醫用耗材支付管理暫行辦法(徵求意見稿)》 issued by the NHSA in November 2021 proposes to formulate a Catalog of Medical Consumables Under Basic Medical Insurance Scheme (《基本醫療保險醫療耗材目錄》) and include medical devices under such catalog into the coverage of medical reimbursement, and there was no national or regional medical reimbursement list of medical devices released by authorities in China as of the Latest Practicable Date. For details, see “Regulatory Overview.” As the competent authorities have not formulated any rules on the determination method of reimbursement coverage for medical devices under such catalog, there is no assurance that we will not be adversely impacted. For example, we may need to lower the prices of our products in order to have them included in such catalog, and such price cut and reimbursement may not necessarily lead to increase in our sales and our results of operations may be adversely affected.

RISKS RELATING TO MANUFACTURE AND SUPPLY OF OUR PRODUCTS

The manufacture of our products is highly complex and subject to strict quality controls. If we or any of our suppliers or logistics partners encounters manufacturing, logistics or quality problems, including as a result of natural disasters, our business could suffer.

We have a comprehensive product portfolio with a total of 30 commercialized products and product candidates. The manufacture of our products is highly complex. Our key manufacturing equipment is specially designed for each type of product. As we continue to expand our footprint into new markets, we may face unanticipated surges in demand for our existed products, or new demand for new products or new generations of existing products, which could strain our production capacity.

In addition, the manufacture of our products is subject to strict quality controls. 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. Despite our quality control and assurance system and procedures, we cannot eliminate the risk of

RISK FACTORS

product defects or failure. Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, defects or other issues in raw materials, or human error. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

Furthermore, if contaminants are discovered in our products or pipeline products or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, failure to maintain production stability may affect the manufacture and delivery schedule of our commercialized products and product candidates. 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 the NMPA or other applicable regulatory body, 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 and if we fail to raise our production capacity and construct the new manufacturing facility as planned, our business prospects could be materially and adversely affected.

As of the Latest Practicable Date, we conducted manufacturing activities primarily at our manufacturing facility located in our leased properties in Zhoupu, Shanghai. 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. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. There can be no assurance that our existing manufacturing facilities will produce products in sufficient volumes in the event of any significant change in market demand. In such event, we may have to engage third parties to produce a portion of such products. Consequently, we are 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.

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, or if the process to do so is delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to supply our products in a sufficient quantity to meet future demand, which would limit our development and commercialization activities and our opportunities for growth.

Manufacturing of our products depends on the continued service of qualified manufacturing personnel. Competition for qualified manufacturing in the medical devices industry is intense and the pool of qualified candidates is limited. Although we have not historically experienced unique

RISK FACTORS

difficulties attracting and retaining qualified manufacturing personnel, we could experience such problems 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, to scale up our production capacity, we may plan to establish new production facilities in China and the United States. New production facility may require prior review by regulatory authorities and/or approval of the manufacturing process and procedures in accordance with applicable requirements. This review may be costly and time-consuming and could delay or halt the launch of our products. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the products made at the new facility are equivalent to the products made at the former facility by physical and chemical methods, which are costly and time consuming. Regulatory authorities may also require clinical testing as a way to prove equivalency, which would result in additional costs and delay. In the event we fail to increase our production capacity or develop the new manufacturing facility, we may not capture the expected growth in demand for our products, or to successfully commercialize new products, each of which could materially and adversely affect our business prospects.

We may not be able to secure a stable supply of qualified raw materials at all times or at all.

Our key raw materials include alloy metal wires, metal tubes and polymer plastic tubings, which we use to make our stent, coil and catheter products. To ensure the quality of our principal raw materials, we only procure them from selected suppliers that can satisfy our stringent requirements. Although we believe that we have stable and long-term relationships with our existing suppliers and we are also exploring other qualified suppliers, we cannot assure you that we will be able to secure a stable supply of qualified raw materials at all times. If any of these suppliers loses its qualification or eligibility for a variety of reasons including its 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 and, if our inventory of the relevant raw material does not sufficiently cover the deficiency over the relevant time period, interruption in our manufacturing process. In addition, we are also exposed to risks associated with fluctuations in prices of raw materials. A significant increase in the costs of raw materials may disrupt our operations and have a negative impact on our gross margin directly.

In addition, we import materials from foreign suppliers. General economic conditions could adversely affect the financial viability of our oversea suppliers, resulting in their inability to provide materials and components to us. While we work closely with suppliers to monitor their financial viability, assure continuity of supply, and maintain high quality and reliability, these efforts may not be successful. As the production volume of our products ramps up, we have developed strategies to obtain alternative suppliers. However, the loss of any existing supply contract could have a material adverse effect on us. Moreover, we plan to develop our own production capacity of certain key raw materials to further enhance the stability of supply. However, we cannot assure you that we will be able to manufacture raw materials on our own in a cost-effective manner, or at all.

RISK FACTORS

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

Our production and manufacturing processes are required to meet certain quality standards. We have established a quality control and assurance system and adopted standardized operating procedures in order to prevent quality issues with respect to our products and operation processes. For further details of our quality control and assurance system, see “Business—Quality Control.” Despite our quality control and assurance system and procedures, we cannot eliminate the risk of product defects or failure. Quality defects may fail to be detected or remediated as a result of a number of factors, many of which are outside of our control, including:

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

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

Any product recall would damage our brand name and could have a material adverse effect on our reputation, business, financial condition and results of operation.

