Investment in our Shares involves significant risks. You should carefully consider all of the information in this prospectus, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the "Financial Information" section, before making an investment in our Shares. Our business, financial conditions and results of operation and growth prospects could be materially and adversely affected by any of these risks and uncertainties. The trading price 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 prospectus.

### RISKS RELATING TO THE DEVELOPMENT OF OUR PRODUCTS AND PIPELINE PRODUCTS

We have only recently begun commercializing our products and our sales currently rely on one product,  $VitaFlow^{TM}$ , which may make it difficult to evaluate our future prospects. As a result, you may lose substantially all of your investment in us given the nature of biotech industry.

We began to commercialize VitaFlow<sup>TM</sup> in China in August 2019. As a result, all of our revenue in 2019 and the seven months ended July 31, 2020 was derived from the sale of VitaFlow<sup>TM</sup>. In 2019 and the seven months ended July 31, 2020, we sold 271 and 601 units of VitaFlow<sup>TM</sup>. We expect sales of VitaFlow<sup>TM</sup> will continue to account for a significant portion of our total sales in the foreseeable future. However, we cannot assure you that the demand for VitaFlow<sup>TM</sup> will continue to grow as anticipated or our revenue generated from VitaFlow<sup>TM</sup> will be substantial in the future. Accordingly, our operating history and historical results of operations may not be a reliable indicator of our future performance or serve as an adequate basis for evaluating our business prospects and financial performance.

There is also no assurance that we will be able to maintain and further improve our sales and profit margin for VitaFlow<sup>TM</sup>, which may be adversely affected by many factors out of our control, including business disruption due to epidemics (for example, the recent COVID-19 pandemic), 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 the procedure, downward pricing pressure caused by changes in market competition, coverage of medical insurance, expiration of patent protection, and disputes over intellectual property or other matters with third parties. If we are unable to maintain and further improve the sales volumes and optimize pricing level or profit margin of VitaFlow<sup>TM</sup>, our business, financial condition and results of operations may be materially and adversely affected. Moreover, there is no guarantee that we may be able to successfully develop or commercialize new products that would diversify our product portfolio and reduce our dependence on VitaFlow<sup>TM</sup>, or to do so in a timely or competitive manner. Furthermore, even if we are able to bring more products to market, we may not be able to expand our business and capture market share,

maintain our competitive position, or sustain growth and profitability. As a result, any predictions about our future success or viability may not be as accurate as they could be even if we had a history of successfully commercializing our products.

Our future growth depends substantially on the success of our pipeline products. If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our pipeline products, or experience significant delays in doing so, our business may be materially and adversely affected.

Our ability to generate revenue and become profitable in the future substantially 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 process with uncertain outcomes. A failure of one or more of our clinical trials can occur at any stage of testing and clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. In addition, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations and the rate of dropout among clinical trial participants. 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 and 2019 and the seven months ended July 31, 2020, our research and development costs amounted to RMB44.7 million, RMB96.7 million and RMB38.2 million, respectively. We expect to continue to incur substantial and increasing expenditures through the projected commercialization of pipeline products.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or successfully commercialize our pipeline products, 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;
- clinical trials of our pipeline products may have undesirable side effects, produce negative
  or inconclusive results, or other unexpected characteristics, and we may decide, or
  regulators may require us, to conduct additional clinical trials, suspend or terminate the
  product development programs;
- the initial or interim results of clinical trials may not be predictive of the final clinical trial results and may be subject to adjustments;
- the number of patients required for clinical trials of our pipeline products may be larger than anticipated;
- the patient enrollment may be insufficient or slower than anticipated or patients may drop out at a higher rate than anticipated;

- our inability to reach agreements on acceptable terms with prospective CROs, SMOs and hospitals as trial centers, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, SMOs and hospitals as trial centers;
- 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;
- we might have to suspend, delay or terminate clinical trials of our pipeline products for various reasons, including a finding of lack of clinical response or other unexpected characteristics, a finding that participants are being exposed to unacceptable health risks or reasons outside of our control, such as occurrences of epidemics like the outbreak of COVID-19;
- regulators or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our pipeline products may be greater than anticipated; and
- the supply or quality of our pipeline products for use in a clinical trial or other materials
  necessary to conduct clinical trials of our pipeline products may be insufficient or
  inadequate.

If we are unable to conduct additional clinical trials or other testing of our pipeline products beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our pipeline products or other testing or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our pipeline products or not be able to obtain regulatory approval at all;
- obtain approval for modified or narrowed indications with additional pre-requisites;
- have the product removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing study requirements;
- be subject to restrictions on how the product is distributed or used;
- be unable to obtain reimbursement for use of the product; or
- be inferior to products of competitors when being selected by physicians and hospitals.

Whether we can generate profit from our operating activities largely depends on the successful commercialization of our pipeline products. The success of our pipeline products will depend on several factors, including but not limited to:

 receipt of regulatory approvals from the NMPA, EMA and other regulatory authorities for our pipeline products;

- establishing sufficient commercial-scale manufacturing capabilities, either by expanding our current manufacturing facility or making arrangements with third-party manufacturers;
- 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;
- successful launch of our pipeline products, if and when approved;
- successfully maintain an effective distribution channel for our products;
- obtaining favorable governmental and private medical reimbursement or reimbursement from other third-party payers for our products, if and when approved;
- competition with other medical devices treating valvular heart diseases; and
- continued acceptable safety profile for our products and pipeline products following regulatory approval, if and when received.

Moreover, because we have limited financial and managerial resources, we focus our product pipeline on research and development programs and pipeline products targeting valvular heart diseases, especially severe aortic stenosis and mitral regurgitation. As a result, we may forego or delay pursuit of opportunities with other pipeline products that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and pipeline products for valvular heart diseases treatment may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular pipeline product, we may relinquish valuable rights to that pipeline product through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

# If we encounter difficulties 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 trial until its 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 recruit clinical trial investigators with the appropriate competencies and experience;
- the patients' perceptions as to the potential advantages and side effects of the pipeline products being studied in relation to other available product, pipeline products or therapies; 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 pipeline products that are in the same therapeutic areas as our pipeline products. This competition will reduce the number and types of patients available to us as some patients who might have opted to enroll in a trial being conducted by one of our competitors instead of ours. 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 and timely commercialization of our pipeline products. Further, if clinical trial results of our pipeline products 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 pipeline products.

We may face intense competition in the medical device business, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The TVT medical device industry is intensely competitive and rapidly changing. We face competition from major TVT medical device companies worldwide. There are several multi-national and domestic companies having TVT medical devices at or near commercial stage, or pursuing the development and undergoing clinical trials of medical device targeting the valvular heart diseases, especially severe aortic stenosis, mitral regurgitation and tricuspid regurgitation. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization on TVT medical devices.

Our competitors may be applying for marketing approvals in China, EU, or other countries for medical device products with the same intended use as our products and pipeline products. The ability of the relevant authorities, such as the NMPA, to concurrently review multiple marketing applications for the same type of innovative medical device 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 or other comparable regulatory authorities for their products more quickly than we obtain approval for ours, which could result in our competitors establishing a strong market position or gaining acceptance in the same markets that we are targeting before we are able to enter

the market and/or slow our regulatory approval. As a result, we may be unable to maintain or enhance our market share or achieve our targeted market share in this industry. Even if successfully developed and subsequently approved by regulatory authorities, our pipeline products may face competition based on their safety and effectiveness, the timing and scope of the regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer severe adverse events, or are less expensive than any products that we commercialize or may develop. As a result, we may become obsolete overtime and lose our market share.

Moreover, some of our competitors, including certain first-movers and multi-national companies, may have greater commercial infrastructure, better financial, technical and personnel resources than we have. 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. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our business and results of operations will suffer if we fail to compete effectively.

Disruptive technologies and medical breakthroughs may also render our pipeline products obsolete or noncompetitive. 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. We may have to make significant investments in new products and advanced technologies to face such competitions. However, technical innovations often require substantial time and investment before we can determine their commercial viability, which will have a material adverse impact on our financial conditions. Furthermore, should the new generation of our products succeed in obtaining an approval, it may capture a significant share of our previous generation products and thereby reduce the sales of our previous generation products.

