

OVERVIEW

We are a medical device company in China focusing on the research, development and commercialization of innovative transcatheter and surgical solutions for valvular heart diseases. Our mission is to improve the lives of valvular heart disease patients by providing optimal and affordable medical solutions through continuous innovation.

Our self-developed first-generation TAVI product, VitaFlow™, was approved by the NMPA in July 2019 and subsequently commercialized in China in August 2019. As of the Latest Practicable Date, there were five approved or commercialized TAVI products in China, among which, VitaFlow™ is the first one utilizing bovine pericardium as valve tissue, according to Frost & Sullivan. Generally, bovine materials provide better durability and hemodynamic performance as compared to porcine materials. VitaFlow™ also innovatively features a first-in-China double-layer PET skirt and the only marketed motorized delivery system worldwide, according to Frost & Sullivan. These unique designs have enabled VitaFlow™ to achieve positive clinical trial results⁽¹⁾ among TAVI products in China, delivering a low all-cause mortality rate and low incidences of postoperative complications. For details, see “Industry Overview—Competitive Landscape—TAVI Market.” We also launched our first-generation in-house developed Alwide™ balloon catheter and Alpass™ catheter sheath as part of the VitaFlow™ offering, making us the only medical device company in China that has a comprehensive offering of in-house developed complementary TAVI procedural accessories, according to Frost & Sullivan. Our second-generation TAVI product, VitaFlow™ II, has completed the Registration Clinical Trial in China and is also under clinical trial in Europe. We submitted the registration application for VitaFlow™ II to the NMPA in October 2020. The application was accepted by the NMPA in November 2020 and is currently under review. We currently expect we will complete the registration of VitaFlow™ II in China by the end of 2021. In addition, we plan to apply for the CE Mark of VitaFlow™ II by the end of 2021. According to Frost & Sullivan, as of the Latest Practicable Date, VitaFlow™ II was the only TAVI product developed in China that had commenced a clinical trial in Europe. In addition to our TAVI products, we currently have five TMV pipeline products, strategically targeting all mainstream viable TAVI options for mitral regurgitation, enabling us to penetrate the vast but underserved TMV market through in-house development and collaboration with our global partners, namely 4C Medical and ValCare, each being a medical device company focusing on the R&D of mitral and tricuspid valve medical devices.

We are deeply rooted in the vast, rapid-growing and substantially underpenetrated heart valve medical device market. According to Frost & Sullivan, in 2019, approximately 213.2 million patients worldwide suffered from valvular heart disease, which led to 2.6 million deaths. In recent years, transcatheter valve therapy has gradually replaced traditional open-chest surgeries as another clinical option for patients suffering from valvular heart diseases, which includes TAVI, TMV repair/replacement and TTV repair. Our product portfolio strategically focuses on addressing the most prevalent aortic valve and mitral valve diseases, including aortic stenosis and mitral regurgitation.

- **Aortic stenosis.** According to Frost & Sullivan, patients suffering from aortic stenosis globally is expected to grow at a CAGR of 14.3% from 19.7 million in 2019 to 22.1 million in 2025. As a result, the global TAVI market size is expected to increase at a

⁽¹⁾ VitaFlow™ has achieved positive clinical trial results with respect to all-cause mortality rate and postoperative complications including moderate/severe PVL, major stroke and vascular complications, which according to Frost & Sullivan, are major clinical trial endpoints to demonstrate the safety and efficacy of TAVI products. For details, see “Industry Overview—Competitive Landscape—TAVI Market.”

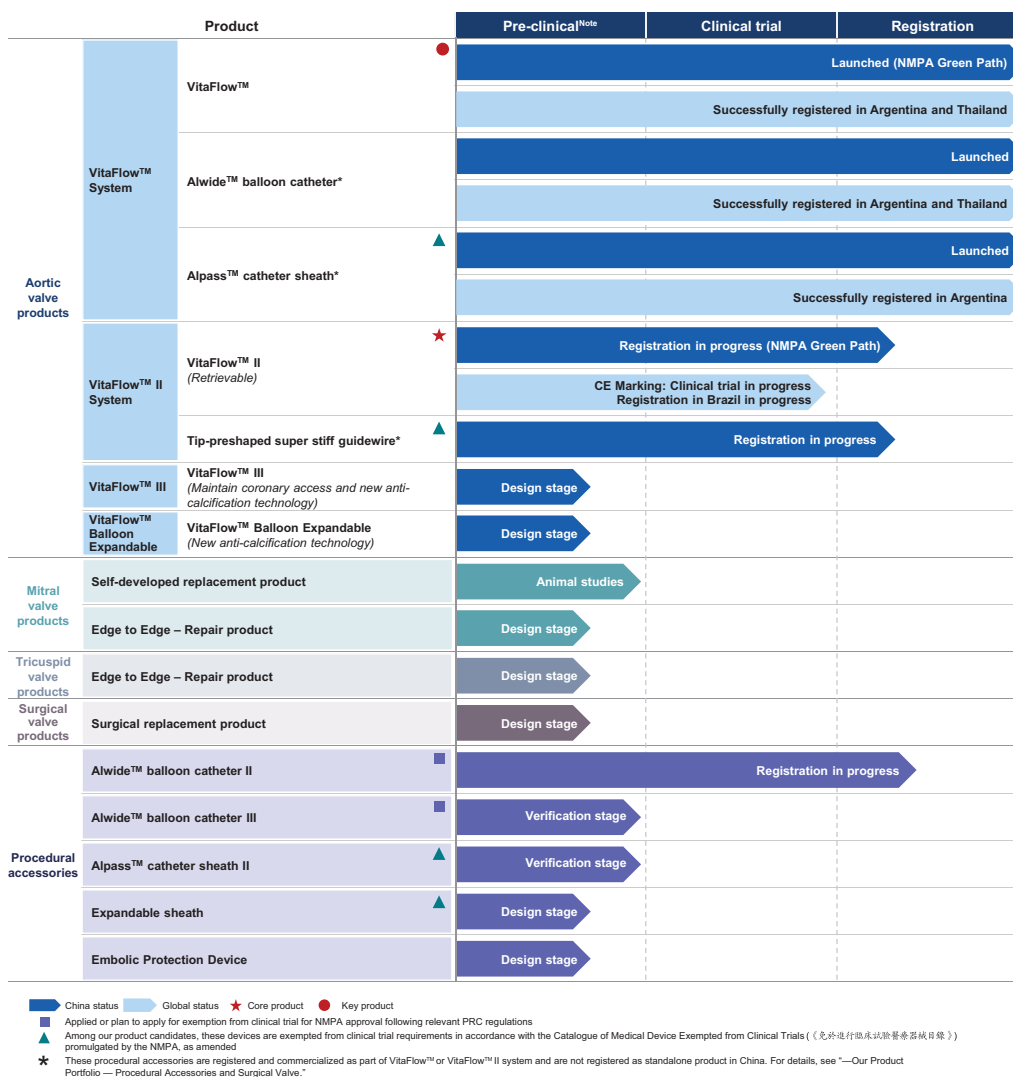
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CAGR of 12.9% from US\$4.8 billion (or RMB32.3 billion) in 2019 to US\$10.0 billion (or RMB67.3 billion) in 2025. Compared to the TAVI market in developed countries, such as the United States, China's TAVI market is significantly under-penetrated. In 2019, there were approximately 2,400 TAVI procedures performed in China with a penetration rate of 0.3%, as compared to approximately 66,800 TAVI procedures performed and a penetration rate of 23.4% in the U.S. It is expected that in 2025, there will be approximately 42,000 TAVI procedures performed in China, representing a CAGR of 60.7% for the next five years and a penetration rate of 4.5% in 2025. As such, China's TAVI market is expected to grow from RMB392.0 million in 2019 to RMB5,055.7 million in 2025 at a CAGR of 53.1%.

- **Mitral regurgitation.** In 2019, there were 96.7 million patients worldwide and 10.6 million patients in China suffering from mitral regurgitation. Due to the complexity of TMV therapy, global TMV market is still in a relatively early stage with only six approved TMV repair products and one approved TMV replacement product globally. Most of the existing TMV technologies have certain clinical limitations, such as causing obstructions on the left ventricular outflow tract, impairing function of the left ventricle and leading to device embolization. As a result, we believe the TMV products that can address these clinical limitations will benefit the most from the vast but unmet medical demands in this area. According to Frost & Sullivan, driven by the increasing market demands of TMV repair/replacement products and emerging innovative TMV technologies, global TMV market is expected to reach US\$17.4 billion (or RMB117.0 billion) by 2030 and will eventually grow to three or four times of the global TAVI market.

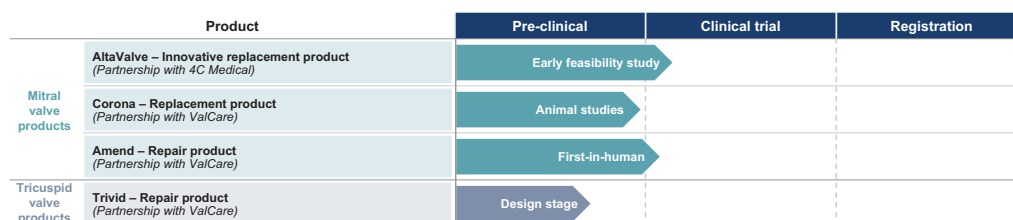
To seize the tremendous market opportunities and to address the unmet medical demands of valvular heart diseases, we began developing our first-generation TAVI product in 2010 as an incubation project within the MicroPort Group. Led by a senior management team with extensive experience with and insights on TAVI technologies and the overall medical device industry, we have built a robust product portfolio strategically targeting aortic valve, mitral valve and tricuspid valve diseases. As of the Latest Practicable Date, we had successfully developed and commercially-launched one TAVI product (including two procedural accessories as part of its offering). We are also developing or collaborating with our partners on our next generation TAVI pipeline products, five TMV pipeline products, two TTV products, our surgical valve product and several procedural accessory products at different stages of development. The chart below summarizes our in-house developed product portfolio as of the Latest Practicable Date.