Complex medical devices may receive claims arising from the improper performance of the products or the way physicians use such products, which in both cases require review and possible corrective action by the manufacturer. In addition, from time to time, we receive feedback from physicians relating to issues they have encountered while using our products, including technical difficulties in the delivery or placement of some of our products. We expect that we will continue to receive such feedback from time to time. Furthermore, component failures, manufacturing errors or design defects could result in danger or injuries to patients. Any serious failures or defects could cause us to withdraw or recall products, which could result in significant costs such as repair and product replacement costs. The occurrence of any market withdrawals or product recalls of our products would damage our brand name and would have a material adverse effect on our business, financial condition and results of operation.

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

We face an inherent risk of product liability as a result of the commercialization of our products in China and the clinical testing and any future commercialization of our pipeline products globally. For example, we may be sued if our products or pipeline products cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or

RISK FACTORS

sale. During the Track Record Period, we had not experienced any product liability lawsuits that had a material adverse impact on our business operations. However, 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. Claims could also be asserted under applicable consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products and pipeline products. 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;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any pipeline product; and/or
- a decline in our share price.

If we are unable to defend ourselves against such claims in the PRC, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products are found to be defective. In addition, we may be required to recall the relevant products, suspend sales or cease sales. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management.

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

To operate our business successfully and meet our customers’ demands and expectations, we must maintain a certain level of inventory for our products to ensure 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. If our forecasted demand is lower than actual demand, we may not be able to maintain an adequate inventory level of our products or

RISK FACTORS

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, risk of inventory obsolescence or write-offs.

Although we monitor the inventory level of our distributors, there is no assurance that such information would be reported to us accurately and/or in a timely manner. As our ability to directly track the inventory levels of distributors is limited and may not be on a real-time basis, it is difficult for us to gather sufficient information and data regarding the market acceptance of our products. As the tracking of inventory levels would provide us with useful information on the market acceptance of our products in a particular region, limitation in accurately tracking the sales and inventory levels of distributors may make it difficult for us to predict sales trends, and we may not be able to implement effective marketing or product strategies. As a result, our business, financial condition and results of operations will be materially and adversely affected.

RISKS RELATING TO OUR FINANCIAL POSITION

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 obtain that financing, we may be unable to complete the development and commercialization of our pipeline products.

We cannot assure you that our historical operating results, such as our revenue, gross profit, net profit, gross profit margin and net profit margin, will be indicative of future performance for various reasons, including uncertainties of the success of our existing and new products, and 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 R&D, advancing the clinical development of our product candidates, commercializing our products and launching and commercializing any product candidates for which we receive regulatory approval, including building our own R&D, production and commercialization teams in China and overseas. 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 through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. 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;

RISK FACTORS

- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions and/or the development of other product candidates;
- the cost and timing of development and completion of commercial-scale internal or outsourced, if any, manufacturing activities; and/or
- our headcount growth and associated costs.

In addition, many aspects of our general business operations have on-going 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 outside of our control, including our financial condition, results of operations and cash flows, the economic conditions in the PRC, 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 historically received government grants and subsidies for our R&D activities and we may not receive such grants or subsidies in the future.

We have historically received government grants in the form of subsidies received from local government for encouragement of research and development activities. For the years ended December 31, 2018, 2019 and 2020 and the eight months ended August 31, 2020 and 2021, we recognized government grants under other net income of RMB0.6 million, RMB6.6 million, RMB9.6 million, RMB4.6 million and RMB0.8 million, respectively. Our eligibility for government grants 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 received government grants may be halted by the relevant government entities at their sole discretion. There is no assurance that we will continue to receive such government grants or receive similar level of government grants, or at all, in the future.

Fluctuation in the value of the Renminbi may result in foreign currency exchange losses.

We are subject to foreign exchange fluctuations. Certain of our cash and cash equivalents are denominated in foreign currencies, and thus we are exposed to foreign currency risk. In addition, as we purchase certain raw materials from overseas suppliers, market and sell our products to overseas customers, the costs for procurement and the revenue from overseas sales are also subject to foreign exchange fluctuations. The exchange rate of the Renminbi against foreign currencies fluctuates and is affected by, among other things, the policies of the PRC government and changes in China’s and international political and economic conditions, as well as supply and demand in the local market. It is

RISK FACTORS

difficult to predict how market forces or government policies may impact the exchange rate between the Renminbi and foreign currencies in the future. In addition, the PBOC may respond to limit the fluctuations of Renminbi against foreign currencies. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects.

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

As of August 31, 2021, we had intangible assets of RMB129.0 million and inventories of RMB78.2 million. Our determination on whether intangible assets and inventories are impaired requires an estimate of the recoverable amount of the intangible assets or inventories, which is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, the carrying amount of the intangible assets may exceed its recoverable amount, and our intangible assets or inventories may accordingly be impaired. As a result, we may be required to have a significant write-off of our intangible assets or inventories and record a significant impairment loss. The impairment of intangible assets and inventories could have a material adverse effect on our business, financial condition and results of operations.

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

We generally grant credit terms of 60 days to our distributors. As of December 31, 2018, 2019 and 2020 and August 31, 2021, we had trade receivables of RMB32.5 million, RMB46.3 million, RMB42.2 million and RMB9.7 million, respectively. The average turnover days of our trade receivables for the same periods were 72 days, 78 days, 73 days and 27 days, respectively. If our distributors' cash flows, working capital, financial condition or results of operations deteriorate, they may be unable, or they may otherwise be 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 we could be required to terminate our relationships with distributors in a manner that will impair the effective distribution of our products.

Our business benefits from certain preferential tax and financial incentives, the expiration of or changes to which could adversely affect our profitability.