## RISKS RELATING TO COMMERCIALIZATION AND DISTRIBUTION OF OUR PRODUCTS

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

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

In addition, our products may be perceived to cause severe adverse events if one or more regulators, such as the NMPA and/or the EMA, determine that other companies' products containing the same or similar key parts or using the same delivery technologies as our products' cause or are

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

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

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

### 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. Physicians and patients may prefer other treatments to TAVI procedures. As a treatment recently developed and introduced to the market, TAVI procedures may fail to receive broad acceptance from patients or physicians as anticipated. As an alternative, open-chest surgery may have a competitive advantage over TAVI procedure, given its established market acceptance, comparatively lower price and coverage by governmental and private medical insurance. 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 products or pipeline products (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. For example, current TVT products or devices, such as the valve systems developed by some of our competitors are well established in China and the global transcatheter heart valve medical device industry, and doctors may continue to rely on these treatments to the exclusion of our products and pipeline products. Furthermore, the favorable policy changes on TAVI market in the PRC, for example, Guidelines of Plan for Development of the Pharmaceutical Industry (醫藥工業發展規劃指南), which was issued to encourage the research and development and commercialization of innovative medical devices, will also intensify competition in the market. In addition, physicians, patients and third-party payors may prefer other novel products to ours. If our products and pipeline products do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our products and pipeline products, if approved for commercial sale, will depend on a number of factors, including:

the clinical indications for which our products and pipeline products are approved;

- physicians, hospitals, valvular heart diseases treatment center and patients considering our products and pipeline products (upon commercialization) as a safe and effective treatment;
- the potential and perceived advantages and disadvantages of our products, pipeline products (upon commercialization) and relevant treatments compared to alternative products and treatments;
- the prevalence and severity of any side effects, adverse effects or complications;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our products and pipeline products (upon commercialization) as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and/or
- the effectiveness of our sales and marketing efforts.

If any products that we commercialize but fail to achieve market acceptance among physicians, patients, hospitals, valvular heart diseases treatment centers or others in the medical community or if we fail to maintain good relationships with them, we will not be able to generate significant revenue. 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.

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

In August 2019, we began to commercialize our first approved product, VitaFlow<sup>TM</sup> in China. As we just recently began commercialize our pipeline products, compared with other companies within the same industry, we have relatively limited experiences in launching and commercializing our pipeline products and sales and marketing of our products in China or worldwide. For example, we have limited experience in building a commercial team, conducting a comprehensive market analysis, obtaining licenses and approvals, or managing distributors and sales force for our products. As a result, our ability to successfully commercialize our pipeline products may involve more inherent risks, take longer and cost more than it would if we were a company with sufficient experience launching pipeline products.

We cannot assure you that our pre-launch efforts will guarantee immediate market success for our future products or the distribution channel for our products would be definite effective. There may be circumstances during the actual sales of our future products that we did not anticipate prior to commercialization that may require us to adjust our sales and marketing strategies, recruit additional personnel or incur unforeseen costs and expenses to address those circumstances. In such event, our business prospects and sales of relevant products could be materially and adversely affected.

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

To further penetrate into China's TAVI market and enhance our brand recognition in hospitals, we adopt an academic promotion approach, including participating in industry-leading academic conference and organizing hospital training sessions and valvular heart diseases seminars. We also collaborate with KOLs to promote our TAVI products. As of the Latest Practicable Date, TAVI procedures using VitaFlow<sup>TM</sup> had been performed at over 145 hospitals in China, most of which are Class IIIA Hospitals located at tier-one and tier-two cities, including 18 of the Top 20 TAVI Hospitals. We expect to continue our focus on increasing penetration into Top 20 TAVI Hospitals and expand into other hospitals that either have existing TAVI capabilities or the potential to perform TAVI procedures but had not performed TAVI procedure. However, we may not be able to do so if we are unable to expand and deepen our hospital penetration 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 qualified and professional employees in our sales and marketing team who have, among other things, the sufficient expertise in the cardiovascular areas and are able 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, sales volumes or margin of our existing and future products may be adversely affected and we may be unable to extend our hospital coverage and deepen our market penetration as contemplated.

## Our pricing strategy and downward change in pricing of our products may have a material adverse effect on our business and results of operations.

As of the Latest Practicable Date, VitaFlow<sup>TM</sup> was priced at approximately RMB196,000 per unit under the public wholesale tender scheme in China, which according to Frost and Sullivan, is significantly lower than other commercialized TAVI products in China. As such, our profit margin from sales of VitaFlow<sup>TM</sup> may be lower than our competitors. In addition, we may negotiate with certain distributors for price discount on a case-by-case basis in light of their hospital coverage and expected procurement amount. For details, see "Business—Customers—Pricing." Depending on the availability of alternative products, demands of patients and the preference of physicians, hospitals may bargain with the distributors for lower retail prices of our products and therefore reduce the profitability of our distributors. Thus, 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.

Since 2007, China started to adopt a centralized procurement regime in an effort to regulate prices of medical devices through group procurement at the provincial level. For details, see "Regulatory Overview—Laws and Regulations Relating to Medical Devices—Reform Plan on High-Value Medical Consumables." As of the Latest Practicable Date, TAVI products were not included in the centralized procurement regime and there was generally no special tender or bidding process or price guidance set on TAVI procedures and related products for enterprises by the PRC government. The absence of a tender process and price guidance is primarily because TAVI procedures and related products have only been introduced to the Chinese market in recent years, and there are only a limited number of TAVI products approved for marketing in China and the application of TAVI procedures is still limited to top-tier cardiology hospitals in tier 1 and tier 2 cities. With the development of

technologies and increasing competition in the industry, more competing TAVI products may become available and the launch of new products that can replace or further improve the safety and efficacy profile of our existing products. The PRC government may also issue price guidance in relation to our products and pipeline products or introduce tender process and exercise any control measures on the tendering process of any of our products and pipeline products, either at the national or provincial level by the hospital, medical institutions or governments, which may result in uncertainties regarding the timing of such procedures. In particular, our bids may not be successful and our products may not be chosen for a number of reasons, including among others: (i) our prices are not competitive; or (ii) our product quality or any other aspect of our operation fails to meet the relevant requirements. Even if our products win the bids in the centralized procurement process, there is no guarantee that hospitals would purchase our products as they have the sole discretion in selecting between our products and other competing products. These may negatively affect the price of our products and therefore have a material adverse effect on our business and results of operations. Further, we may also face downward pricing pressure if our products are included in the medical insurance reimbursement list, even if such inclusion in the medical insurance reimbursement list is expected to increase the sales volume of our products.

## Our sales may be affected by the level of medical insurance reimbursement for TVT medical devices, including TAVI procedure.

Our ability to commercialize our pipeline products will depend in part on the extent to which reimbursement for our products and related treatments will be available to hospitals and other medical institutions ordering these product for use by their patients, which is out of our control. China has a complex medical insurance system that is undergoing reform. The governmental insurance coverage or reimbursement level in China for new procedures such as TAVI procedures and the medical device used in such procedures is subject to significant uncertainty and varies from region to region, as local government approvals for such coverage must be obtained in each geographic region in China. Since TVT medical devices, including TAVI procedures have been introduced to China only in recent years, in order for these medical devices and related procedures to be covered by medical insurance, they first need to be categorized by the hospital under the heart valve replacement procedure or another procedure that is reimbursable.

We have pursued, and plan to actively pursue reimbursement opportunities at national and provincial levels in China. However, we cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with newly introduced technology or medical devices. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any pipeline product that we successfully develop.

In the absence of sufficient medical insurance coverage for the use of our products, patients may choose alternative treatment methods, and hospitals may recommend such 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 operation. Moreover, we may need to lower the prices of our products in order to have them included in the medical insurance

reimbursement list, 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 OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant net losses since inception and expect to continue to incur losses, and may never achieve or maintain profitability. As a result, you may lose substantially all of your investment in us if our business fails.

Investments in medical device development are highly speculative. It entails substantial upfront capital expenditure and significant risks that a pipeline product may fail to gain regulatory approval or become commercially viable. We have incurred significant expenses related to the research and development of our pipeline products in the past. For the years ended December 31, 2018 and 2019 and the seven months ended July 31, 2020, our research and development costs amounted to RMB44.7 million, RMB96.7 million and RMB38.2 million, respectively. In addition to our significant research and development costs, we also incurred distribution costs and administrative expenses associated with our operations. See "Financial Information—Discussion of Certain Items in the Consolidated Statements of Profit or Loss." As a result, we recorded net losses of RMB60.3 million, RMB144.5 million and RMB192.6 million for the years ended December 31, 2018 and 2019 and the seven months ended July 31, 2020, respectively.