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Note: Design stage refers to the designing and developing of the sample product. Verification stage refers to performing verification testing on the sample product to finetune its design.

The following chart summarizes the product portfolio that are developed by our business partners and for which we owned the exclusive commercial rights in China. With respect to these products, our business partners are primarily responsible for research, development and manufacturing of the products and we are responsible for product registrations and commercialization in China.



We have developed a medical device platform focusing on valvular heart disease. The platform covers our four key business functions namely R&D, clinical trial, manufacturing and commercialization. By leveraging this platform, all the key business functions are integrated to enable smooth collaboration during the whole life-cycle of a product candidate to speed up the product development process in a cost-effective manner. The platform lays a solid foundation and builds the

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strategic moat for our research, development and commercialization competitiveness. Driven by strong innovation capabilities and supported by stringent quality controls, our platform primarily focuses on (i) technological innovation, product design and biological material processing technique; (ii) efficient design and execution of clinical trials; and (iii) manufacturing efficiency. This platform has enabled us to continuously expand our product portfolio to tackle valvular heart diseases with innovative treatment methods. We have also established a quality control system in accordance with GMP standards required by the NMPA and ISO13485:2016.

We have a proven track record of product commercialization. As of July 31, 2020, we had sold 872 units of VitaFlow™—an average of over 70 units per month in the first year of its commercialization. As of the Latest Practicable Date, TAVI procedures using VitaFlow™ had been performed at over 120 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 have established a dedicated in-house sales and marketing team with professional medical background, primarily focusing on academic promotions. Supported by the positive clinical trial results of VitaFlow™, with respect to all-cause mortality rate and postoperative complications including moderate/severe PVL, major stroke and vascular complications, patient-oriented pricing strategy, strong endorsement from KOLs and hospitals, our enabling distributor network and the brand recognition of “MicroPort” in the cardiology field, we believe we are well-positioned to benefit from the rapid growth of China’s TAVI market and to further gain market share.

Complemented by our proven commercialization capabilities, medical device platform focusing valvular heart diseases and experienced management team with continuous support from Shareholders, we have successfully developed and launched a TAVI product with positive clinical trial results with respect to all-cause mortality rate and postoperative complications including moderate/severe PVL, major stroke and vascular complications, in China and we are also developing our second-generation TAVI product, which is at near-commercialization stage. We are also dedicated to serving the vast but underserved TMV market, strategically targeting all mainstream viable TVT options for mitral regurgitation through in-house development and collaboration with our global partners, namely 4C Medical and ValCare, each being a medical device company focusing on the R&D of mitral and tricuspid valve medical devices. We believe these competitive strengths are difficult to replicate and we are well-positioned to capture the tremendous growth potential of the valvular heart disease market. At the same time, we plan to continue to strengthen our presence in China’s TAVI market, advance our international strategy, rapidly advance our TMV pipeline and other product candidates and improve operational efficiency and achieve economies of scale to support long-term growth.

COMPETITIVE STRENGTHS

Medical device company in China focusing on the transcatheter valve therapy technology, offering innovative TAVI solution

Our self-developed first-generation TAVI product, VitaFlow™, has obtained the NMPA marketing approval through the Green Path for Innovative Medical Device in China in July 2019 and was commercialized in China in August 2019. As of the Latest Practicable Date, there were five approved or commercialized TAVI products in China, among which, VitaFlow™ is the only one utilizing bovine pericardium as valve tissue, according to Frost & Sullivan. VitaFlow™ also

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innovatively features a first-in-China double-layer PET skirt and the only marketed motorized delivery system worldwide, according to Frost & Sullivan. These unique designs enabled VitaFlow™ to deliver positive clinical trial results among marketed TAVI products in China. For details, see “Industry Overview—Competitive Landscape—TAVI Market.” We also launched our first-generation in-house developed Alwide™ balloon catheter and Alpass™ catheter sheath as part of the VitaFlow™ offering, making us the only medical device company in China that has a comprehensive offering of in-house developed complementary TAVI procedural accessories, according to Frost & Sullivan.

VitaFlow™ has completed a prospective, multi-center and single-arm pivotal clinical trial in China on 110 patients, who had an average STS Score of 8.8. Compared with other TAVI products currently commercialized in China, VitaFlow™ achieved positive clinical trial results with respect to all-cause mortality rate and postoperative complications including moderate/severe PVL, major stroke and vascular complications.

- **Mortality rate.** The all-cause mortality rate was 0.9% at discharge, 0.9% at 30 days, 2.7% at six months, 2.7% at 12 months, 4.5% at 24 months and 10.9% at 36 months post-implantation.
- **PVL.** None of the patients experienced moderate or severe PVL during the 12 months following the TAVI procedure.
- **Major stroke.** None of the patients experienced a major stroke during the 24 months following the TAVI procedure and only two patients experienced a major stroke during the 36 months following the TAVI procedure.
- **Vascular complications.** During the 36 months following the TAVI procedure, only 2.7% of the patients experienced major vascular complications.

We believe the positive clinical trial results of VitaFlow™ are attributable to the innovative and unique designs of VitaFlow™.

- **The first commercialized TAVI product with bovine pericardium valve tissue in China.** According to Frost & Sullivan, among the five currently approved or commercialized TAVI products in China, VitaFlow™ is the first one utilizing bovine pericardium as the valve tissue. Existing clinical trial data on SAVR have demonstrated that bovine material can provide better durability and hemodynamic performance as compared to porcine material, and leads to lower risks of postoperative complications. As a result, bovine pericardium has been dominating the global TAVI market with over 55% market share and substantially the entire global SAVR market. Patients treated with TAVI products utilizing bovine pericardium as valve tissue are able to live with the implanted prosthetic aortic valve for a longer period of time, lowering the chance for another TAVI procedure.
- **First double-layer PET skirt design in China.** PVL is one of the major complications post TAVI procedures, which may lead to atrial fibrillation, pulmonary hypertension, or even heart failure. VitaFlow™ features an innovative first-in-China double-layer PET skirt design, according to Frost & Sullivan. One layer of the PET skirt is attached to the inner side of the nitinol frame and the other layer is attached to the outer side. The configuration optimizes the sealing effect of the valve and effectively reduces PVL.

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- ***Only marketed motorized delivery system worldwide.*** According to Frost & Sullivan, as of the Latest Practicable Date, among all the commercialized TAVI products worldwide, VitaFlow™ was the only one that had a motorized delivery system. Compared to a manual delivery system, which generally depends more on physician's experiences in TAVI procedures, physicians can position the guidewire and deploy the PAV more precisely and stably with the motorized delivery system, which in turn improves the overall success rate of TAVI procedures. We believe the motorized delivery system can significantly benefit physicians by lowering the challenges in performing TAVI procedures and shortening the learning curve of physicians for TAVI procedures.

In addition, we have also launched two in-house developed TAVI procedural accessories in China, namely our first-generation balloon catheter (Alwide™) and catheter sheath (Alpass™), which are offered as part of the VitaFlow™ offering. According to Frost & Sullivan, we are the only medical device company in China that has a comprehensive offering of in-house developed complementary procedural accessories. We believe these procedural accessories can help lower the challenges in performing TAVI procedures and shorten the learning curve for physicians. Alwide™ provides low compliance with a high burst pressure for patients with severe calcification and can achieve a shorter inflation/deflation pacing time. Alpass™ is kink-resistant and has excellent tractability, making it highly compatible with various physical conditions that the patients may have.

Next-generation TAVI solutions under development, with a clear roadmap to penetrate international markets

We are dedicated to optimizing our existing TAVI solutions to address the industry pain points and unmet medical demands in the global TAVI market. Currently, we are developing the upgraded version of TAVI products, aiming to benefit patients in China and worldwide. Our second-generation TAVI product, VitaFlow™ II is an upgraded product based on VitaFlow™ with retrievable function. We had completed the Registration Clinical Trial for VitaFlow™ II and submitted the registration material to the NMPA in October 2020. The application was accepted by the NMPA in November 2020 and is currently under review. We currently expect we will complete the registration of VitaFlow™ II in China by the end of 2021. Targeting the international market, we commenced a pivotal clinical trial for VitaFlow™ II in Europe for CE Mark registration in 2018. In addition, we are in the process of developing our third-generation self-expanding TAVI product and another balloon-expandable TAVI product, and other upgraded procedural accessories. We are developing an upgraded anti-calcification technology, which will be adopted in our future TAVI products, and an upgraded valve design, which will be adopted in the third-generation self-expanding TAVI product.

In addition to all the innovative features offered by VitaFlow™, VitaFlow™ II adopts an advanced delivery system with a retrievable function. During the TAVI procedure, the retrievable function allows physicians to retrieve the PAV and make up to three attempts to adjust the PAV's position if the initial release position is not ideal, provided the deployment of PAV has not exceeded 75% of the maximal deployment range. The retrievable function is designed to improve the accuracy of positioning and deploying PAV, which will further improve the overall success rate of TAVI procedures and lower the risks of postoperative complications.