We currently benefit from certain preferential tax treatments. During the Track Record Period, we benefited from a preferential PRC income tax rate of 15%, compared with the 25% income tax rate generally applicable to PRC tax resident enterprises under the EIT Law. The qualification as a High and New Technology Enterprise will expire in 2023. We plan to renew this qualification in due course. However, if we fail to renew its qualification, its applicable enterprise income tax rate would revert to 25%, which may have a material adverse effect on our financial condition and results of operations.

In addition, according to a tax incentive policy promulgated by the SAT of the PRC 2018, we started to enjoy an additional 75% of qualified research and development costs incurred to be deducted from our taxable income in January 2018 and, since January 2021, 100% of such qualified expenses incurred has been allowed to be deducted from taxable income. We cannot assure you that

RISK FACTORS

we will continue to received such preferential tax treatment at historical levels, or at all. 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.

RISKS RELATING TO GOVERNMENT REGULATION

The research, development and commercialization of our products are heavily regulated.

All jurisdictions in which we conduct our research, development and commercialization activities regulate these activities in great depth and detail. We intend to focus our activities in the major markets of China and gradually expand our market overseas. 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.

Undesirable adverse events caused by our products and product candidates 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.

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

Any adverse events reported in our clinical trials will affect patient recruitment or the ability of enrolled subjects to complete the trial, and any result in potential product liability claims. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly. In this document and from time to time, we disclose clinical results for our products and products candidates, including the occurrence of adverse events and serious adverse events. Each such document speaks only as of the date of the data cutoff used in such document, and we undertake no

RISK FACTORS

duty to update such information unless required by applicable law. For details of the adverse events of our products as observed during clinical trials as of the date of this document, see “Business—Our Product Portfolio.”

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

- we may be required to suspend marketing or remove relevant products from the marketplace;
- regulatory authorities may withdraw approvals of the product;
- we may be required to change the way our products are distributed or administered, 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 pipeline product, and could significantly harm our business, results of operations and prospects.

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

Our products and any product candidates that will be approved by the regulators are and will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conducting post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China and other applicable jurisdictions where the products are approved. For example, manufacturers and manufacturers’ facilities are required to comply with extensive regulatory requirements from the NMPA or other comparable authorities. As such, we are and will be subject to continual review and inspections by the regulators in order to assess our compliance with applicable laws and requirements.

The NMPA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products placed on the market. The regulatory approvals for our products and any

RISK FACTORS

approvals that we receive for our pipeline products are and may be subject to limitations on the indicated uses for which our product may be marketed. Products may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The approvals we obtain may also be subject to other conditions which may require potentially costly post-marketing activities to monitor the safety and efficacy of our products or pipeline products. Such limitations and conditions could adversely affect the commercial potential of our products.

The NMPA or comparable regulatory authorities may withdraw marketing approval if we fail to maintain compliance with these ongoing regulatory requirements and standards or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our products or pipeline products including adverse events of unanticipated severity or frequency, or with our manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling or requirements to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, and voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our products and pipeline products; and/or
- injunction or the imposition of civil or criminal penalties.

We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or overseas, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained and we may not sustain profitability. In addition, if we were able to obtain conditional approval of any of our pipeline products, the NMPA and other regulatory authorities may require us to conduct a confirmatory study to verify the predicted clinical benefit and additional safety studies. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn. While operating under conditional approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

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

In China and overseas, a number of legislative and regulatory changes and proposed changes regarding healthcare could prevent or delay regulatory approval of our product candidates, restrict or

RISK FACTORS

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. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for medical devices. We cannot be sure whether additional legislative changes will be enacted, or whether NMPA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. For example, 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《醫療器械註冊與備案管理辦法》) came into effect on October 1, 2021, the requirements of clinical trials, sales and regulation of medical devices have been changed in some aspects. For details, see “Regulatory Overview—Laws and Regulations on Medical Devices—Supervision over Medical Devices and their Classification.” The impact of these more specific requirements and whether it will adversely affect the registration of our products with the NMPA are yet to be observed.

The State Administration for Market Regulation promulgated the Interim Measures for the Administration of the Examination and Administration of Drugs, Medical Devices, Health Foods, and Formula Foods for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), which came into effect on March 1, 2020. For details, see “Regulatory Overview—Laws and Regulations on Medical Devices—Advertisements of Medical Devices.” If we fail to limit the contents of advertisements on the contents of the registration certificate or filing certificate approved by the drug administrations, or the registered or filed product instructions, we may be subject to an administrative penalty.

The Notice on Printing and Distributing the Reform Plan for the Management of High-value Medical Consumables (《關於印發治理高值醫用耗材改革方案的通知》), issued and came into effect on July 19, 2019 by General Office of the PRC State Council, encourages local governments to adopt the “Two Invoice System” on a case-by-case basis to encourage reducing resales of high-value medical consumables and promote the transparency of purchase and sales. As of the Latest Practicable Date, a few provinces had implemented the “Two Invoice System” in the field of medical consumables. As the implementation of the “Two-Invoice System” is still at an early stage, and the interpretation and enforcement of such system in the medical device industry are evolving and subject to uncertainty, we cannot predict how the implementation and enforcement will evolve in different provinces in China, or whether and how that will affect our business and results of operations in the future.

In addition, in 2019, China started to initiate centralized procurement pilot programs in an effort to regulate prices of medical devices through group procurement at the provincial level. For details, see “Regulatory Overview—Laws and Regulations on Medical Devices—The Reform Plan of High-Value

RISK FACTORS

Medical Consumables.” As of the Latest Practicable Date, coil products had been covered by centralized procurement in Hebei province and microcatheter products had been covered by centralized procurement in Zhejiang province, see “Business—Sales, Distribution and Marketing by Sales to Distributors—Pricing” for details. We cannot be sure whether our other products will also be covered in the near future. If our products were covered by the centralized procurement in the future, the price of our products may decrease, which could harm our profitability, if any increase in sales volume fails to fully compensate for such decrease in price.