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

Our results of operations, financial condition and prospects may be adversely affected by the fluctuations in the fair-value of financial instruments.

Our results of operations, financial condition and prospects may be affected by fair-value changes in the financial instruments. During the Track Record Period, our fair-value changes in financial instruments consisted of changes in fair value of (i) our investment in 4C Medical; (ii) put options issued to Witney Global Limited ("Witney Global"); and (iii) the Series D Adjustment. For details, see "History, Development and Corporate Structure—Strategic Investments" and "Business—Collaboration with Third Parties." For the year ended December 31, 2019 and seven months ended July 31, 2019 and 2020, we realized fair-value losses in financial instruments of RMB8.6 million, RMB11.3 million, and RMB28.1 million. The estimated changes in fair value involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by

their nature, are subjective and uncertain. For more details, see "Financial Information—Significant Accounting Policies, Judgments and Estimates—Critical Judgments and Estimates—Fair Value of Unlisted Equity Investments and Derivative Financial Liabilities." Our management determines the fair value of our level 3 financial assets and liabilities using valuation techniques that incorporated unobservable inputs, including expected probability of event, expected volatility, and others. See Note 28(e) to the Accountants' Report in Appendix I to this prospectus for more information about the fair value measurement of our level 3 valuations. As such, fair-value changes in financial instruments have been, and will continue to be, subject to uncertainties in accounting estimation, which may not reflect actual fair value of these financial instruments and result in significant fluctuations in profit or loss from year to year. Changes in these unobservable inputs will also affect the estimated fair value of our level 3 financial assets and financial liabilities at fair value through profit or loss, which leads to uncertainty in our financial results. A range of factors, many of which are beyond our control, may influence and cause adverse changes to the estimates we use and thereby affect the fair value of these assets and liabilities. These factors include, but are not limited to, general economic condition, change in market interest rates and stability of the capital markets. Any of these factors, as well as others, could cause our estimates to vary from actually results and cause the fair value of our financial assets and liabilities at fair value through profit or loss to fluctuate substantially. We may recognize additional losses from the fair-value changes of financial instruments after July 31, 2020, and we may retain accumulated losses due to the fair-value losses of financial instrument.

## 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 intended to support our R&D activities and business operations. For the years ended December 31, 2018 and 2019 and the seven months ended July 31, 2020, we recognized government grants under other net income of RMB0.3 million, RMB3.9 million and RMB2.3 million, respectively. For details, see "Financial Information—Discussion of Certain Items in the Consolidated Statements of Profit or Loss—Other Net Income/(Loss)." Our eligibility for government grants is dependent on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, 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.

### We had net operating cash outflows during the Track Record Period.

We had net cash used in operating activities of RMB70.2 million, RMB142.7 million and RMB75.7 million, for the years ended December 31, 2018 and 2019 and the seven months ended July 31, 2020, respectively. We cannot assure you that we will be able to generate cash flows from operating activities in the future. Our liquidity and financial condition may be materially and adversely affected by negative net cash flows. In addition, our existing cash and cash equivalents may not be sufficient to enable us to complete all development or commercially launch all of our current pipeline products for the anticipated characteristics and to invest in additional programs. Accordingly, we may require further funding through public or private offerings, debt financing, collaboration and

licensing arrangements or other sources. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that the financing may be available when we need them, on terms that are favorable to us, or at all. Our ability to raise funds will also depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funds are not available to us on a timely manner, we may have to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or the commercialization for one or more of our pipeline products, which in turn will adversely affect our business prospects.

We had net current liabilities and net liabilities during the Track Record Period. We cannot assure you that we will not experience net current liabilities or net liabilities in the future, which could expose us to liquidity risks.

We had net current liabilities during the Track Record Period. In addition, we had net liabilities of RMB228.2 million as of July 31, 2020. For details, see "Financial Information—Discussion of Certain Key Consolidated Statements of Financial Position Items." Our net current liabilities position and deficit position were in part due to the accounting treatment for Series C Preferred Shares and Series D Preferred Shares, which were classified as other financial liabilities in accordance with HKFRSs. Such Preferred Shares will automatically convert into Shares upon Listing, at which time we expect to reclassify them from liabilities to equity and, accordingly, turn into net current asset position and net asset position. However, there can be no assurance that we will not experience liquidity problems in the future. If we fail to maintain sufficient cash and financing, we may not have sufficient cash flows to fund our business, operations and capital expenditure and our business and financial position will be adversely affected.

Raising additional capital may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or pipeline products.

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 new businesses from third-parties, and the amount of cash flow from our operations. We may seek additional funding through a combination of equity offerings, debt financings, credit facilities, collaborations and licensing arrangements.

To the extent that we raise additional capital through the issuance of new Shares, sale of equity, equity linked securities or convertible debt 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, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares.

The incurrence of additional indebtedness, the issuance of certain equity securities or obtaining credit facilities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition,

issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline.

In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or pipeline products that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

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

As of July 31, 2020, we had intangible assets of RMB226.2 million which comprised of RMB226.1 million related to capitalized development costs and RMB0.1 million related to software. Our capitalized development costs are primarily related to the VitaFlow<sup>TM</sup> and VitaFlow<sup>TM</sup> II. Our determination on whether intangible assets are impaired requires an estimation on recoverable amount of the intangible assets, which is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, the carrying amount of the intangible assets may exceed its recoverable amount, our intangible assets may be impaired. As a result, we may be required to have a significant write-off of our intangible assets and record a significant impairment loss. The impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations. For more information regarding our impairment policy in relation to intangible assets, see Note 2 "Significant Accounting Policies—(i) Intangible Assets" and Note 3 "Accounting Judgments and Estimates—(a) Impairment of Capitalized Development Costs" to the Accountants' Report in Appendix I to this prospectus.

#### We are subject to credit risk in collecting trade receivables from our customers.

We started to generate revenue in 2019 after we commenced commercial sales of VitaFlow<sup>TM</sup>, therefore, our cash flow and profitability would be affected by the timely settlement of payments by our customers. During the Track Record Period, all of our customers were our distributors. Except for two distributors in 2020 to whom we granted a credit term of 10 business days starting from June 2020 and approximately 30 days starting from October 2019, respectively, we typically require distributors to make full payment of our products the following day we confirmed their order and we will only arrange product delivery after receiving a copy of the payment invoice. As a result, we only recorded trade receivables of RMB3.2 million as of July 31, 2020. Although we did not experience any material credit risk for trade receivables during the Track Record Period, however, if our distributors' cash flows, working capital, financial condition or results of operations deteriorate or they experience delays in payments from the hospitals, they may be unable, or they may otherwise be unwilling, to make payments 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. Therefore, we may be exposed to credit risk in relation to our customers.

We are subject to credit risk with respect to other receivables. As a result, the recoverability of value-added tax recoverable and deposits and prepayments may affect our business operations.

Value-added tax recoverable, or VAT recoverable, represented our VAT input credit, resulting from the difference between our VAT input tax (arising from our purchase of goods, including raw materials, consumables, other inventories and services) and our VAT output tax (arising from our sales of products). As of December 31, 2018 and 2019 and as of July 31, 2020, our VAT recoverable was RMB22.3 million, RMB30.4 million and RMB27.4 million, respectively, as the input tax exceeds the output tax for the periods. In general, VAT recoverable will be deducted from future VAT payables or can be received from the tax authorities, for which we consider to have relatively low credit risk. However, the majority of such excess VAT cannot directly result in a refund, instead, it may be carried forward and used to offset output VAT generated in future. Under such circumstance, it may limit our liquidity efficiency and we cannot guarantee the recoverability of the deductible VAT, and to what extent it may affect our financial positions in the future.

In addition, there are uncertainties about the recoverability of our deposits and prepayments which primarily represented the prepaid fees to suppliers and service providers. As of December 31, 2018 and 2019, and July 31, 2020, we recorded current and non-current deposits and prepayments of RMB5.0 million, RMB4.0 million and RMB4.7 million, respectively. However, there is no guarantee that the suppliers and service providers will perform their obligations in a timely manner and we are subject to credit risk in relation to deposits and prepayments. We conduct assessments on the recoverability of deposits and prepayments based on, among others, our historical settlement records, our relationship with relevant counterparties, payment terms, current economic trends and to a certain extent, the larger economic and regulatory environment, which involve the use of various judgments, assumptions and estimates by our management. However, there is no assurance that our expectations or estimates will be entirely accurate for the future, as we are not in control of all the underlying factors affecting such deposits and prepayments. Therefore, if we are not able to recover the deposits and prepayments as scheduled, our financial position and results of operations may be adversely affected.