VitaFlow™ II had achieved positive clinical trial results during the Registration Clinical Trial with respect to its safety and efficacy. During the 30-day follow-up period, none of the patients

experienced a disabling stroke. We had also observed a significant improvement in patients' cardiac functions, measured by the NYHA Classification. Prior to the TAVI implantation, none of the patients were classified as class I and only 18.3% of the patients were classified as class II under the NYHA Classification, which significantly improved to 19.3% and 68.4% at 30-day follow-up evaluation. Although there were three mortality cases observed, as reviewed and adjudicated by the clinical endpoints committee, none of the mortality cases were related to the function of VitaFlow™ II.

As a China-based medical device company with a global vision, we are taking measured steps to enter the international market. We are conducting a pivotal clinical trial for VitaFlow™ II in Europe for CE Mark registration. According to Frost & Sullivan, as of the Latest Practicable Date, VitaFlow™ II was the only TAVI product developed in China that had commenced clinical trials in Europe. As the CE Mark application for VitaFlow™ II will be based on the 12-month follow-up evaluations of the Registration Clinical Trial and the data we will obtain from the planned clinical trial in Europe, we plan to submit the application for CE Mark by the end of 2021.

Strategically targeting the most prevalent mitral valve disease

According to Frost & Sullivan, mitral regurgitation is the most prevalent among all valvular heart diseases, representing 45.4% of all the patients suffering from valvular heart diseases in 2019. However, as of the Latest Practicable Date, there were only six approved TMV repair products and one approved TMV replacement product reaching commercial stage globally with only one TMV repair product being approved in China. Further, the approved TMV replacement product can only be eligible for mitral regurgitation patients with certain characteristics, representing only a limited portion of the total patient group. Most of the existing TMV technologies have certain clinical limitations, such as causing an obstruction on the LVOT, impairing function of the left ventricle and leading to device embolization. The vast but unmet medical demands for mitral regurgitation patients present great potential for innovative solutions. We believe the TMV products that can address the current limitations will benefit the most from the vast market opportunities. According to Frost & Sullivan, the global and China patients of mitral regurgitation is approximately 96.7 million and 10.6 million in 2019, which are approximately 4.9 times and 2.5 times of the global and China patients of aortic stenosis, implying significant market potential.

Since our inception, we closely monitor and evaluate the market trends and innovative treatment options in global TMV market. In addition, we also actively seek opportunities to collaborate with industry-leading medical device companies focusing on mitral valve diseases, especially mitral regurgitation. We believe that the current challenges and difficulties of mitral regurgitation will eventually be addressed by technology breakthroughs and innovative treatment options. Capitalizing on our strong in-house R&D capabilities and our close cooperation with our global partners, namely 4C Medical and ValCare, each being a medical device company focusing on the R&D of mitral and tricuspid valve medical devices, we have five TMV pipeline products, strategically targeting all mainstream viable TAVI options for mitral regurgitation. Our efforts in the TMV market are summarized below.

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TMV Repair

- Amend

We invested in and collaborated with ValCare, a medical device company organized in the U.S. with an Israeli subsidiary on a TMV repair pipeline product—Amend. As of the Latest Practicable Date, Amend was undergoing a feasibility study on humans and had completed the first phase of its first-in-human MRCT in Israel and Europe. The purpose of the first-in-human MRCT is to evaluate the product safety and efficacy on human bodies and to obtain data for the initiation of clinical trials. Amend adopts an innovative semi-rigid, D-shaped ring with unique anchoring capabilities that emulates the current annuloplasty rings used in open-chest surgeries, which will be delivered via a catheter into the mitral annulus in a minimally-invasive procedure. Amend will maintain the original mitral valve’s structural integrity, and as a result improves its long-term performance. The design of the ring also makes Amend compatible with various delivery approaches, including transseptal or transapical approach. We have recently entered into a Master Distribution Agreement with ValCare under which, subject to and pending upon the execution of a mutually agreed upon agreement for the territory of China and certain other preconditions set forth in the Master Distribution Agreement, we shall be granted with exclusive distribution rights in relation to Amend in China. For details, see “—Collaboration with Third Parties.”

- *In-house developed TMV repair product*

We are currently conducting early-stage design of an edge-to-edge TMV repair product, which will adopt a transseptal approach.

TMV Replacement

- Corona

We are also collaborating with ValCare in relation to a TMV replacement product—Corona. As of the Latest Practicable Date, Corona was undergoing animal studies. The purpose of the animal studies is to verify the product design and to obtain preliminary safety and efficacy data. Corona is specifically designed to fit inside the Amend D-shaped repair ring. Corona and Amend together provide a valve-in-ring solution for patients that are ineligible for TMV repair and Corona can either be implanted alongside Amend or at a later stage after TMV repair is performed using Amend. The unique four-leaflet valve of Corona is also designed to improve its coaptation and sealing efficacy. We have recently entered into a Master Distribution Agreement with ValCare under which, subject to and pending upon the execution of a mutually agreed upon agreement for the territory of China and certain other preconditions set forth in the Master Distribution Agreement, we shall be granted with exclusive distribution rights in relation to *Corona* in China. For details, see “—Collaboration with Third Parties.”

- AltaValve

We invested in 4C Medical, which is developing an innovative TMV replacement medical device, AltaValve. As of the Latest Practicable Date, AltaValve was undergoing an early-stage human feasibility study. The purpose of the early-stage human feasibility study is to obtain preliminary product safety and efficacy data on human bodies. AltaValve’s supra-annular fit and atrial-only

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fixation are designed to overcome the concerns of anchoring and fixation difficulties present in existing TMV technologies. Further, AltaValve leaves the left ventricle geometry intact and therefore reduces the risks of LVOT obstruction and damage. AltaValve can be implanted through transseptal or transapical approach, which is suitable for the vast majority of patients suffering from mitral regurgitation. We enjoy the exclusive distribution rights in relation to AltaValve and manufacturing rights in relation to the delivery system of AltaValve in China. For details, see “—Collaboration with Third Parties.”

- *In-house developed TMV replacement product*

We are conducting animal studies on our in-house developed TMV replacement pipeline product. Our unique design of this product is expected to reduce the risks of LVOT obstruction and damage while preserving the ventricle function. The pipeline product has a thin diameter of 32 Fr, which has the potential to cause less vascular damage during delivery. As of the Latest Practicable Date, we had observed positive results during a three-month follow-up animal study.

With our long-term focus on the TMV market, we believe we are well-positioned to identify the limitations and risks associated with current treatment options and to strategically direct our R&D efforts to address mitral regurgitation, which in turn, will enable us to benefit from vast but substantially underpenetrated TMV market.

Proven commercialization capability with rapid penetration into hospitals in China, supported by collaboration with KOLs

We have a proven track record in the commercialization of our products. We have invited industry-leading KOLs to participate in our product design and clinical trials before the commercial launch of our products to increase the awareness and recognition of our products. Driven by positive clinical trial results of VitaFlow™, patient-oriented pricing, strong KOLs’ endorsement on our products and the overall brand awareness of the “MicroPort” brand, we had successfully sold 271 and 601 units of VitaFlow™ in the last five months of 2019 and the seven months ended July 31, 2020, respectively—an average of over 70 units per month in the first year of its commercialization.

We adopt a patient-oriented pricing strategy which we believe can achieve the balance between patients’ affordability and market demands. We have conducted extensive market research with KOLs, hospitals, physicians and patients as well as regulatory bodies prior to setting the market price. We believe our competitive pricing can significantly benefit the large patient pool eligible for TAVI procedures and drive our future business growth.

We adopt an academic promotion approach in introducing our products into hospitals, which we believe will increase the market awareness of our products and support our commercialization efforts. According to Frost & Sullivan, 73.5% of the TAVI procedures performed in China in 2020 are expected to be performed at the Top 20 TAVI Hospitals. We focus on penetrating these hospitals as the first step of our marketing strategy. In order to gain a higher market share in these hospitals, we maintained regular interaction and communication with KOLs from these hospitals. We invited these KOLs to carry out clinical studies for our pipeline products and post-launch clinical studies. In general, these KOLs highly recognized the unique and innovative design of VitaFlow™ and its positive clinical trial results with respect to mortality rate and postoperative complications including

moderate/severe PVL, major stroke and vascular complications. As of the Latest Practicable Date, we had successfully penetrated 18 of the Top 20 TAVI Hospitals.

We also focus our academic promotion efforts on exploring and penetrating new hospitals which are eligible for performing TAVI procedures. According to Frost & Sullivan, there are strong demands in qualified hospitals with an experienced TAVI operation team to support the growth of China's TAVI market. In 2019, there were 604 hospitals that are eligible for performing TAVI procedures but only 156 hospitals had performed TAVI procedures. We believe this represents ample opportunities for us to further penetrate China's TAVI market. In order to strengthen our product recognition among these hospitals, we actively participate in industry-leading academic conferences and host hospital training sessions. In 2019, we introduced VitaFlow™ through lectures or case studies seminars at over eleven industry-leading academic conferences in China, each of which attracted over 100 physicians in the cardiovascular area in China. As of July 31, 2020, we had organized approximately 90 hospital seminars and training sessions in 24 provinces and over 50 cities in China. These academic presences enable us to introduce TAVI technology and our product to a wider hospital and physician group. With our frequent participation in academic conferences and close interaction with physicians and hospitals, as of the Latest Practicable Date, TAVI procedures using VitaFlow™ had been performed at over 145 hospitals in China and no incidence of major postoperative complication had been observed. In September 2020, VitaFlow™ became the first TAVI product to obtain the Shanghai Basic Medical Insurance Medical Device Settlement Code (“上海市基本醫療保險儀器設備/醫療器材結算編碼”), a prerequisite for medical device to be commercially sold at substantially all the hospitals in Shanghai, according to Frost & Sullivan. According to the same source, Shanghai is one of the cities in China that have the most eligible hospitals for TAVI procedures and VitaFlow™ has successfully penetrated most eligible hospitals for TAVI procedures in Shanghai. As of the Latest Practicable Date, we were also in the process of penetrating the remaining eligible hospitals in Shanghai.