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

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

We routinely receive, collect, generate, store, process, transmit and maintain medical data and treatment records of the subjects enrolled in our clinical trials. 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, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement action against us,

RISK FACTORS

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. In particular, certain industry-specific laws and regulations may affect the collection and transfer of personal data in China, including 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》). For details, see “Regulatory Overview—Laws and Regulations on Medical Devices—Sampling and Collecting Human Genetic Resources Filing.” 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 human genetic resources samples and associated 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 would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

RISK FACTORS

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

We could be unsuccessful in obtaining or maintaining adequate patent protection for our products and pipeline products 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 depend, in large part, on our ability to obtain, maintain and enforce our intellectual property rights, including patent rights to protect our proprietary technology, products and pipeline products. We seek to protect the technology, products and pipeline products that we consider commercially important by filing patent applications in the PRC and other countries, 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 pipeline products, 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 had applied 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 pipeline products could have a material adverse impact on our business.

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

The issuance of a patent is not conclusive as to its inventor, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the PRC, the United States and other countries. Moreover, we may have to participate in interference proceedings declared by the the United States or other related intellectual property offices to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and pipeline products. Such proceedings also may result in

RISK FACTORS

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 whether any of our technologies, products or pipeline products will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords is limited. We may face competition for any approved pipeline products even if we successfully obtain patent protection once the patent life has expired for the product. The issued patents, for our products and pipeline products are expected to expire on various dates as described in “Business—Intellectual Property Rights” of this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, 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 pipeline products, patents protecting such pipeline products might expire before or shortly after such pipeline products are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our patent applications may not be ultimately granted.

Patent applications may not be granted for a number of reasons, including known or unknown prior deficiencies in the patent application or the lack of novelty of the underlying invention or technology. As of the Latest Practicable Date, we had 144 patents under application in and outside China. For details, see “Business—Intellectual Property Rights.” There is no assurance that the patent applications will be granted in a timely manner, or at all. Certain of our patent applications remained with an “applied” status. Such patent applications were under substantial review by the CNIPA as of the Latest Practicable Date. As the time required for the substantial review is at the discretion of the CNIPA, we are unable to predict the expected time frame of receiving material updates in relation to the pending patent applications. If any of the patent applications was rejected, we may lack patent protection covering certain key characteristics of our key products.

We may not be able to enforce, defend or otherwise protect our intellectual property rights.

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

RISK FACTORS

countries do. Consequently, we may not be able to prevent third parties from practicing our inventions in all 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 pipeline products and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

As of the Latest Practicable Date, we had 89 patents in China. To facilitate our strategy to enter overseas market, we also had 28 patents registered overseas. Most of the patents that we owned or applied for are related to self-developed technologies by our in-house R&D team. In addition, as of the Latest Practicable Date, we also owned 93 trademarks in China and 40 trademarks overseas. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in countries such as China. 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.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our products and product candidates could be found invalid or unenforceable if being 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 China or abroad, 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 pipeline products. Accordingly, despite our efforts, we may not be able to prevent third

RISK FACTORS

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.

If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our pipeline products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would substantially divert resources from our business. 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 pipeline products, 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 need to obtain licenses from third parties to advance our research or allow commercialization of our pipeline products. 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 pipeline products, 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. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. 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 claim that we infringe upon their intellectual property rights, we may incur liabilities and financial penalties and may have to redesign or discontinue selling the affected product.

Companies operating in our industry routinely seek patent protection for their products, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves an analysis of complex legal and factual issues, the determination of which is often uncertain. We face the risk of claims that we have infringed on third parties' intellectual property rights in the countries where we operate, principally China. In addition, a number of our employees have previously worked for one or more of our competitors. There can be no assurance that

RISK FACTORS

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 evaluate existing intellectual property rights. However, our competitors may also have filed for patent protection which is not as yet a matter of public knowledge or claim trademark rights that have not been revealed through our searches of relevant public records. Our efforts to identify and avoid 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 procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the CNIPA and other patent agencies in several stages over the lifetime of the patent. The CNIPA 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 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 would have a material adverse effect on our business.

RISK FACTORS

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

The scope of patent protection in various jurisdictions is uncertain. Changes in either the patent laws or their interpretation in China or other countries 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.

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

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

In addition to our 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 pipeline products. 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 scientific collaborators, external advisers, sponsored researchers, consultants, advisors and other third parties. We also enter into employment agreement or consulting agreement with our employees and consultants that includes undertakings regarding assignment of inventions and discoveries. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any material threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

RISK FACTORS

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.

RISKS RELATING TO OUR OPERATIONS

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We have a limited operating history compared to some of our competitors. Our limited operating history, particularly in light of the rapidly evolving nature of our industry, may make it difficult to evaluate our current business and reliably predict our future performance. Any predictions you make about our future success or viability may be subject to uncertainty and may not be as accurate as they could be if we had a longer operating history. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

Our operations and business plans may be adversely affected by the COVID-19 pandemic.