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

In 2018 and 2019 and the seven months ended July 31, 2020, we recorded net losses of RMB60.3 million, RMB144.5 million and RMB192.6 million, respectively. As a result, during the Track Record Period, we did not record any income tax. We may be subject to PRC corporate income tax in the future, which could reduce our profitability. In addition, according to a tax incentive policy promulgated by the SAT of the PRC in September 2018, we enjoy an additional 75% of qualified research and development costs incurred to be deducted from the taxable income. We cannot assure you that 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.

Share-based payment may cause shareholding dilution to our existing Shareholders and have a material and adverse effect on our financial performance.

We adopted Share Option Scheme for the benefit of our employees (including Directors) and non-employees as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the development of our Company. For details, see "Appendix IV—Statutory and General Information—D. Share Option Scheme." To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares in accordance with such Share Option Scheme may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such sharebased payment may also increase our operating expenses and therefore have a material and adverse effect on our financial conditions.

#### RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATIONS

The research, development and commercialization of our products are heavily regulated in all material aspects.

All jurisdictions in which we conduct our research, development and commercialization activities regulate these activities in great depth and details. We intend to focus our activities in the major markets of China and Europe. These geopolitical areas all have comprehensive regulation on medical devices, and in doing so they employ broadly similar regulatory strategies, including regulation of product development, approval, manufacturing, sales and marketing and distribution of medical devices. However, there are differences in the regulatory regimes in different regions, which make regulatory compliance more complex and costly for companies like us that plan to operate in each of these regions.

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

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

Obtaining regulatory approvals is a lengthy, expensive and uncertain process, and approvals may not be obtained. When we submit a filing application to the regulatory authorities, the regulatory authorities will decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the regulatory authorities. In addition, the time required to obtain approval from the regulatory authorities is unpredictable but typically takes years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. The marketing approval for VitaFlow<sup>TM</sup>, was granted by the NMPA in July 2019. As of the Latest Practicable Date,

other than VitaFlow<sup>TM</sup>, we had not received marketing approval for any of our product portfolio, and it is possible that none of our existing pipeline products or any pipeline products we may discover, in-license or acquire and seek to develop in the future will ever obtain such approval.

Our pipeline products could fail to obtain regulatory approval for many reasons, including:

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

Currently, we are exploring opportunities for VitaFlow<sup>TM</sup> in emerging markets, such as Argentina, Thailand and Russia. For VitaFlow<sup>TM</sup>, we had successfully registered it in Argentina and Thailand in July 2020 and November 2020, respectively, and we plan to register it in Russia in the next two years. For VitaFlow<sup>TM</sup> II, currently, it is under near-commercialization and clinical trial stage in China and Europe, respectively. We plan to register VitaFlow<sup>TM</sup> II in China and Europe and other emerging markets including Argentina, Brazil, India, Russia, South Korea and Thailand. However, regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products. Obtaining regulatory approval in one country does not necessarily mean that regulatory approval will be obtained in any other country. For example, certain jurisdictions may have more stringent requirements on clinical trials and clinical data than those of the NMPA or the EMA. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval in such emerging countries could require additional nonclinical studies or clinical trials, if required by the local authorities, which could be costly and time consuming. For these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all. If we are unable to obtain regulatory approval for our products in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our products will be materially and adversely affected.

Our products and pipeline products may cause undesirable adverse events which could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved production 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 side effects, 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, EMA 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 EMA and other comparable regulatory authorities could order us to cease further development of, or deny approval of, our pipeline products.

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

Additionally, if our pipeline products receive regulatory approval, and undesirable side effects 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, change the labeling or add additional warnings on the labeling of such products;
- 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 suffer.

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 pipeline products will be subject to ongoing regulatory obligations and continued regulatory review even if we receive regulatory approval for our pipeline products, 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 pipeline products.

Our products and any additional pipeline products that are 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, Europe, 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, the EMA and/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 and adherence to commitments we made in any application materials with the NMPA, the EMA or other authorities.

The NMPA, the EMA 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 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 testing and surveillance 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, the EMA or comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval if we fail to maintain compliance with these ongoing regulatory requirements and standards is not maintained 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, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;

- refusal by the NMPA, the EMA, 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 achieve or sustain profitability. In addition, if we were able to obtain conditional approval of any of our pipeline products, the NMPA, the EMA, 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.

If we or parties on whom we rely on fail to maintain or renew the necessary permits, licenses and certificates required 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). For details, see "Regulatory Overview-Laws and Regulations Relating to Medical Devices." 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.

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

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 Management." 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.

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

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 involve the use of hazardous and flammable materials, including chemicals. 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 also could incur significant costs associated with civil or criminal fines and penalties. We may incur substantial costs in order 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 manufacturing activities. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Recently enacted and future legislations may increase the difficulty and cost for us to obtain regulatory approval of or successfully commercialize our pipeline products and therefore adversely affect our business.

In China and some other jurisdictions, a number of legislative and regulatory changes and proposed changes regarding healthcare could prevent or delay regulatory approval of our pipeline products, restrict or regulate post-approval activities and affect our ability to profitably sell our products and any pipeline products 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 successfully commercialize our pipeline 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 pipeline products, if any, may be. For example, on June 25, 2018, a revised draft amendment to the Regulations on the Supervision and Administration of Medical Devices was published by the Ministry of Justice (《醫療器械監督管理條例修正案(草案送審稿)》) (the "**Draft Amendment**") for public comments. As a medical device company, if the Draft Amendment is passed, the requirements of clinical trial, sales and regulation would be changed. The impact of these more specific requirements and whether it will adversely affect the registration of our products with the NMPA is yet to be observed.

According to the Notice on Opinions on the Implementation of the "Two Invoice System" in Drug Procurement by Public Medical Institutions (for Trial Implementation) (關於在公立醫療機構藥品採購中推行"兩票制"的實施意見 (試行)的通知), the Notice on Consolidating the Achievements of Cancelling Drug Markups and Deepening Comprehensive Reforms in Public Hospitals (關於鞏固破除以藥補醫成果持續深化公立醫院綜合改革的通知) and 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), as of the Latest Practicable Date, a few provinces have implemented the "Two Invoice System" in the field of medical consumables. For more details, see "Regulatory Overview." 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.

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, treatment records and other personal details of the subjects enrolled in our clinical trials, along with

other personal or sensitive information. 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 personal 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 everincreasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officers and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

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. Whilst 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 Interim Measures for the Administration of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) and the implementation guidelines issued by the Ministry of Science and Technology and Ministry of Health. For details, see "Regulatory Overview-Laws and Regulations Relating to 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, 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.

#### RISKS RELATING TO MANUFACTURE AND SUPPLY OF OUR PRODUCTS

The manufacture of our products is highly exacting and complex process and subject to strict quality controls. Our business could suffer if our products and pipeline products are not produced in compliance with all the applicable quality standards.

The manufacture of our products is highly complex and subject to strict quality controls. In addition, quality is extremely important due to the serious and costly consequences of a product failure. 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 details of our quality control and assurance system, please refer to the paragraphs headed "Business—Quality Management" in this prospectus. Despite our quality control and assurance system and procedures, we cannot eliminate the risk of 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 material, or human error. If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. 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 supply of 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. Stability failures and other issues relating to the manufacture of our products or pipeline products could occur in the future. Although closely managed, disruptions can occur during implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions.

As we expand into new markets, we may face unanticipated surges in demands for our products which could strain our production capacity. If these problems arise or if we otherwise fail to meet our internal quality standards or those of the 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 rely on a limited number of suppliers, and may not be able to secure a stable supply of qualified raw materials at all times or at all.