Medical device platform to provide innovative treatment solutions

Driven by our strong innovation capabilities and supported by our strict quality control system in accordance with global leading standards, our platform primarily focuses on (i) technological innovations, advancements in product design, and improvement in biological material processing techniques; (ii) efficient design and execution of clinical trials; and (iii) manufacturing efficiency.

R&D

We have a strong track record of in-house R&D achievements. As of the Latest Practicable Date, we had self-developed and owned over 150 patents in China and overseas and had over 80 patent applications pending in China. Benefiting from our long-time R&D efforts and dedication in valvular heart diseases, we have built a core R&D team with key technology expertise in areas including biological material, suturing technique, structure design and processing technique, among others. Our R&D capabilities and expertise have enabled us to make significant progress in product innovation, technology development and manufacturing process optimization to address industry pain points. For example, we use bovine pericardium as valve tissue due to its better durability and hemodynamic performance as compared to the porcine pericardium. To address suturing challenges presented due to the additional thickness of bovine pericardium and the double-layer PET skirt design, which contributes to extra thickness, our biological material team, suturing technique team and processing technique team worked together to develop a unique suturing technology with better designs for valve

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leaflets and PET skirt. Going forward, we will continuously expand our product pipeline through our R&D effort to strengthen our competitive advantages. In addition, we also have an international scientific advisory board, consisting of global leading scientists and physicians in the cardiovascular field, namely Dr. Nicolo Piazza, Dr. Thomas Modine and Dr. Darren Mylotte, who share their abundant experiences with and insights on the latest technology breakthroughs and latest trends in the treatment of valvular heart diseases worldwide.

Clinical Development

Through our over ten years of R&D experience in the Class III medical device field, we gain a deep understanding of the laws and regulations relating to Class III medical devices in China and overseas. We also have accumulated extensive experience in managing and executing clinical trials efficiently and simultaneously in both China and overseas. With VitaFlow™ II being the only TAVI product developed in China that had commenced clinical trial in Europe, we accumulated unique know-how and experiences in clinical trial management overseas.

We have abundant experience in clinical trial execution, covering every critical stage of clinical trials including planning, designing, execution, data management and data analysis. As of the Latest Practicable Date, we had designed and executed three clinical trials in China and Europe. By closely cooperating with PIs from leading hospitals in China and overseas and benefiting from our effective clinical trial management, the pivotal clinical trial for VitaFlow™ took only eleven months from the first patient enrollment to completing TAVI procedures on all the patients, which, according to Frost & Sullivan, is significantly shorter than that of clinical trials of competing TAVI products in China. With respect to our ongoing clinical trial in Europe, in response to the impact of the COVID-19 pandemic, we have been actively monitoring the latest status of each clinical site in Europe. We expect our application for CE Mark will be partially supported by the clinical trial data obtained in China, which we believe will expedite our CE Mark registration process.

Manufacturing

We have built a strong manufacturing team to bring our products from the clinical trial stage to commercial production seamlessly. In particular, manufacturing prosthetic aortic valves is a complex process. Suturing the bovine pericardium to the frame, a key step in the manufacturing process, must be done manually by experienced technicians, which currently cannot be replaced by machines as it requires significant know-how in assessing the thickness and hardness of bovine pericardia. As of July 31, 2020, we had over 30 full-time technicians that are capable of completing the suturing task. The manufacturing of VitaFlow™ needs to be carefully managed in a temperature and humidity controlled environment. As of the Latest Practicable Date, we had two manufacturing facilities in Shanghai, namely the Nanhui Facility and the Zhangjiang Facility, with a total GFA of approximately 3,863.8 square meters. We have established a stringent quality control management system in accordance with the GMP standard required by the NMPA as well as the ISO13485:2016.

Experienced management team with international expertise and commitment to valvular heart diseases and strong shareholder support with trusted brand name of “MicroPort”

We are led by a management team who has rich working experience in the cardiovascular field. Our Chairman, Dr. Luo Qiyi, has over 29 years of experience in the medical device industry. Dr. Luo

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has held key positions responsible for research and development at international leading medical device companies, such as C.R.Bard, Inc and Medtronic. Dr. Luo participated in the invention process of over 300 patents registered in China and overseas. Our President and executive Director, Mr. Chen Guoming, had over ten years of experience in the research and development of medical devices. He has successfully led the research and development of VitaFlow™ and VitaFlow™ II. Our management team also include Ms. Yan Luying and Mr. Wu Guojia, each being an executive Director and our Vice President. Ms. Yan Luying is mainly responsible for regulatory affairs and clinical trials, who has over 16 years of experience in registration, clinical investigation and management regarding active, non-active, interventional and implantable devices. Mr. Wu Guojia is mainly responsible for sales and marketing, who has over 16 years of experience in medical device companies and more than six years of experience as an interventional cardiologist. Mr. Wu has worked at several international medical device companies, including Boston Scientific, among others. For details, see “Directors and Senior Management.”

Since our inception, we have received strong support from our Shareholders. Our Controlling Shareholder, the MicroPort Group, is a leading medical device company focusing on innovating, manufacturing and marketing high-end medical devices globally, which has been listed on the Main Board of the Stock Exchange since 2010. Benefiting from the brand recognition of “MicroPort”, we believe we are well-positioned to promote our products among cardiovascular physicians. In addition, we have been inspired by the rich experiences in R&D, manufacturing and quality control of the MicroPort Group.

We receive strong endorsements from committed and Sophisticated Investors, including international leading investors such as Hillhouse Capital as well as private equity investors in China, such as China Renaissance Holdings Limited, China International Capital Corporation and CPE Global Opportunities Fund, L.P., among others.

BUSINESS STRATEGY

We intend to capitalize on our strengths to pursue a business strategy in the following aspects.

Continue to strengthen our presence in China’s TAVI market

According to Frost & Sullivan, the China TAVI market is significantly under-penetrated. In 2019, there were approximately 2,400 TAVI procedures performed in China with a penetration rate of 0.3%, as compared to approximately 66,800 performed and a penetration rate of 23.4% in the U.S. It is expected that approximately 42,000 TAVI procedures will be performed in China, representing a CAGR of 60.7% for the next five years and a penetration rate of 4.5% in 2025. We intend to further increase our sales of TAVI products in China through the following.

- ***Expand and deepen hospital penetration.*** We will continue our focus on increasing penetration into Top 20 TAVI Hospitals, in which we believe we can gain a substantial advantage by leveraging our positive clinical trial results of VitaFlow™ with respect to mortality rate and postoperative complications including moderate/severe PVL, major stroke and vascular complications and excellent KOLs’ endorsement. We plan to further penetrate these hospitals to gain a leading market share in the near future. We will also expand into other hospitals that either has existing TAVI capabilities or the potential to

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perform TAVI procedures. According to Frost & Sullivan, it is expected that there will be 1,149 eligible hospitals for TAVI procedures in China, among which 616 hospitals are expected to have performed TAVI procedures in 2025. These hospitals indicate high potential for TAVI penetration. We will also recruit more sales and marketing personnel with experience in or knowledge of valvular heart diseases and expand our distributor network to further penetrate China's TAVI market.

- ***Further advance development of next-generation products.*** We intend to rapidly advance the R&D of our TAVI pipeline products. In October 2020, we submitted the registration application for VitaFlow™ II to the NMPA which was accepted in November 2020 and is currently under review. We currently expect we will complete the registration of VitaFlow™ II in China by the end of 2021. We will also advance the development of our third-generation self-expanding TAVI product and another balloon-expandable TAVI product, in order to provide full solution to all suitable patients, especially younger patients and patients with lower surgical risks.
- ***Strengthen academic promotion.*** In addition to maintaining our KOL and physician network in the medical specialty of cardiology, we also intend to expand our KOL and physician network to physicians in cardiothoracic surgery, which we believe potentially also have strong demand for our products. We have kept, and will continue to keep frequent communications with several leading medical associations and conferences in these medical specialty fields, such as the Asia Valvular Heart Disease Conference, to design customized training programs for cardiac surgeons. We believe our KOL and physician coverage in the medical specialty of cardiothoracic surgery will enable us to gain advantages to promote our products in the cardiothoracic surgery department.
- ***Long-term postoperative follow-ups and marketing surveillance.*** We will continue to conduct postoperative follow-up evaluations for up to five years post-TAVI procedure to further monitor the long-term safety and efficacy of VitaFlow™. We believe we are well-positioned to further enhance our relationship with physicians and boost our brand recognition through these valuable long-term clinical data.

Continue to advance our international strategy

We will continue our efforts in the international markets with a tailored strategy for both VitaFlow™ and VitaFlow™ II in various international markets with significant market potential. Leveraging the global awareness of the “MicroPort” brand, we plan to collaborate with global enablers, including medical device companies, research institutes, hospitals and distributors, to advance our international strategy

- ***VitaFlow™.*** We are exploring opportunities for VitaFlow™ in emerging markets that recognize the NMPA approval. In July 2020, we successfully registered VitaFlow™ with the National Administration of Drugs, Foods and Medical Devices in Argentina. In November 2020, we successfully registered VitaFlow™ in Thailand. We plan to increase academic promotion activities and ramp up sales in these territories. We also plan to register VitaFlow™ in Russia in the next two years.