Since early 2020, a growing number of countries and regions around the world have encountered an outbreak of COVID-19, a highly contagious disease known to cause respiratory illness. On March 11, 2020, the World Health Organization announced the COVID-19 outbreak a pandemic. The spread of COVID-19 continues to affect Mainland China, where we conduct our business and engage in substantial pre-clinical studies and clinical trials. It is difficult to predict the impact that COVID-19 will have on our business or our industry. Our business, including our existing and future clinical and pre-clinical trials, as well as our ability to continue to manage it effectively, could be impacted by the current pandemic or future continuance or reoccurrence of COVID-19 in numerous ways, including but not limited to delay or interruption of the supply of the resources as well as temporary closure or flexible working hours of competent regulatory authorities.

The full effects of the current COVID-19 pandemic or future outbreaks on our business or our industry will depend on a number of factors outside our control, including the extent to which the current pandemic continues to spread, particularly in China, and the level of the medical resources needed to treat COVID-19 patients in China and other countries, as well as the impact of COVID-19 on our employees, subject participating in our clinical trials, the personnel necessary to continue our clinical trials and our CROs, and such effects could be material.

We are subject to the risks of doing business globally.

We expect to continue to expand our global presence. We are also planning and building localized R&D, sales and marketing teams and production capacity in our overseas markets.

RISK FACTORS

Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including but not limited to:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in or difficulties or failure to comply with laws and regulatory requirements in local jurisdictions;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potential disputes with foreign parties we work with;
- exposure to litigation or third-party claims outside of China;
- concerns of local governments and regulators on our research and products and on the relevant management arrangements;
- inadequate intellectual property protection in certain countries;
- economic sanctions, trade restrictions, discrimination, protectionism or unfavorable policies against PRC companies;
- enforcement of anti-corruption and anti-bribery laws, such as the FCPA;
- the effects of applicable local tax regimes, royalties and other payment obligations owed to local governments, and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

We may not timely realize the benefits of collaborations.

We may from time to time establish collaborations with third parties that we believe will complement or augment our development and commercialization efforts. However, 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 pipeline products because they may be deemed to be at too early of a development stage for collaborative effort and third parties may not view our pipeline products as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a product, we can expect to relinquish some or all of the control over the future success of that product to the third party. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing Shareholders, or disrupt our management and business. For any products or pipeline products that we may seek to in-license from third parties, we may face significant competition from other medical device companies with greater resources or capabilities than us, and any agreement that we do enter may not result in the anticipated benefits. We had entered into distribution agreements with Asahi Intecc since November 2016 to distribute their neurovascular guidewires in mainland China. We have also entered into a distribution

RISK FACTORS

agreement with Rapid Medical since October 2019 to distribute their products in Greater China, which collaboration is further strengthened through our strategic investment in Rapid Medical as we prepare for further global expansion of our products. For details, see “Business—Collaborations.”

Further, collaborations are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our pipeline products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a pipeline product, repeat or conduct new clinical trials, or require a new design of a pipeline product for clinical testing;
- collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our products, or that result in costly litigation or arbitration that diverts management attention and resources;

As a result, if we enter into collaboration agreements and strategic partnerships or license our products, we may not be able to timely realize the benefit of such transaction if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a pipeline product, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to

RISK FACTORS

undertake the necessary development and commercialization activities, we may not be able to further develop our products or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

We engage third parties to conduct certain aspects of our clinical trials. If we lose our relationship with these third parties, or if these third parties do not successfully carry out their contractual duties or meet expected deadlines, 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 leading academic institutions, hospitals, clinics, experienced physicians and CROs, to assist us in implementing and monitoring our preclinical research and conducting clinical trials. If such third parties with which we contract for preclinical research and clinical trials do not perform in an acceptable manner, or if we suffer setbacks in these preclinical studies or clinical trials, we may be unable to develop and successfully commercialize our pipeline products as anticipated. Therefore, we have less control over the quality, timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials wholly by ourselves. If we are unable to maintain or enter into agreements with these third parties on favorable terms 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 pipeline products covered by those agreements could be substantially delayed.

In addition, 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 the expected deadlines, maintain of clinical trial information regarding our future pipeline products or in accordance with regulatory requirements, including clinical, laboratory and manufacturing guidelines. Our reliance on these third parties may result in delays in completing, or in failing to complete, these studies if they fail to perform in accordance with the contractual arrangements. 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, then clinical trials of our future pipeline products may be extended, delayed or terminated, or our data generated by those studies may be rejected or not accepted by the applicable regulatory authorities, such as the NMPA, which would increase the cost of and the development time for the relevant pipeline product. If any of the preclinical studies or clinical trials of our pipeline products 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 future success depends on our ability to retain key personnel senior management or key clinical and scientific personnel. 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.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. 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

RISK FACTORS

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

Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous medical device companies for similar personnel. We also experience competition for the hiring of R&D and clinical personnel from universities and research institutions. Our consultants and advisors may be engaged by our competitors and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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 completed, in-process or potential 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;

RISK FACTORS

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products and pipeline products 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.

We may be subject to penalties for the non-registration of lease agreements in the PRC.

We are subject to a number of laws, regulations and local rules. If we fail to comply with applicable local regulations, we may be subject to penalties by the competent authorities. For example, during the Track Record Period and up to the Latest Practicable Date, seven lease agreements relating to our leased properties had not been filed with the relevant PRC housing administration authorities. For each lease agreement that is not filed with the relevant PRC housing administration authority, we may be subject to an administrative fine. See “Business—Properties” for details. The laws and regulations applicable to our business, whether national, provincial or local, may also change in ways that materially increase the costs of compliance, and any failure to comply could result in significant financial penalties which could have a material adverse effect on our business, financial position and results of operations.