Our principal raw materials for the manufacturing of TAVI products are bovine pericardium and nitinol components. To ensure the quality of our principal raw materials, we only procure bovine pericardium and nitinol frame from selected suppliers that can satisfy our stringent raw material

requirements. In order to acquire raw materials in high quality, we currently rely on a limited number of selected third-party suppliers to supply key raw materials used in the research, development and manufacturing. Although we believe that we have stable and long-term relationships with our existing suppliers and we are also exploring other qualified suppliers, however, we cannot assure you that we will be able to secure a stable supply of qualified raw materials at all times going forward. Further, the custom clearance procedures for importing raw materials could be lengthy and thus could adversely affect the timely supply of such raw materials. 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 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 directly negative impact on our gross margin. In particular, during the Track Record Period, certain raw materials were procured from the MicroPort Group on normal commercial terms or better when compared with other third-party suppliers. For details, see "Connected Transactions—Continuing Connected Transactions—B. Non-exempt Continuing Connected Transactions." Going forward, if we choose to procure these raw materials from other third-party suppliers, we may not achieve similar commercial terms as compared to those from MicroPort Group and our costs of raw material may further increase, which will have a negative impact on our gross margin.

General economic conditions could also adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products. In addition, some of our suppliers are located outside China, therefore trade or regulatory embargoes imposed by foreign countries or China could result in delays or shortages of our raw materials that could harm our business. In particular, in recent months, trade tensions between China and Australia have escalated and China has imposed trading restrictions on imports of certain products from Australia, where we primarily procure bovine pericardium for VitaFlow<sup>TM</sup>. As advised by our PRC Legal Advisers, based on their search of recent announcement of the official website of General Administration of Customs of the PRC (中華人民共和國海關總署) and the Ministry of Commerce of the PRC (中華人民共和國商務部), as of the Latest Practicable Date there had been no restrictions in China that materially and adversely affect bovine pericardium from Australia. However, the development of the trade policy between China and Australia and the trading restriction on imports from Australia imposed by China as well as the related impact on our business are unclear at this time. We cannot foresee whether and how developments in these trading restrictions, or other trading restrictions taken by the Australia or Chinese government will impact our business and financial performance. If we are unable to identify alternative materials or suppliers and secure approval for their use in a timely manner, our business could be harmed.

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 had two manufacturing facilities in Shanghai in compliance with GMP standard, namely the Nanhui Facility and the Zhangjiang Facility, with a total GFA of approximately 3,863.8 square meters. 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.

Our utilization rate for our major product, VitaFlow™ in 2019 and the seven months ended July 31, 2020 was 86.2% and 63.1%, respectively. To scale up our production capacity, we have engaged a third party to construct a new manufacturing facility in Shanghai with a total GFA of approximately 13,000 square meters. We expect that the new manufacturing facility will commence production in 2022. New manufacturing 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 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 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 the inventory levels in line with the level of demand for our products could have a material adverse effect on our business, financial conditions 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, including bovine pericardium 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 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 (for example, VitaFlow™ typically has a shelf life of one year and are subject to expiration and VitaFlow™ II is expected to have similar shelf life). During the Track Record Period and up to the Latest Practicable Date, all of the VitaFlow™ we sold to our distributors were within its shelf life. 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 RELIANCE ON THIRD PARTIES

We rely on third parties to conduct certain aspects of our clinical trials. 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 pipeline 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 CRO/SMOs, to assist us in designing, 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 and the EMA, 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.

We depend on third parties to provide a stable and adequate supply for our pipeline development and manufacturing needs.

During the Track Record Period, we relied on third parties to supply raw materials, such as bovine pericardium and nitinol components, used in research and development, and the manufacturing of pipeline products for clinical trials and for commercial sales. We expect to continue to rely on third parties to supply raw materials for the research, development and commercialization of our pipeline products. See "Business—Raw Materials and Suppliers."

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. In addition, due to the rigorous regulations and requirements of the NMPA and/or foreign regulatory authorities regarding the manufacture of our products (including the need for approval of any change in supply arrangements), we may have difficulty establishing additional or replacement sources in a timely manner or at all if the need arises. Certain suppliers may also elect to no longer service medical device companies due to the high amount of requirements and regulation or failure to supply the raw materials in a timely manner or at all due to any other causes such as the act of God. In addition, we also require adequate and increasing amount of raw materials for commercial-scale manufacturing in anticipation of more marketing approvals to be received in the coming years. Our suppliers may not be able to keep up with our growth needs or may reduce or cease their supply of materials to us at any time. In addition, we cannot assure you that our suppliers have obtained and will be able to renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations, and failure to do so by them may lead to interruption in their business operation, which in turn may result in shortage of materials supplied to us. Furthermore, some of our suppliers are based overseas and may need to maintain export or import licenses to continue supplying to us. Any interruption in our supply of materials due to any of the above or for any other reason would force us to procure supplies from replacement suppliers, which may not be available to us on commercially favorable terms or with sufficient quantities or at all. This in turn could have a material adverse effect on our business, financial condition and results of operations.

### We may fail to maintain or renew relationships with distributors, or further expand our network of distributors.

We rely on third-party distributors to distribute our products. Our ability to maintain and expand our business will depend on our ability to maintain effective distributor networks that ensure timely distribution of our products to the relevant markets where we generate market demand through our sales and marketing activities. We rely on our distribution agreements to manage our distributors. However, our distributors are all third parties over whom we have limited control. Moreover, 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 across our distributor network in order to maintain the relationship with our distributors. Our distributors might elect not to renew their agreements with us or otherwise terminate their business relationships with us for various reasons, including in the event that PRC pricing regulations or other factors limit the margins our distributors can obtain through the resale of our products to hospitals and medical institutions. For details, see "Business—Sales and Marketing."

For the year ended December 31, 2019 and the seven months ended July 31, 2020, the aggregate sales to our five largest customers were RMB14.9 million and RMB28.2 million, representing 69.4% and 58.2% of our total revenue, respectively. Sales to the largest customer in 2019 and the seven months ended July 31, 2020 were RMB5.8 million and RMB10.6 million, representing 27.1% and 21.8% of our total revenue, respectively. All of our five largest customers in 2019 and the seven months ended July 31, 2020 were our distributors. We believe alternative distributors are readily available in China. However if any of our large distributors, or a significant number of our distributors, voluntarily or involuntarily suspend or terminate their relationships with us, or we are otherwise unable to maintain and expand our distributor network effectively, our sales volume and business prospects could be adversely affected. For further information, see "Business—Customers."

In addition, although we typically require distributors to make payments in full on the next business day after receiving our notice of the confirmation to the purchase orders, however, if we ever experience any delays in collecting payments from distributors, our cash flows and operations could be adversely affected and we could be required to terminate our relationships with distributors in a manner that will impair the effective distribution of our products.

#### We may fail to effectively manage our network of distributors.

We have limited control over the operations and actions of our distributors, all of whom, to the best of our Directors' knowledge, are Independent Third Parties during the Track Record Period. 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—Customers—Distributor Inventory Management." 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—Customers—Selection 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.

Moreover, some of our distributors may engage sub-distributors to distribute our products. We do not engage these sub-distributors directly or maintain contractual relationships with them, and mainly rely on our distributors to manage and control their sub-distributors in accordance with regulatory requirements, the terms of the distribution agreements we entered into with our distributors and our policies and measures that our distributors agree to comply with. As a result, we have a more limited control over these sub-distributors. There is no assurance that the sub-distributors will comply with the geographical restrictions we have agreed with our distributors, distribute only to authorized hospitals or other medical institutions or comply with other distribution requirements under our distribution agreements and policies. Furthermore, we cannot assure you that we will be able to identify or correct all the sub-distributors' practices that are detrimental to our business in a timely manner or at all, which may adversely affect our results of operations and reputation. As there is no contractual relationship between us and these sub-distributors, we have no direct legal recourse against them if their activities cause harm to our business or reputation.

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

We may from time to time establish or seek strategic alliances, form joint ventures or collaborations, equity investment, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our pipeline products and any future pipeline products that we may develop. As of the Latest Practicable Date, we had collaborated with two medical device companies, ValCare and 4C Medical, in relation to our TMV and TTV pipeline products. For details, see "Business—Our Product Portfolio" and "History, Development and Corporate Structure—Strategic Investments." In addition, Rose Emblem Ltd. or Rose Emblem is accounted for as a joint venture of our Company under the equity method. For details of the accounting treatment of our equity interests in Rose Emblem, see Note 13 to the Accountants' Report in Appendix I to this prospectus.

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 pipeline product, we can expect to relinquish some or all of the control over the future success of that pipeline 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.