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- ***VitaFlow™ II.*** We will focus on product registration and commercialization of VitaFlow™ II overseas, especially in Europe. Currently, we are conducting a pivotal clinical trial for VitaFlow™ II in Europe for CE Mark registration. With our extensive experience in product development, registration and manufacture of TAVI products and the awareness of “MicroPort” brand, we believe VitaFlow™ II has the potential to become the first commercialized China-developed TAVI product in Europe. We will also advance product registrations in emerging markets, especially countries that recognize CE Mark or the NMPA approval such as Argentina, Brazil, South Korea, Russia, Thailand and India. We are also evaluating opportunities in other territories and we may consider enter such territories and conduct local clinical trials for product registration of VitaFlow™ II in such territories in the future.
- ***Overseas collaborations.*** As part of our international strategy, we will steadily expand our academic coverage into overseas markets. During the Track Record Period, we were one of the few Chinese companies that had presented case study at international leading academic conferences, including PCR London and the SOLACI conference (also known as the Latin American Society of Interventional Cardiology). Leveraging the experience and the expertise of our international scientific advisory board, we intend to participate in more leading international cardiovascular conferences by organizing presentations and case studies to introduce our product to enhance our brand awareness globally.

Rapidly advance our TMV pipeline and other product candidates

We will continue our focus on the development of other pipeline products to expand our product portfolio, including TMV pipeline products, TTV pipeline products and next-generation procedural accessories and surgical accessories designated to strengthen our position in the transcatheter medical device market. Capitalizing on our market position and extensive know-how in the valvular heart disease field, we will further expand our product portfolio through in-house R&D capabilities. We believe we can leverage our experiences and know-how accumulated during the development of the current product portfolio in our future products.

We will also seek opportunities for third-party cooperation with a focus on valvular heart disease. Our deep and unique understanding and insights on valvular heart diseases will enable us to identify the technologies that we believe are of great clinical potential to tackle aortic valve, mitral valve and tricuspid valve diseases. We will prudently assess investment opportunities to expand our product portfolio through acquisition, collaboration or in-licensing arrangement with regard to these technologies.

We also intend to recruit and train additional talented R&D personnel to expand our in-house R&D team. Our in-house R&D team will work closely with our international scientific advisory board and KOLs to follow the market trends and technology breakthroughs, which will in turn enable us to better understand the clinical demands.

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Improve operational efficiency and achieve economies of scale to support our long-term growth

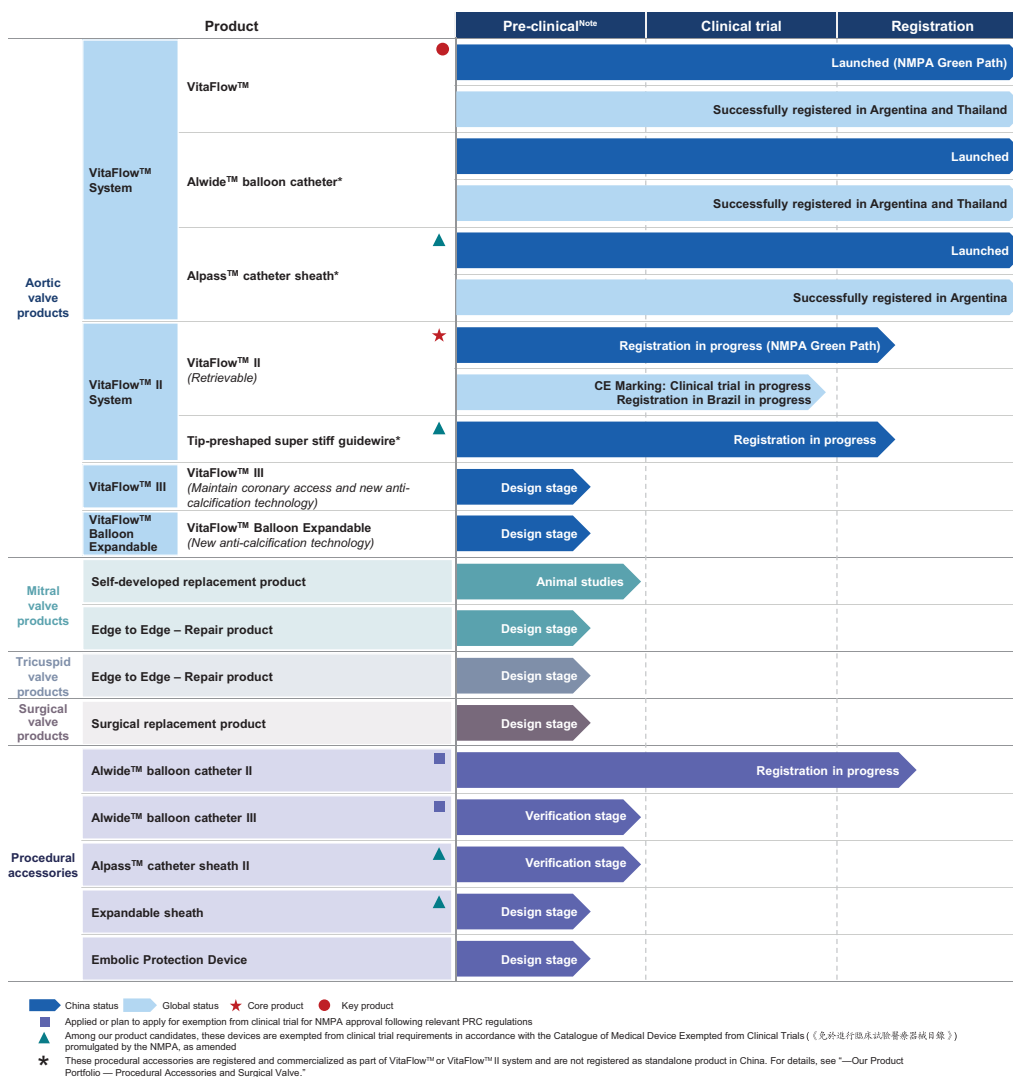
We plan to improve operational efficiency to achieve long-term growth through the following measures.

- **Manufacturing.** To support our future sales growth, we have engaged a third party to construct a new manufacturing facility in Shanghai with a total GFA of approximately 13,000 square meters, which is currently expected to commence production in 2022. We expect the manufacturing capacity expansion will enable us to achieve economies of scale. In addition, we intend to further improve the automation and manufacturing efficiency through continuous infrastructure upgrade and facility automation.
- **Operation.** We will continue our efforts to pursue lean management and operational excellence strategy. We plan to upgrade our digital supply management system and information management system to achieve real-time monitoring of our supply chain. We are also exploring methods to optimize our inventory management system, which will improve our operational efficiency.

OUR PRODUCT PORTFOLIO

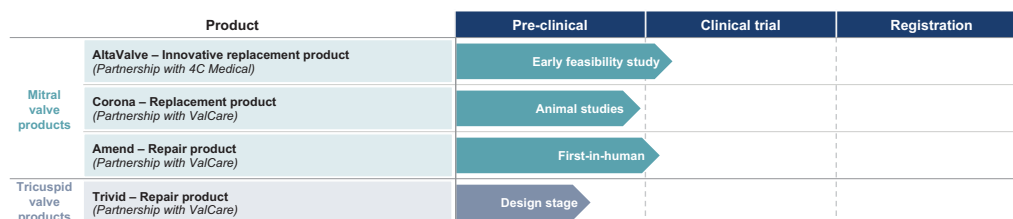
We are a medical device company in China focusing on the research, development and commercialization of innovative transcatheter and surgical solutions for valvular heart diseases. As of the Latest Practicable Date, we had successfully developed one marketed product, VitaFlow™, and various pipeline products at different stages of development by our in-house team or through collaboration with our global partners, namely 4C Medical and ValCare, each being a medical device company focusing on the R&D of mitral and tricuspid valve medical devices. For regulatory pathways for our products and pipeline products, see “Regulatory Overview.” The chart below summarized our in-house developed product portfolio as of the Latest Practicable Date.

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Note: Design stage refers to the designing and developing of the sample product. Verification stage refers to performing verification testing on the sample product to finetune its design.

The following chart summarizes the product portfolio that are developed by our business partners and for which we owned the exclusive commercial rights in China. With respect to these products, our business partners are primarily responsible for research, development and manufacturing of the products and we are responsible for product registrations and commercialization in China.



Aortic Valve Products

VitaFlow™—Our Key Product

Our first-generation TAVI product, VitaFlow™, was approved for commercialization for the treatment of severe aortic stenosis by the NMPA under the Green Path for Innovative Medical Device

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in China in July 2019. Subsequently, VitaFlow™ was commercialized in China in August 2019. It is the first marketed TAVI product in China utilizing bovine pericardium as valve tissue, according to Frost & Sullivan. As of the Latest Practicable Date, VitaFlow™ was the only TAVI product featuring the first-in-China double-layer PET skirt and the only marketed motorized delivery system worldwide according to the same source. Our unique product designs have enabled VitaFlow™ to achieve positive clinical trial results, including a low all-cause mortality rate and low incidences of postoperative complications. For details, see “Industry Overview—Competitive Landscape—TAVI Market.” We also launched our first-generation in-house developed Alwide™ balloon catheter and Alpass™ catheter sheath as part of the VitaFlow™ offering, making us the only medical device company in China that has a comprehensive offering of in-house developed complementary TAVI procedural accessories, according to Frost & Sullivan.