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. As of the Latest Practicable Date, we were not aware of any pending or threatened litigations and legal proceedings that may materially affect our research and development of our pipeline products, business and results of operations. On-going or threatened litigation, legal or contractual disputes, investigations or administrative proceedings may divert our management’s attention and consume their time and our other resources. In addition, any similar claims, disputes or legal proceedings involving us or our employees may result in damages or liabilities, as well as legal and other costs and may cause a distraction to our management. 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. 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. 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.

RISK FACTORS

Our internal IT systems may fail or suffer security breaches.

Our internal IT systems are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we had not experienced any material system failure or security breach up to the Latest Practicable Date, if such an event were to occur and cause 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 applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business 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 revenues. 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 company and vendor confidential data. 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 is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the

RISK FACTORS

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.

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 China and other jurisdictions, which could expose us to criminal sanctions, administration penalties, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and application of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback statutes, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China, including, without limitation, the Criminal Law of the PRC (《中華人民共和國刑法》), Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and the Administrative Measures for the Registration and Recordation of Medical Devices (《醫療器械註冊與備案管理辦法》). These laws may impact, among other things, our 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 PRC government.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, we 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.

RISK FACTORS

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations. We are subject to the anti-bribery laws of various jurisdictions, particularly in China, that generally prohibits companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities we acquire. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violate such laws.

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, and other misconduct involving employees and other third parties that had any material and adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

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 damages, 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,

RISK FACTORS

this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

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

Our insurance coverage may 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 properties. As of the Latest Practicable Date, we had maintained certain insurance policies for our properties, manufacturing facilities, plant and machinery, equipment and inventories against damage caused by accidents. We also maintain clinical trial liability insurance policies against losses arising from severe adverse events that may occur during clinical trials. For details, see “Business—Insurance.” We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as product liability insurance (except for product candidates in clinical trial). Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. There is no assurance that our insurance policies will be adequate to cover all losses incurred. Losses incurred and associated liabilities may have a material adverse effect on our results of operation if such losses or liabilities are not covered by our insurance policies.

Specifically, we currently carry product liability insurance covering our clinical trials. Although we maintain such 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. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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

Any negative publicity concerning us, our affiliates or any entity that shares the name of the Company, even if untrue, could adversely affect our reputation and business prospects. We cannot assure you that negative publicities about us or any of our Controlling Shareholder, our affiliates or any entity that shares the “MicroPort” name of the Company would not damage our brand image and such unauthorized use of our brand name by any third parties may adversely affect the value of our brand name, reputation and business. In addition, any legal actions including litigation to enforce our rights to our brand name may involve significant costs and divert of our limited resources. This may result in a material adverse effect on our business, operation results and financial condition.

RISK FACTORS

We, our Shareholders, Directors, officers, employees, distributors, sub-distributors, suppliers, or other parties we cooperate with may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our employees, distributors, sub-distributors, suppliers, or other parties we cooperate with were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Given our specialized industry, any negative publicity regarding our industry could also affect our reputation and confidence in our brand and products. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our investors, customers, hospitals and physicians.

RISKS RELATED TO DOING BUSINESS IN CHINA

Changes in the political and economic policies of the PRC government 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.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources.

While the PRC economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.

The majority of our operations are conducted in China, and 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

RISK FACTORS

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.

You may experience difficulties in effecting service of legal process and enforcing judgments against us and our management.

Most of our assets, and a significant portion of the assets of our Directors and senior management are located in China. Therefore, it may not be possible for investors to effect service of process upon us or those persons inside China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions. On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “2006 Arrangement”), pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a PRC court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a PRC court is expressly designated as the court having sole jurisdiction for the dispute. Therefore, it may not be possible to enforce a judgment rendered by a Hong Kong court in China if the parties in the dispute do not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors to effect service of process against our assets or Directors in China in order to seek recognition and enforcement of foreign judgments in China. Although the 2006 Arrangement became effective on August 1, 2008, the outcome and effectiveness of any action brought under the 2006 Arrangement may still be uncertain.

On January 18, 2019, the Supreme People’s Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the

RISK FACTORS

Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “2019 Arrangement”), which seeks to establish a bilateral legal mechanism with further clarity and certainty for recognition and enforcement of judgments in a wider range of civil and commercial matters between Hong Kong and mainland China, based on criteria other than a written choice of court agreement. The 2006 Arrangement will be superseded upon the effectiveness of the 2019 Arrangement. Although the 2019 Arrangement has been signed, it remains unclear as to its effective date and uncertain as to the outcome and effectiveness of any action brought under the 2019 Arrangement.

Our dividend income from our PRC subsidiaries may be subject to a higher rate of withholding tax than that which we currently anticipate

Under the EIT law and relevant PRC tax laws and regulations, PRC withholding tax at a rate of 10% is normally applicable to dividends from a PRC source paid to investors that are “non-resident enterprises,” which do not have an establishment or place of business in China, or which have such establishment or place of business but whose relevant income is not effectively connected with the establishment or place of business, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. Any gain realized on the transfer of shares by such is generally subject to a 10% PRC enterprise income tax if such gain is regarded as income derived from sources within China.

If we are treated as a PRC resident enterprise, dividends we pay with respect to our Shares, or the gain realized from the transfer of our Shares, may be treated as income derived from sources within China and as a result be subject to the PRC income taxes described above. However, shareholders who are not PRC tax residents and seek to enjoy preferential tax rates under relevant tax treaties may apply to the PRC tax authorities to be recognized as eligible for such benefits in accordance with the Announcement of the SAT on Promulgating the Administrative Measures for Tax Convention Treatment for Non-resident Taxpayers (國家稅務總局關於發佈《非居民納稅人享受稅收協定待遇管理辦法》的公告) (the “Circular 35”), which was issued on October 14, 2019 and became effective on January 1, 2020. According to the Circular 35, the preferential tax rate does not automatically apply. With respect to dividends, the “beneficial owner” tests under the Circular on Relevant Issues relating to Beneficial Owner under Tax Treaties (國家稅務總局關於稅收協定中“受益所有人”有關問題的公告) (the “Circular 9”) will also apply. If determined to be ineligible for the foregoing tax treaty benefits, gains obtained from sales of our Shares and dividends on our Shares paid to such Shareholders would subject to higher PRC tax rates. In such cases, the value of your investment in our Shares may be materially and adversely affected.