Further, collaborations involving our products and pipeline products 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 products or 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 pipeline 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;
- a 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 pipeline products, or that result in
  costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable pipeline products; and/or
- collaborators may own or co-own intellectual property covering our products that results
  from our collaborating with them, and in such cases, we would not have the exclusive
  rights to commercialize such intellectual property.

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

Additionally, there can be no assurance that any joint venture will achieve the results intended and we may be subject to liquidity risk if no dividend is declared by such joint venture. Any disputes or breaches by the joint venture, or the inability of the joint venture to fulfill contractual obligations or declare dividends due to its businesses or financial condition, could have an adverse effect on our business, financial condition and results of operations. Additionally, the investment in joint venture are not as liquid as other investment products such as short-term wealth management products, since there is no cash flow until dividends received even if profits are reported under equity accounting. Therefore, our financial condition and results of operations might be affected by the share of results of joint venture.

#### 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, the EU 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. We may be subject to a third-party pre issuance submission of prior art to the CNIPA, EUIPO, USPTO or other related intellectual property offices, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. In particular, as of the Latest Practicable Date, the European Patent Office had received an opposition filed by a third party with respect to one of our patent relating to our TAVI products and the European Patent Office had not reached its rulings with respect to such opposition. Please see "Business-Intellectual Property." for details. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or pipeline products and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products and pipeline products without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the CNIPA, EUIPO, USPTO 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 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 and pending patent applications, if issued, for our products and pipeline products are expected to expire on various dates as described in "Business—Intellectual Property" of this prospectus. 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.

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

Filing, prosecuting, maintaining and defending patents on products and pipeline products in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength from those in some other countries. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as the laws of certain other countries do. Consequently, we may not be able to prevent third parties from practicing our inventions in 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 owned 98 patents and had 82 pending patent applications in China. To facilitate our strategy to enter overseas market, we also own 55 patents in UK, Italy, Germany, France, Spain, America, Korea, Australia and Brazil, among others. All 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 31 trademarks in China and 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 and may delay us from developing or commercializing our pipeline products. Our patent rights relating to our products and pipeline products could be found invalid or unenforceable if being challenged.

Competitors may infringe 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 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 market price 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.

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.

#### We may face intellectual property dispute with our business partners.

We may from time to time establish or seek strategic alliances that we believe will complement or augment our development and commercialization efforts with respect to our pipeline products and any future pipeline products that we may develop and we will seek to enjoy the intellectual property rights through intellectual property delegation, join intellectual property application or in-licensing arrangements. As of the Latest Practicable Date, we had collaborated with two medical device companies, ValCare and 4C Medical, in relation to three TMV pipeline products and one TTV pipeline product. For details, see "Business—Collaboration with Third Parties." We cannot assure that we will not be subject to intellectual property claims brought by our business partners or any third party. We may be subject to injunctions, damages or other reliefs if such claims are successful, which could prevent us from developing and commercializing such pipeline products.

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

In addition to our 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.

Furthermore, many of our employees, including our senior management, were previously employed at other medical device companies, including our competitors or potential competitors. Some of these employees, including one of our senior management, are subject to proprietary rights, non-disclosure and non-competition obligations in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. 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. 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.

# Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our pipeline products.

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.

### RISKS RELATING TO OUR OPERATIONS

Our business, results of operations and financial position could be adversely affected by the outbreak of COVID-19.

Since early 2020, a growing number of countries and regions around the world have encountered an outbreak of COVID-19 or Novel Coronavirus Pneumonia, a highly contagious disease known to cause respiratory illness. The disease quickly spread within the PRC and globally, and the affected cases and death tolls continued to increase. The World Health Organization (the "WHO") declared the outbreak a Public Health Emergency of International Concern on January 30, 2020, and on March 11, 2020, amid the escalating situation, the WHO further characterized COVID-19 as a global pandemic. The spread of COVID-19 continues to affect China, where we conduct our business and engage in preclinical studies and clinical trials, as well as certain other countries and regions where we are conducting global clinical trials.

Our business, including our existing and future clinical and preclinical 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: (i) requirements for us to quarantine certain of our employees or facilities or take extra security precautions for our operations, which may result in higher costs; (ii) delay or interruption of the supply of raw materials; (iii) delay in patient enrollment for our clinical trials; (iv) diversion of medical resources required for our clinical trials for the treatment of patients with COVID-19; (v) lowered demand by hospitals for TAVI products, which commenced commercial sales in August 2019, as many patients rescheduled their visits to hospitals to avoid cross-infections; (vi) temporary closure or flexible working hours of competent regulatory authorities, such as administration and registration authorities, which may delay regulatory submissions and required approvals of our pipeline products, and could cause us to incur additional costs and affect our ability to carry out our operations as planned.

To protect our employee and slow down the spread of the virus in strict compliance with national governments' instructions, we temporarily suspended our business operations, including some clinical trial development, manufacturing, sales and marketing related works, from the end of Chinese New Year holidays to early February, 2020. Although we have resumed operations, the COVID-19 outbreak has negatively impacted our business and financial performance, and our revenue for the seven months ended July 31, 2020 has been significantly affected by the COVID-19 pandemic as the sales of our TAVI product has been decreased primarily due to the decreases in the hospital treatment rate of patients with aortic stenosis. In addition, the recent COVID-19 outbreak in Europe has negatively impacted our ongoing clinical trials as patient enrollment and patient follow-ups were temporarily suspended. The COVID-19 outbreak may have a negative impact on the local, national and global economy and financial and market conditions.

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 other countries in which we are conducting clinical trials, and the level of the medical resources needed to treat COVID-19 patients in those countries, as well as the impact of the COVID-19 pandemic on our employees, subject participating in our clinical trials, the personnel and the oversea supplement that are necessary to continue our clinical trials and our CROs, and such effects could be material. Furthermore, we cannot predict when the COVID-19 outbreak will become completely under control and we cannot guarantee that the COVID-19 outbreak will not worsen. Having considered that the past occurrences of epidemics, depending on their scale, have caused different degrees of damage to the national and local economies in China, the COVID-19 outbreak and any other public health crisis in China especially in the cities where we have presence, may result in material disruptions to our operations, which in turn may materially and adversely affect our financial condition and results of operations.

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

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 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.

To induce valuable employees to remain at our Company, in addition to salary and cash incentives, we have provided share awards to our employees. The value to employees of these equity grants may be significantly affected by movements in the Share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees including the non-competition arrangements for key scientific employees as required under the Listing Rules, any of our employees could leave our employment at any time, with or without notice. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development

and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

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.

# 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 operations to date have focused on business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials of our pipeline products and the commercialization of our products. With respect to VitaFlow<sup>TM</sup>, we are also still in early stages of their lifecycle. Other than VitaFlow<sup>TM</sup>, a majority of our pipeline products are still at various development stages, and we have not yet demonstrated ability to successfully obtain regulatory approvals for any such pipeline products.

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. We may encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transit to a company capable of supporting commercial activities. In addition, as a new business, 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.

### We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our pipeline products through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our development and commercialization plans and strategies evolve, we need to recruit a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

identifying, recruiting, integrating, maintaining and motivating additional employees;

- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our pipeline products, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop and commercialize our products and pipeline products and to compete effectively will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and pipeline products and, accordingly, may not achieve our research, development and commercialization goals. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our Company.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, 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;

- 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.