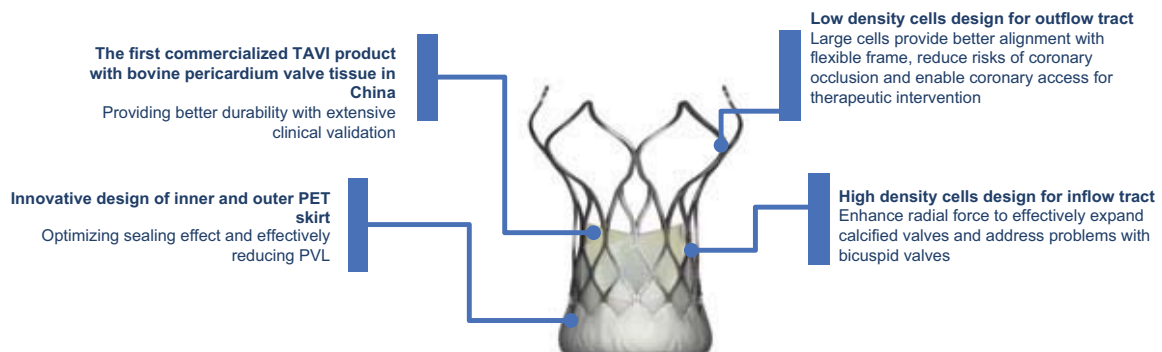
Since the commercial launch of VitaFlow™ and as of July 31, 2020, we had sold 872 units of VitaFlow™. As of July 31, 2020, we had 19 distributors and we plan to further expand our distributor network in the future to cover all the eligible hospitals for TAVI procedures in China. We are also evaluating the opportunities to market VitaFlow™ overseas, especially in emerging markets that recognize the NMPA marketing approval. In July and November 2020, VitaFlow™ was registered in Argentina and Thailand, respectively, we also plan to register VitaFlow™ in Russia in the next two years. We plan to enter into local agency or distributors with respect to our overseas strategies in these emerging markets. As of the Latest Practicable Date, we had engaged a local distributor in Argentina to gradually penetrate the Argentine market.

Product Structure

VitaFlow™ is a TAVI device that primarily consists of a prosthetic aortic valve (“PAV”), a motorized delivery system and certain procedural accessories.

Prosthetic Aortic Valve

The PAV is a self-expanding bio-prosthesis valve that is manufactured by suturing bovine pericardial valve leaflets and double-layer polyethylene terephthalate (PET) skirt onto a self-expanding nitinol frame. The picture below illustrates the key features of the PAV of VitaFlow™.



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The PAV is designed to enhance the durability of the aortic heart valve and the safety of the TAVI procedure, which enables VitaFlow™ to achieve a low mortality risk and low incidence of postoperative complications. The key features of the PAV of VitaFlow™ are summarized below.

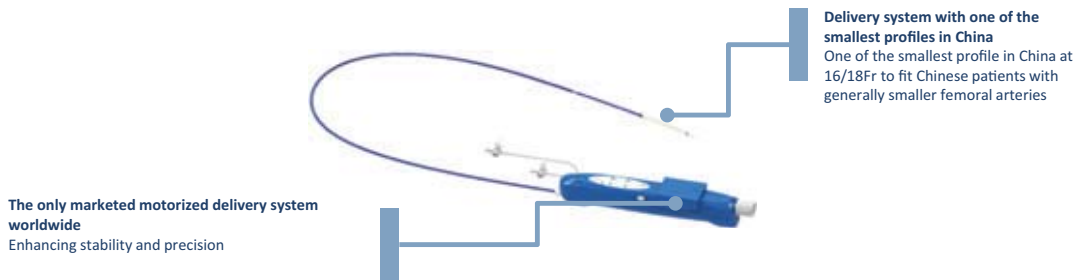
- ***Bovine pericardium valve tissue.*** According to Frost & Sullivan, among the five currently approved or commercialized TAVI products in China, VitaFlow™ is the first one utilizing bovine pericardium as the valve tissue. Existing clinical trial data on SAVR have demonstrated that bovine material can provide better durability and hemodynamic performance as compared to porcine material, and leads to lower risks of postoperative complications. As a result, bovine pericardium has been dominating the global TAVI market with over 55% market share and substantially the entire global SAVR market. Patients treated with TAVI products utilizing bovine pericardium as valve tissue are able to live with the implanted prosthetic aortic valve for a longer period of time, lowering the chance for another TAVI procedure.
- ***Double-layer PET skirt design.*** PVL is one of the major complications post TAVI procedures, which may lead to atrial fibrillation, pulmonary hypertension, or even heart failure. VitaFlow™ features an innovative first-in-China double-layer PET skirt design, according to Frost & Sullivan. One layer of the PET skirt is attached to the inner side of the nitinol frame and the other layer is attached to the outer side. The configuration optimizes the sealing effect of the valve and effectively reduces PVL.
- ***Hybrid density frame.*** The bottom high-density cells are designed to significantly benefit patients with severely calcified valves or bicuspid valves as the enhanced high radial force at the annulus level will help push aside the leaflet. As a result, the hybrid density frame can increase the implantation success rate for patients with severely calcified valves or bicuspid valves, which can be demonstrated by the clinical trial results we collected from the pivotal clinical trial in China. For details, see “—Summary of Clinical Trial Results— Safety Results.” The hybrid density frame uses low-density cells at the upper level, which provide better alignment with flexible frame, reduce risks of coronary occlusion and enable coronary access for future coronary intervention.

Our PAVs have four models with different dimensions in aortic annulus diameter and valve height, which allows physicians to select the most suitable in accordance with a patient’s particular physical conditions.

Motorized Delivery System

According to Frost & Sullivan, among all the commercialized TAVI products worldwide, VitaFlow™ was the only one that had a motorized delivery system as of the Latest Practicable Date. The delivery system consists of a catheter and a motorized handle. The deployment end of the delivery system features a radiopaque catheter tip and a capsule that covers and maintains the PAV in the loading position. The motorized handle is on the proximal end of the catheter device and is used to load and deploy the PAV. In addition, a traditional manual operation knob is also available as a backup option. The picture below illustrates the key features of the delivery system of VitaFlow™.

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The key features of the VitaFlow™ delivery system are summarized below.

- ***The only marketed motorized handle.*** According to Frost & Sullivan, among all the commercialized TAVI products worldwide, VitaFlow™ was the only one that had a motorized delivery system as of the Latest Practicable Date. Compared to the manual delivery system which generally depends more on physician's experiences in TAVI procedures, physicians can position the guidewire and deploy the prosthetic aortic valve more precisely and stably with the motorized delivery system, which in turn improves the overall success rate of TAVI procedures. We believe the motorized delivery system can significantly benefit physicians by lowering the challenges in performing TAVI procedures and shortening the learning curve of physicians for TAVI procedures.
- ***Delivery system with one of the smallest profiles in China.*** According to Frost & Sullivan, Chinese patients suffering from aortic valve diseases generally have smaller femoral arteries than patients in the U.S or Europe. The delivery system of VitaFlow™ is specifically designed for Chinese patients with the outer diameter of the sheath tube as thin as 16Fr or 18Fr. According to Frost & Sullivan, the delivery system of VitaFlow™ has one of the smallest profiles among all the commercialized TAVI products in China.

Procedural Accessories

As part of the comprehensive TAVI solutions offered by VitaFlow™, we also offer two procedural accessories, namely the Alwide™ balloon catheter and the Alpass™ catheter sheath. The pictures below illustrate the key features of our marketed procedural accessories.

Alwide™ balloon catheter



Alpass™ catheter sheath



Key features

- Low compliance ability enables accurate sizing.
- High burst pressure is suited for severe calcification.
- Fast inflation/deflation minimizes pacing time
- Better kink-resistance
- Excellent tractability

Operational procedure

The physician will insert the flushed balloon catheter through guidewire until it arrives at the root of the aorta, then the balloon is inflated to dilate the calcified aortic annulus or the implanted valve prosthesis.

The physician will insert a dilator into the catheter sheath after flushing, then insert them as an entirety into patient's femoral artery and iliac artery. Afterwards, the physician will withdraw the dilator. The catheter sheath will then form the access for TAVI device system and balloon catheter.

Operational Procedure

The key steps of the TAVI operational procedure are summarized below.

- **Pre-procedure.** Pre-procedures mainly include (i) establishing of a vascular access site; (ii) administering anticoagulation; (iii) inserting the pacemaker electrode; (iv) positioning the distal tip of the pigtail in the non-coronary cusp of the native aortic valve; and (v) advancing the guidewire across the native aortic valve into the left ventricle.
- **Deployment.** The deployment of the valve can be performed either by the motorized handle or the manual knob. A physician first presses the back button (or rotate the knob) to slowly expand the valve to six to eight mm in diameter and perform an angiogram to assess the location of the valve. The valve is deployed until both frame loops disengage. The physician then uses orthogonal views under fluoroscopy to confirm that the frame loops have detached from the catheter.
- **Withdrawal.** After the frame loops are completely disengaged from the catheter, the physician will withdraw the catheter while maintaining the guidewire in position and then remove the catheter through the introducer sheath after the capsule is closed.
- **Post-procedure.** The physician is required to perform a post-implant aortography inspection to ensure coronary patency and assess aortic regurgitations.