PRC regulations relating to the establishment of offshore special purpose vehicles by PRC residents may subject our PRC resident Shareholders to personal liability, limit our PRC subsidiaries’ ability to distribute profits to us, or otherwise adversely affect our financial position.

The SAFE promulgated Circular 37 on July 4, 2014 to replace the Circular of the SAFE on Relevant Issues Concerning Foreign Exchange Administration for Financing and Return Investments by Domestic Residents through Special-Purpose Overseas Companies 《國家外匯管理局關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》(匯發[2005]75號). According to Circular 37, PRC residents (including PRC citizens and PRC enterprises) shall apply to the SAFE or its local branch to register foreign exchange for overseas investments before contributing to special

RISK FACTORS

purpose vehicles (the “SPVs”) with legitimate domestic and overseas assets or rights and interests. In the event of any alteration in the basic information of the registered SPVs, such as the change of a PRC citizen shareholder, name and operating duration; or in the event of any alteration in key information, such as increases or decreases in the share capital held by PRC citizens, or equity transfers, swaps, consolidations, or splits, the registered PRC residents shall timely submit a change in the registration of the foreign exchange for overseas investments with the foreign exchange bureaus. If the shareholders of the offshore holding company who are PRC residents do not complete their registration with the local SAFE branches, the PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore company, and the offshore company may be restricted in its ability to contribute additional capital to its PRC subsidiaries. SAFE promulgated the Notice on Further Simplifying and Improving the Administration of the Foreign Exchange Concerning Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) in February 2015, which took effect on June 1, 2015. Such Notice amended Circular 37 requiring PRC residents or entities to register with qualified banks rather than SAFE or its local branch in connection with the establishment or control of an offshore entity established for the purpose of overseas investment.

We may not at all times be fully aware or informed of the identities of all our beneficiaries who are PRC nationals, and may not always be able to compel our beneficiaries to comply with the requirements of the Circular 37. As a result, we cannot assure you that all of our Shareholders or beneficiaries who are PRC nationals will at all times comply with, or in the future make or obtain any applicable registrations or approvals required by the Circular 37 or other related regulations. Under the relevant rules, failure to comply with the registration procedures set forth in the Circular 37 may result in restrictions on the foreign exchange activities of the relevant PRC enterprise and may also subject the relevant PRC resident to penalties under the PRC foreign exchange administration regulations.

The heightened scrutiny over acquisitions from the PRC tax authorities may have an adverse impact on our business, acquisitions or restructuring strategies.

On February 3, 2015, the SAT promulgated the Announcement on Several Issues concerning the Enterprise Income Tax on Income from the Indirect Transfer of Assets by Non-Resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》) (“the Circular 7”), which provides comprehensive guidelines relating to, and heightened the PRC tax authorities’ scrutiny on indirect transfers, by a non-resident enterprise, of assets (including equity interests) of a PRC resident enterprise.

There is uncertainty as to the application of the Circular 7. The Circular 7 may be determined by the tax authorities to be applicable to our offshore restructuring transactions or sale of the shares of our offshore subsidiaries, where non-resident enterprises being transferors were involved. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with the Circular 7 or to establish that we and our non-resident enterprises should not be taxed under the Circular 7 for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial conditions and results of operations.

RISK FACTORS

PRC regulations of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the [REDACTED] of the [REDACTED] to make loans or additional capital contributions to our PRC subsidiaries.

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of SAFE. Additionally, our capital contributions to the foreign-invested enterprise must be filed or reported with the MOFCOM or its local counterpart and registered with the SAMR or its local branch. We cannot assure you that we will be able to obtain these government registrations or approvals or to complete filing and registration procedures on a timely basis, if at all, with respect to future loans or capital contributions by us to our subsidiaries or any of their respective subsidiaries. If we fail to obtain such approvals or registrations, our ability to make equity contributions or provide loans to our PRC subsidiaries or to fund their operations may be materially and adversely affected. This may materially and adversely affect our PRC subsidiaries' liquidity, their ability to fund their working capital and expansion projects, and their ability to meet their obligations and commitments. As a result, this may have a material adverse effect on our business, financial conditions 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. A substantial majority of our future revenue is expected to be denominated in Renminbi and our PRC subsidiaries will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our shares. 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 SAFE, but our PRC subsidiaries are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. 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.

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

During the Track Record Period, we purchased raw materials for our products from certain overseas suppliers in the United States. We may also engage in cross-border sales of our products between foreign countries and regions and China in the future. Our business is therefore subject to

RISK FACTORS

constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. 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.

China’s political relationships with those foreign countries and regions may affect the prospects of our relationship 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.

Furthermore, we rely on certain overseas suppliers to obtain raw materials for our products. 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 materially and adversely affected. Since July 2018, there has been a trade dispute between the United States and China, where the United States successively imposed tariffs on Chinese imports and China responded by imposing tariffs on U.S. imports. Although such trade dispute did not have any material negative impact on the cost and supply of raw materials the Company sourced from suppliers located in the United States, there remains much uncertainty as to whether the trade negotiations between the United States and China will be successful and how the trade disputes between the United States and China will progress. If the trade disputes between the United States and China continues or escalates, the businesses, results of operations, financial condition and prospects of our Group may be materially and adversely affected.