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

We are in the process of conducting clinical trial for VitaFlow<sup>TM</sup> II in Europe and we will seek product registrations in emerging markets, especially markets that recognize CE Mark or NMPA marketing approvals afterwards, including Argentina, Brazil, India, Thailand, South Korea and Russia. We are also exploring opportunities to expanding our business for VitaFlow<sup>TM</sup> in emerging markets that recognize the NMPA marketing approval, such as Russia and we had successfully registered VitaFlow<sup>TM</sup> in Argentina and Thailand in July 2020 and November 2020, respectively. However, our limited experience in overseas markets may expose us to risks and uncertainties, including the risks associated with the following:

- dealing with regulatory regimes, regulatory bodies and government policies which may differ materially from those in the PRC or with which we may be unfamiliar;
- substantial time which may be required for us to obtain approval for registering and selling our products in additional countries, especially in developed countries;
- some emerging markets, where we were in the process of establishing our brand awareness, may lack necessary resources;
- commercializing our products in new markets where we have limited experience with the dynamics and no sales and marketing infrastructure;
- some doctors in new markets may lack the knowledge to conduct TAVI procedures and we
  may need to provide product training to enhance doctors' knowledge and recognition of
  our products and TAVI procedures;
- reliance on overseas partners or distributors for the distribution, commercialization and marketing of our products;
- product liability litigation and regulatory scrutiny arising from the marketing and sale of
  products in overseas markets and the costs incurred dealing with such procedures, as well
  as our ability to obtain insurance to adequately protect us from any resulting liabilities;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness and inflation;

- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest; and
- business interruptions resulting from geo-political actions, including war and terrorism, sanctions, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

## Our business strategy of growth through acquisitions may not succeed.

As part of our business strategy, we may consider to pursue acquisitions that we believe would benefit our business in the future. Our ability to grow through such means depends upon our ability to identify, negotiate, complete and integrate suitable opportunities as well as to obtain the necessary financing and required governmental or third-party consents, approvals and permits in a timely manner. Even if we engage in such acquisitions in the future, we may have limited experience and we may be exposed to the following risks, among others:

- difficulties in integrating any acquired businesses, technologies or personnel into our existing business, particularly integrating different quality control procedures and measures, business, operations, financial and risk management, and other business functions; and
- difficulties in implementing and enforcing our management and internal control
  mechanisms as well as quality assurance program that timely and adequately respond to
  our expanded scope 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 involved in any 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.

## We could be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials.

Our clinical trials routinely collect and maintain medical data, treatment records and other personal details of enrolled subjects. Laws and regulations of the various jurisdictions in which we conduct our clinical trials 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. Such institutions and personnel will be liable for damage caused by divulging the subjects' private or medical records without consent. We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring our employees to maintain the confidentiality of our subjects' medical records. However, these measures may not be always effective due to human error, employee misconduct or system breakdown.

In addition, our clinical trials frequently also involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We also cooperate with third parties including principal investigators, hospitals, CROs and SMOs for our clinical trials. We cannot ensure that such persons will always comply with our data privacy measures. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. 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. Whilst we have made efforts to ensure our compliance with the applicable privacy regulations in various jurisdictions, we may not be capable of adjusting our internal policies in a timely manner and any failure to comply with applicable regulations could also result in regulatory enforcement actions against us. Furthermore, 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 to protect the confidentiality of subjects' medical records and personal data, or any restriction on or liability as a result of, our use of medical data, could have a material adverse effect on our business, financial condition and results of operations.

## Our internal IT systems may fail or suffer security breaches.

Despite the implementation of security measures, our internal IT systems are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have 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 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, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback, 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, 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 of Medical Devices (《醫療器械註冊管理辦法》). These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC 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.

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 may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees or other third parties.

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.

## 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. We maintain different types of insurance policies, such as personal accident insurance. 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) and fixed asset insurance. 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.

Our business and reputation may be adversely affected by negative publicity involving us, our Shareholders, Directors, officers, employees, PIs, KOLs, distributors, sub-distributors, suppliers, or other parties we cooperate with, or by general negative publicity in the industry.

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.

We, our Shareholders, Directors, officers, employees, PIs, KOLs, 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, PIs, KOLs, 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.

Our Controlling Shareholder may have substantial influence over our Company and their interests may not be aligned with the interests of our other Shareholders.

Our Controlling Shareholder has substantial influence over our business, including matters relating to our management, policies and decisions regarding acquisitions, mergers, expansion plans, consolidations and sales of all or substantially all of our assets, election of Directors and other significant corporate actions. Immediately after completion of the Share Subdivision and the Global Offering, assuming the Over-allotment Option is not exercised, our Controlling Shareholder will hold (including direct and indirect shareholdings) approximately 45.59% of the issued share capital in our Company. Our Controlling Shareholders will, through their voting power at the Shareholders meetings and their delegates on the Board, have substantial influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our Controlling Shareholders may not act in the best interests of our minority

Shareholders. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their Shares as part of a sale of our Company and might reduce the price of our Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of our Controlling Shareholder may differ from the interests of our other Shareholders. It is possible that our Controlling Shareholder may exercise its substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

#### RISKS RELATING TO DOING BUSINESS IN CHINA

The medical device industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our pipeline products.

We conduct the majority of our operations in China. The medical device industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new devices. See "Regulatory Overview" for a discussion of regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the medical device industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our pipeline products in China and reduce the benefits we believe are available to us from developing and manufacturing products in China. PRC authorities have become increasingly vigilant in enforcing laws in the medical device industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach will continue to be aligned.

PRC economic, political, social conditions as well as government policies could materially and adversely affect our business, financial condition, results of operations and prospects.

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 30 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.

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

Natural disasters, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

# 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 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.

Additionally, the reform of the medical device approval system in 2017 may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our pipeline products in a timely manner. 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.

Restrictions on currency exchange may limit our ability to utilize our revenue effectively, to pay dividends and other obligations, and affect the value of your investment.

The PRC government imposes controls on the convertibility of RMB 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. Shortages in availability of foreign currency may then restrict our ability to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations. The RMB is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and loans, including loans we may secure from our onshore subsidiaries. Currently, we and our PRC subsidiaries may purchase foreign currency for settlement of "current account transactions," including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in Renminbi to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

### 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 are exposed to foreign currency risk. For the year ended December 31, 2018 and the seven months ended July 31, 2020, we recorded net foreign exchange loss of RMB0.4 million and RMB4.8 million. For the year ended December 31, 2019, we recorded net foreign exchange gain of RMB1.1 million. The exchange rate of the Renminbi against the U.S. dollar and other 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 difficult to predict how market forces or government policies may impact the exchange rate between the Renminbi and the Hong Kong dollar, the U.S. dollar or other currencies in the future. In addition, the PBOC regularly intervenes in the foreign exchange market to limit fluctuations in Renminbi exchange rates and achieve policies goals.

There remains significant international pressure on the PRC government to adopt a more flexible currency policy, which, together with domestic policy considerations, could result in a significant appreciation of Renminbi against the U.S. dollar, the Hong Kong dollar or other foreign currencies.

Our proceeds from the Global Offering will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our proceeds from the Global Offering. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends

payable on, our Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our Shares in foreign currency terms.

Dividends payable by us to our foreign investors and gains on the sale of our Shares may become subject to withholding taxes under PRC tax laws.

Under the EIT law, 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. 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.

Under PRC Individual Income Tax law and its implementation rules, dividends from sources within China paid to foreign individual investors who are not PRC residents are generally subject to a PRC withholding tax at a rate of 20% and gains from PRC sources realized by such investors on the transfer of shares are generally subject to PRC income tax at a rate of 20% for individuals. Any PRC tax may be reduced or exempted under applicable tax treaties or similar arrangements.

If we are treated as a PRC resident enterprise as described under the risk factor headed "— The Company may be deemed to be a PRC tax resident under the EIT Law and our global income may be subject to a 25% PRC enterprise income tax," 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 Taxpayors (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.

We rely principally on dividends paid by our subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to pay dividends to us could have a material and adverse effect on our ability to conduct our business.

We operate our core businesses through our operating subsidiaries in China. Therefore, the availability of funds to pay dividends to our Shareholders depends upon dividends received from these subsidiaries. If our subsidiaries incur debts or losses, such indebtedness or loss may impair their ability to pay dividends or other distributions to us. As a result, our ability to pay dividends will be

restricted. The PRC laws and regulations require that dividends be paid only out of the net profit calculated according to the PRC accounting principles, which differ in many aspects from generally accepted accounting principles in other jurisdictions, including HKFRSs. The PRC laws and regulations also require foreign-invested enterprises to set aside part of their net profit as statutory reserves. These statutory reserves are not available for distribution as cash dividends. Therefore, these restrictions on the availability and usage of our major source of funding may impact our ability to pay dividends to our Shareholders.

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

Under the EIT Law, if a foreign entity is deemed to be a "non-resident enterprise" as defined under the EIT Law, a withholding tax at the rate of 10% will be applicable to any dividends for earnings accumulated since January 1, 2008 payable to the foreign entity, unless it is entitled to reduction or elimination of such tax, including by tax treaties or agreements. According to the Arrangement between the Mainland of China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Incomes (內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排),dividends paid by a PRC foreign-invested enterprise to its shareholder(s) incorporated in Hong Kong will be subject to withholding tax at a rate of 5% if the Hong Kong company directly holds 25% or more interests in the PRC foreign-invested enterprises. The SAT promulgated the Circular 9 on February 3, 2018, which addresses the methods to determine the "beneficial owners" under the treaty articles on dividends, interest and royalties. According to the Circular 9, the PRC tax authorities must evaluate whether an applicant qualifies as a "beneficial owner" on a case-by-case basis.