Summary of Clinical Trial Results

Overview of Clinical Trial

In order to evaluate the efficacy and safety of VitaFlow™, we conducted a prospective, multi-center and single-arm pivotal clinical trial in China. The clinical trial was conducted in eleven sites, with Zhongshan Hospital of Fudan University (复旦大学附属中山医院) as the lead research institution. The comprehensive trial results demonstrated the lowest all-cause mortality rate among competitors worldwide based on a side-by-side comparison and significant improvements in the function of the patients' cardiovascular system post-implantation. With the first-in-China double-layer PET skirt design, we also observed that PVL was effectively and stably reduced during the follow-up period. Further, we also demonstrated that there were no statistical differences in clinical trial outcomes between bicuspid and tricuspid aortic valve patients.

Study Protocol and Design

From October 2015 to September 2016, 110 patients were enrolled in the pivotal clinical trial and TAVI procedures were performed on all of them. The patients enrolled had an average STS Score of 8.8. Each patient was required to sign an informed consent for the pivotal clinical trial. The decision to proceed with TAVI was made by a dedicated medical team consisting of experienced clinical and interventional cardiologists, imaging specialists, cardiac surgeons, and anesthesiologists at each clinical trial site. Set forth below are the patient inclusion criteria for the pivotal clinical trial.

- the age of the patient is 70 years old or above;
- the patient is diagnosed with severe native aortic stenosis;
- the patient is classified as class II or above under the NYHA Classification;
- the patient has a life expectancy of at least 12 months after implantation;
- the patient is deemed to be anatomically eligible for TAVI procedures; and
- the patient is prohibitive for SAVR procedures or considered to have a high surgical risk for SAVR procedures as evaluated by the multidisciplinary cardiovascular study.

The primary endpoint of the pivotal clinical trial is the all-cause mortality rate at 12 months after implantation. Secondary endpoints include major stroke, new pacemaker implantation, myocardial infarction, vascular complication, PVL, valve performance and class status under the NYHA Classification. The endpoints are self-reported by each trial site and then adjudicated by a clinical endpoints committee of the lead research institution. The degrees of PVL are assessed through echocardiography study at each trial site. We conduct follow-up evaluations at 30 days, six months, 12 months, 24 months, 36 months, 48 months and 60 months post-implantation. As of the Latest Practicable Date, we had completed the 36-month follow-up evaluation with the 110 patients and we were in the process of completing the remaining follow-up evaluations.

Safety Results

The safety of VitaFlow™ is primarily measured by the all-cause mortality rate. The all-cause mortality rate was 0.9% at discharge, 0.9% at 30 days, 2.7% at six months, 2.7% at 12 months, 4.5% at 24 months and 10.9% at 36 months post-implantation. Specifically, the cardiovascular mortality rate was 0.9% at discharge, 0.9% at 30 days, 1.8% at six months, 1.8% at 12 months, 2.7% at 24 months and 7.3% at 36 months post-implantation.

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Other key considerations to evaluate the safety of our TAVI products are incidences of serious adverse events during the follow-up period, mainly including major strokes, minor strokes, major vascular complication and myocardial infarction. The table below illustrates the number and percentage of each type of serious adverse event that occurred among the 110 patients during the respective follow-up period post-implantation.

Clinical endpoints	Discharge (N=110)	30 days (N=110)	Six months (N=110)	12 months (N=110)	24 months (N=110)	36 months (N=110)
All-cause mortality	0.9%(1)	0.9%(1)	2.7%(3)	2.7%(3)	4.5%(5)	10.9%(12)
Cardiovascular mortality	0.9%(1)	0.9%(1)	1.8%(2)	1.8%(2)	2.7%(3)	7.3%(8)
All stroke (Major and Minor)	1.8%(2)	2.7%(3)	4.5%(5)	4.5%(5)	7.3%(8)	11.8%(13)
Major stroke	0.0%(0)	0.0%(0)	0.0%(0)	0.0%(0)	0.0%(0)	1.8%(2)
Minor stroke	1.8%(2)	2.7%(3)	4.5%(5)	4.5%(5)	7.3%(8)	10.0%(11)
Major vascular complication	1.8%(2)	1.8%(2)	1.8%(2)	2.7%(3)	2.7%(3)	2.7%(3)
Myocardial infarction	4.5%(5)	8.2%(9)	9.1%(10)	9.1%(10)	9.1%(10)	10.0%(11)

Efficacy Results²

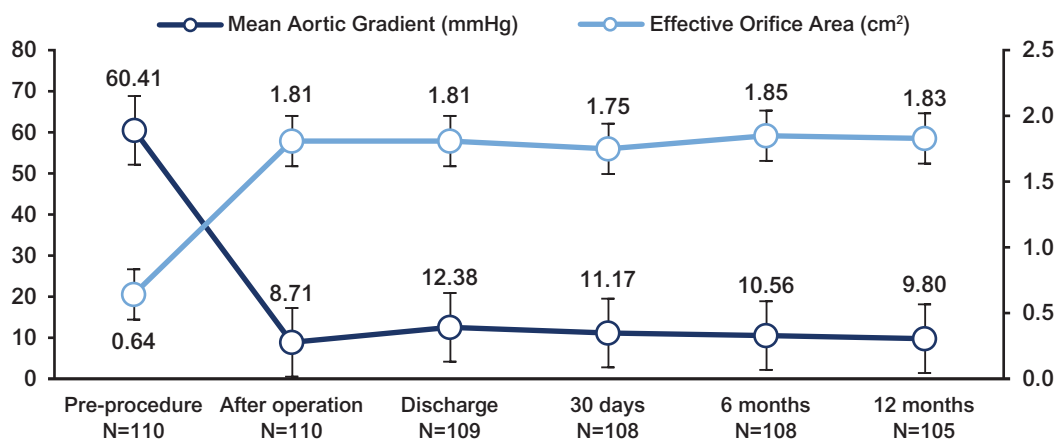
The efficacy of VitaFlow™ is measured by the physical conditions of patients during the follow-up period, mainly including effective orifice area, mean aortic gradient, class status under the NYHA Classification and the incidence and severity of PVL. In general, we observed a significant and stable improvement of the function of the patients' cardiovascular system post TAVI procedure which we believe are results of the innovative features of our VitaFlow™, such as the double-layer PET and hybrid density frame.

Improved Cardiovascular System Functions—Effective Orifice Area, Mean Aortic Gradient and Class Status under the NYHA Classification

The effective orifice area is a standard parameter for the clinical assessment of aortic stenosis severity, which refers to the minimal cross-sectional area of a native or bio-prosthetic aortic heart valve. Patients' effective orifice area increased significantly post-implantation and remained relatively stable during the 12-month follow-up period.

² Unless indicated otherwise, all data presented below are based on patients who survived at each follow-up time.

The mean aortic gradient is another measurement of aortic stenosis. In general, a patient with a mean aortic gradient of over 40 mmHg is considered to have severe aortic stenosis. VitaFlow™ was designed to use high-density cells for the inflow tract. Such high-density cells provide enhanced radial force at annulus level and help to push aside the leaflets. As a result, the mean aortic gradient decreased significantly post-implantation. The following chart illustrates the mean aortic valve gradient and the effective orifice area at each follow-up time.



NYHA Classification is a simple way of classifying the extent of heart failure. It classifies patients into one of four categories based on their symptoms or physical activity limitations. Such symptoms or limitations are with regards to normal breathing and varying degrees in shortness of breath and/or angina pain. In general, class II or below in the NYHA classification refers to mild or no symptoms and no limitations in ordinary physical activity. Class III refers to marked limitation in activities due to symptoms, even during less-than-ordinary activity and class IV refers to severe limitation where the patient experiences symptoms even at rest.

Before the TAVI procedure, only 19.1% of the patients were classified as class I or class II under the NYHA Classification. Following the 24-month and 36-month follow-up post-implantation, 96.2% and 94.9% of the patients achieved class I or class II under the NYHA Classification, respectively. The following table illustrates the class status of our patients under NYHA Classification at the follow-up time indicated.

NYHA Classification ^{Note}	Pre-procedure (N=110)	Discharge (N=109)	Six months (N=106)	12 months (N=107)	24 months (N=107)	36 months (N=98)
Class I	0.0%	6.5%	47.2%	70.1%	69.2%	68.7%
Class II	19.1%	43.5%	48.1%	26.2%	27.0%	26.3%
Class III	59.1%	41.7%	3.8%	2.8%	3.8%	5.0%
Class IV	21.8%	8.3%	0.9%	0.9%	0.0%	0.0%

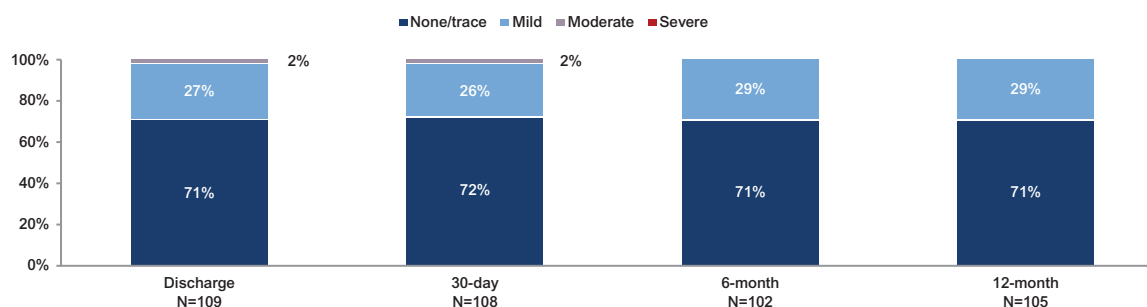
Note: The number of patients represent the patients that undergo the follow-up evaluations with respect to NYHA classification at each follow-up period.