Our products may be subject to punitive tariffs or other trade barriers for cross-border sales between the United States and China. Although as of the Latest Practicable Date, none of our products or product candidates was subject to any punitive tariff due to the trade tension between the United States and China, the governments may impose such tariff or even restrict the sales of our products in the future. Any increase in the tariff or trade restrictions will increase our costs and may adversely affect our sales of products in the global market.

RISKS RELATED 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] volume of our Shares may be volatile.

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED], and the [REDACTED] may differ significantly from the [REDACTED] of the Shares following the [REDACTED]. We have applied to the Hong Kong Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the Shares. However, each existing Shareholder, including our Pre-[REDACTED] Investors, agrees and undertakes to our Company that, subject to the terms and conditions set out in the shareholders agreement dated November 18, 2021 entered into among our Company, MP NeuroTech BVI, MP NeuroTech HK, Shanghai Shenjing, MP NeuroTech Shanghai and the then Shareholders of our Company, without the prior written consent of our Company, it will not, whether directly or indirectly, at any time during the period of six months commencing from the

RISK FACTORS

[REDACTED], directly or indirectly dispose of, or enter into any agreement to dispose of or otherwise create any options, rights, interests or encumbrances in respect of any Shares of our Company. As a result, a [REDACTED] on the Hong Kong Stock Exchange does not guarantee that an active and liquid [REDACTED] market for our Shares will develop, especially during the period when a significant portion of our Shares are subject to [REDACTED] undertakings, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will rise following the [REDACTED].

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

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

- sales of our commercialized products;
- the results of clinical trials of our pipeline products;
- the results of our applications for approval of our pipeline products;
- regulatory developments affecting our industry, healthcare, health insurance and other related matters;
- relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors;
- our financial results;
- unexpected business interruptions resulting from natural disasters or power shortages;
- major changes in our key personnel or senior management;
- changes in laws and regulations in China;
- our inability to compete effectively in the market;
- our inability to obtain or maintain regulatory approval for our operations;
- changes in analysts’ estimates of our financial performance;
- political, economic, financial and social developments in China and Hong Kong and in the global economy; and
- involvement in material litigation.

Moreover, shares of other companies listed on the Hong Kong Stock Exchange with significant operations and assets in China have experienced price volatility in the past. As a result, it is possible

RISK FACTORS

that our Shares may be subject to changes in price not directly related to our performance and as a result, investors in our Shares may suffer substantial losses.

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 initial [REDACTED] to the public of our Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the Shares will not commence [REDACTED] on the Hong Kong Stock Exchange until they are delivered, which is expected to be not more than five Business Days after the [REDACTED]. As a result, [REDACTED] may not be able to sell or otherwise [REDACTED] the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the price of the Shares when [REDACTED] begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of [REDACTED] and the time [REDACTED] begins.

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

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

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

Sales of substantial amounts of Shares in the public market after the completion of the [REDACTED], or the perception that these sales could occur, could adversely affect the market price of our Shares. Although our Controlling Shareholder is subject to restrictions on its sales of Shares within 12 months from the [REDACTED] as described in “[REDACTED]” in this document, future sales of a significant number of our Shares by our Controlling Shareholder in the [REDACTED] after the [REDACTED], or the perception that these sales could occur, could cause the [REDACTED] of our Shares to decline and could materially impair our future ability to raise capital through [REDACTED] of our Shares. We cannot assure you that our Controlling Shareholder will not dispose of Shares held by it or that we will not issue Shares pursuant to the general mandate to issue shares granted to our Directors as described in “Appendix IV—Statutory and General Information” or otherwise, upon the expiration of restrictions set out above. We cannot predict the effect, if any, that any future sales of Shares by our Controlling Shareholder, or the availability of Shares for sale by our Controlling Shareholder, or the issuance of

RISK FACTORS

Shares by the Company may have on the [REDACTED] of the Shares. Sale or issuance of a substantial amount of Shares by our Controlling Shareholder or us, or the market perception that such sale or issuance may occur, could materially and adversely affect the prevailing [REDACTED] of the Shares.

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 HKFRSs. 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 HKFRSs. 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.

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.

There may be dilution because of issuance of new Shares or equity securities.

In spite of our current cash and cash equivalents and the net [REDACTED] from the [REDACTED], we may require additional funds due to changes in business conditions or other future developments relating to, inter alia, our existing operations or any future expansions. The amount and timing of such additional financing needs will vary depending on the timing investments in and/or acquisitions of

RISK FACTORS

new businesses from third-parties, and the amount of cash flow from our operations. If our resources are insufficient to satisfy our cash requirements, we may seek additional financing through selling additional equity or debt securities or obtaining a credit facility.

The sale of additional equity securities could result in additional dilution to our Shareholders. If additional funds are raised by way of issuance of new Shares or equity linked securities other than on a pro rata basis to existing Shareholders, the percentage of ownership of our existing Shareholders in our Company, the earnings per Share and the net asset value per Share may be reduced.

Facts, forecasts and statistics in this document relating to the neurovascular 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 neuro-interventional medical device industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by CIC that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the [REDACTED], the Joint Sponsors, 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.

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].

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

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong in making your investment decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts,

RISK FACTORS

views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective investors should not rely on any such information, reports or publications in making their decisions as to whether to invest in our [REDACTED]. By applying to purchase our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and the [REDACTED].