If our Hong Kong subsidiary holds any equity interest in a PRC subsidiary in the future, based on the abovementioned principles, PRC tax authorities would not consider our Hong Kong subsidiary as the "beneficial owner" of any dividends paid from our PRC subsidiaries and would deny the claim for the reduced rate of withholding tax. Under the current PRC tax law, if our Hong Kong subsidiary is not considered as a "beneficial owner," dividends from our PRC subsidiaries to our Hong Kong subsidiary being subject to PRC withholding tax at a 10% rate instead of a 5% rate. This would negatively impact us and it would impact our ability to pay dividends in the future.

You may experience difficulty in effecting service of legal process, enforcing foreign judgments or bringing original actions in China or Hong Kong based on foreign laws against us, our Directors and senior management.

All 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决的安排) (the "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.

The Company may be deemed to be a PRC tax resident under the EIT Law and our global income may be subject to a 25% PRC enterprise income tax.

The EIT Law provides that enterprises established outside of China whose "de facto management bodies" are located in China are considered "resident enterprises" and are generally subject to the uniform 25% enterprise income tax rate on their global income. "De facto management body" is defined as the body that has the significant and overall management and control over the business, personnel, accounts and properties of an enterprise. In April 2009 and July 2011, SAT issued several circulars to clarify certain criteria for the determination of the "de facto management bodies" for foreign enterprises controlled by PRC enterprises, however, no official implementation rules have been issued regarding the determination of the "de facto management body" for foreign enterprises that are not controlled by PRC enterprises. Being regarded as a PRC resident enterprise may materially and adversely affect our profit and hence our retained profit available for distribution to our Shareholders.

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特殊目的公司境外投融資及返程投資外匯管理有關問題的通知). 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 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 alternation 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 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 has an adverse impact on our business, acquisitions or restructuring strategies.

On February 3, 2015, the SAT promulgated 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.

PRC regulations of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the proceeds of the Global Offering 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 must be filed 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.

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

During the Track Record Period, certain of our raw materials were sourced overseas, and we have engaged certain third parties for clinical trials and commercial collaboration in foreign countries and regions. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. Tensions, political concerns and trade frictions 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, such as customers, suppliers, and global partners. 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. Any tensions, political concerns, and trade frictions between China and the relevant foreign countries or regions may cause a decline in the demand for our services and adversely affect our business, financial condition, results of operations, cash flows and prospects. For instance, China imposed 80.5% anti-dumping and antisubsidy duties on Australian barley after claiming that barley farming was heavily subsidized by the government and suspended imports from four major Australian beef suppliers over labeling issues in May 2020. In recent months, trade tensions between China and Australia have escalated and China has imposed trading restrictions on imports of certain products from Australia, where we primarily procure bovine pericardium for VitaFlow<sup>TM</sup>. As advised by our PRC Legal Advisers, based on their search of recent announcement of the official website of General Administration of Customs of the PRC (中華人民共和國海關總署) and the Ministry of Commerce of the PRC (中華人民共和國商務部), as of the Latest Practicable Date there had been no restrictions in China that materially and adversely affect bovine pericardium from Australia. However, the development of the trade policy between China and Australia and the trading restriction on imports from Australia imposed by China as well as the related impact on our business are unclear at this time. We cannot foresee whether and how developments in these trading restrictions, or other trading restrictions taken by the Australia or Chinese government will impact our business and financial performance. In the event that China and/ or the relevant foreign countries, such as Australia, impose import tariffs, trade restrictions or other trade barriers affecting the importation of raw materials, we plan to engage other qualified suppliers in China or overseas for bovine pericardium. However, we cannot guarantee you that we can do that in a timely manner or on commercially favorable terms to us, if at all. As such, 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.

#### RISKS RELATING TO THE GLOBAL OFFERING

No public market currently exists for our Shares, and an active trading market for our Shares may not develop and the market price for our Shares may decline or became volatile, especially taking into account that all of our existing Shareholders have entered into a lock-up undertaking for six months after Listing.

No public market currently exists for our Shares. The initial Offer Price for our Shares to the public will be the result of negotiations between our Company and the Joint Global Coordinators, and

the Offer Price may differ significantly from the market price of the Shares following the Global Offering. We have applied to the Hong Kong Stock Exchange for the listing of, and permission to deal in, the Shares. However, each existing Shareholder, including our Pre-IPO Investors, agrees and undertakes to our Company that, subject to the terms and conditions set out in the Shareholders Agreement, 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 Listing Date, 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. Therefore, upon completion of the Global Offering and assuming the Over-allotment Option is not exercised, approximately 91.31% of our Shares will be subject to lock-up undertakings. As a result, a listing on the Hong Kong Stock Exchange does not guarantee that an active and liquid trading market for our Shares will develop, especially during the period when a significant portion of our Shares are subject to lock-up undertakings, or if it does develop, that it will be sustained following the Global Offering, or that the market price of the Shares will rise following the Global Offering.

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

The price and trading 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 market price of the shares of other companies engaging in similar business may affect the price and trading volume of our Shares. In addition to market and industry factors, the price and trading volume of our Shares may be highly volatile for specific business reasons, including,

- 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 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 pricing and trading of our Shares, and the price of our Shares when trading begins could be lower than the Offer Price.

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

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

Prior to the Global Offering, there has not been a public market for our Shares. Future sales or perceived sales by our existing Shareholders of our Shares after the Global Offering could result in a significant decrease in the prevailing market price of our Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance immediately after the Global Offering 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 market price of our Shares and our ability to raise equity capital in the future.

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

Sales of substantial amounts of Shares in the public market after the completion of the Global Offering, 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 Listing Date as described in "Underwriting" in this prospectus, future sales of a significant number of our Shares by our Controlling Shareholder in the public market after the Global Offering, or the perception that these sales could occur, could cause the market price of our Shares to

decline and could materially impair our future ability to raise capital through offerings 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 Shares by the Company may have on the market price 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 market price 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 and PRC laws, 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 proceeds from the Global Offering, 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 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.

As the Offer Price of our Offer Shares is higher than our net tangible book value per share, purchasers of our Shares in the Global Offering may experience immediate dilution upon such purchases. Purchasers of Shares may also experience further dilution in shareholdings if we issue additional Shares in the future.

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

We have significant discretion as to how we will use the net proceeds of the Global Offering, and you may not necessarily agree with how we use them.

Our management may spend the net proceeds from the Global Offering in ways with which you may not agree or which do not yield a favorable return to our Shareholders. We plan to use the net proceeds from the Global Offering to fund our ongoing R&D, commercialization and manufacturing activities, as well as potential collaborations with third parties. For details, see "Future Plans and Use of Proceeds" However, our management will have discretion as to the actual application of our net proceeds. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net proceeds from this Global Offering.

Certain statistics contained in this prospectus are derived from a third-party report and publicly available official sources and facts, forecasts and statistics in this prospectus relating to the transcatheter heart valve medical device industry in and outside China may not be fully reliable.

Facts, forecasts and statistics in this prospectus relating to China, the PRC economy and the industry in which we operate are derived from various sources that we believe are reliable, including

official government publications as well as a report prepared by Frost & Sullivan that we commissioned. We have taken reasonable care in the reproduction or extraction of the official government publications or other third-party reports for the purpose of disclosure in this prospectus, however, we cannot guarantee the quality or reliability of such source materials. Specifically, as the global TAVI, TMV and TTV markets are at their early development, we cannot guarantee that these markets will grow in the future as expected. Neither we, the Joint Global Coordinators, the Joint Sponsors, the Underwriters 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 prospectus 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 Global Offering.

Subsequent to the date of this prospectus but prior to the completion of the Global Offering, there may be press and media coverage regarding us and the Global Offering, which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the Global Offering. 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 prospectus, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this prospectus only and should not rely on any other information.

You should rely solely upon the information contained in this prospectus, the Global Offering 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, views or opinions expressed by the press or other media regarding our Shares, the Global Offering 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 Global Offering. By applying to purchase our Shares in the Global Offering, you will be deemed to have agreed that you will not rely on any information other than that contained in this prospectus and the Global Offering.