Reduced Post-Procedural Complications—Mitigating PVL

While improving the functions of the patients’ cardiovascular system, clinical trial results also demonstrated that VitaFlow™ can reduce incidences of postoperative complications, especially the PVL, which may lead to atrial fibrillation, pulmonary hypertension, or even heart failure. The first-in-China double-layer PET skirt provides a better sealing effect around the frame, which in turn

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mitigates PVL. Only 2% of the patients were observed with a moderate PVL and none with severe PVL at discharge and 30 days post implantation, respectively. At six months and 12 months post implantation, none of the patients had moderate or severe PVL. The low rate of moderate or severe PVL also contributes to the observed low all-cause mortality rate. The chart below illustrates the level of PVL at each follow-up period.



No statistical differences between Tricuspid and Bicuspid Aortic Valve

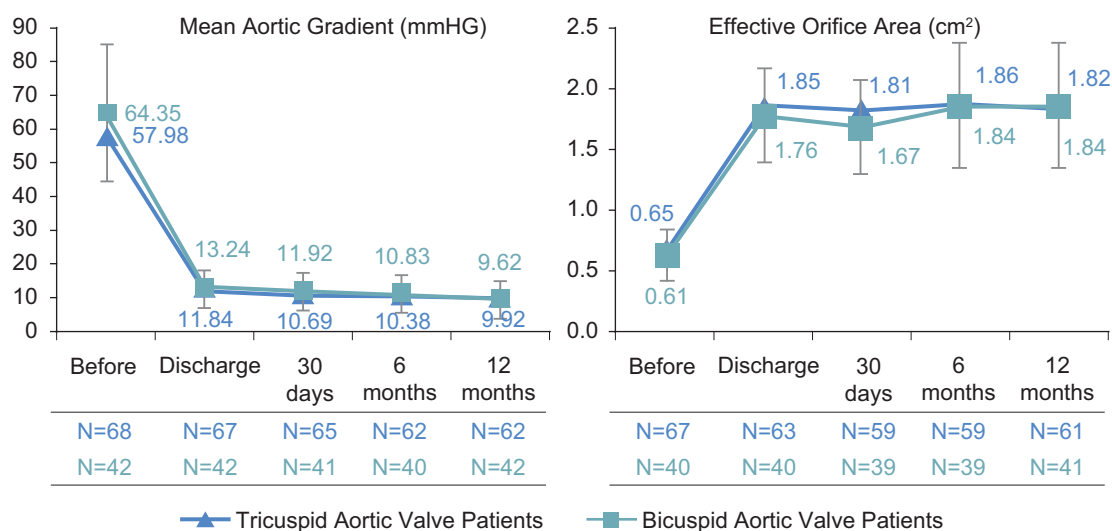
According to Frost & Sullivan, compared with aortic stenosis patients in western countries, aortic stenosis patients in China generally have a higher percentage of bicuspid aortic valve morphology (“BAV”). The incidence of BAV in China is estimated to be 38.4%, while it is merely 1.3% in the U.S. In general, patients with BAV abnormalities only have two leaflets of the aortic valve and these leaflets may be thicker and stiffer than the patients with tricuspid aortic valve. In addition, patients with BAV abnormalities have higher risks of valvular dysfunction followed by severe aortopathy, such as PVL. Those characteristics impose greater challenges for TAVI products treating patients with BAV abnormalities.

VitaFlow™ achieved no statistical differences in clinical trial outcomes between tricuspid aortic valve patients and patients with BAV abnormalities. Among the 110 patients, 42 suffered from BAV abnormalities. In general, the clinical trial results have proven the safety and efficacy of VitaFlow™ in the treatment of both bicuspid and tricuspid aortic valve patients with aortic stenosis. The chart below illustrates a comparison of the clinical trial results between tricuspid and bicuspid valve abnormalities patients during the twelve months following TAVI implantation.

<u>Clinical outcomes</u>	<u>Tricuspid aortic valve patients</u>	<u>Bicuspid aortic valve patients</u>
Number of patients	68	42
All-cause mortality (%)	4.4%	0.0%
Cardiovascular mortality (%)	2.9%	0.0%
All stroke (Major and Minor; %)	4.6%	4.8%
Major vascular complication (%)	4.5%	0.0%
Moderate or severe PVL (%)	0.0%	0.0%
New pacemaker implantation (%)	22.1%	14.3%
NYHA class I (%)	67.7%	73.8%

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The following chart illustrates the comparison of mean aortic gradient and effective orifice area between tricuspid and BAV abnormalities aortic valve patients at the respective follow-ups during the 12-month post-implantation in respect of the mean aortic gradient and effective orifice area.



Market Opportunity and Competition

According to Frost & Sullivan, there were 19.7 million patients worldwide and 4.3 million patients in China suffering from aortic stenosis in 2019. The number of aortic stenosis patients is expected to grow to 22.1 million worldwide and 4.9 million in China in 2025, respectively. Due to the insufficient number of qualified hospitals with experienced physicians, the TAVI market in China is significantly under-penetrated with only 0.3% eligible patients being treated by TAVI procedure in 2019, as compared to 23.4% in the U.S. Driven by the increasing number of qualified physicians, increasing preference to TAVI procedures and the growing aging population, the TAVI market in China in terms of ex-factory price is expected to grow from RMB392.0 million in 2019 to RMB5,055.7 million in 2025 at a CAGR of 53.1%.




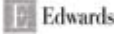

Further, according to Frost & Sullivan, the eligible patient pool of TAVI has great potential to expand, primarily driven by the following factors.

- Applicability for patients with low to intermediate surgical risks.** In August 2019, FDA expanded the indications of TAVI to cover aortic stenosis patients with low to intermediate surgical risks in the U.S. As of the Latest Practicable Date, TAVI was only approved for aortic stenosis patients who were not suitable for surgeries and patients with high surgical risks in China. According to Frost & Sullivan, it is expected that TAVI will be approved for patients with low to intermediate surgical risks in China in the future.
- Potential Indication for aortic regurgitation.** According to Frost & Sullivan, transfemoral TAVI procedures can also be used to treat aortic stenosis patients with regurgitation. However, as of the Latest Practicable Date, transfemoral TAVI procedures had not been approved for treating pure aortic regurgitation patients. It is expected that the expansion of transfemoral TAVI procedures will further contribute to the expansion of the eligible patient pool for TAVI procedure.

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- Patients' affordability.** As of the Latest Practicable Date, TAVI procedures were reimbursable in the U.S. and certain countries in Europe, whereas reimbursement for TAVI procedure in China varies among provinces and even hospitals in the same province depending on whether TAVI procedures can be categorized as heart valve replacement procedure. As of the same date, TAVI procedures were not admitted into the medical insurance reimbursement list in China. However, in certain provinces or cities, TAVI procedures are categorized as heart valve replacement procedures, thus have been partially accredited into the local reimbursement drug scheme. According to Frost & Sullivan, more provinces are expected to offer reimbursement for TAVI procedures in China.

As of the Latest Practicable Date, VitaFlow™ was one of the four domestically-developed TAVI products that had been approved for commercialization in China. In addition to VitaFlow™, VenusA-Valve and VenusA-Plus of Venus Medtech, J-Valve of Suzhou Jiecheng and SAPIEN 3 of Edwards Lifesciences had also been approved for commercialization in China, none of which had been admitted into the medical insurance reimbursement list in China. There are also several TAVI products under or beyond clinical trial stage in China, including VitaFlow™ II of the Company, VenusA-Plus of Venus MedTech and TaurusOne and TaurusElite from Peijia Medical. The following table summarizes major TAVI products under commercialization or clinical trials in China.






Company	Product	Stage	Approval time ¹	Vascular Approach ²	Expanding Mechanism ³	Leaflet Material ⁴	Profile	Retrievability	Outer Sealing Skirt	Motorized Handle	Price ⁵ RMB
	VitaFlow™	Commercialized	2019.7	TF	SE	BP	16F,18F	×	√	√	196,000
	VitaFlow™ II	Registration in progress	NA	TF	SE	BP	NA	√	√	√	NA
	VenusA-Valve	Commercialized	2017.4	TF	SE	PP	16F,18F 19F,20F	×	×	×	248,000
	VenusA-Plus	Approved	2020.11	TF	SE	PP	NA	√	×	×	NA ⁶
	J-Valve	Commercialized	2017.4	TA	SE	PP	NA	×	×	×	260,000
	SAPIEN 3	Commercialized	2020.6	TF	BE	BP	14F,16F	×	√	×	Approximately 380,000
	TaurusOne	Registration in progress	NA	TF	SE	BP	18F	×	√	×	NA
	TaurusElite	Clinical trial	NA	TF	SE	BP	NA	√	√	×	NA

Notes:

- The actual approval time is up to NMPA announcement.
- TF refers to transfemoral approach. TA refers to transapical approach.
- SE refers to self-expanding mechanism. BE refers to balloon-expandable mechanism.
- BP refers to bovine pericardium. PP refers to porcine pericardium.
- The prices of VenusA-Valve, J-Valve and VitaFlow™ set forth herein are provided by Frost & Sullivan, based on the public wholesale tender prices of the relevant products in China as of the Latest Practicable Date. The prices of such products may be subject to changes, over which we do not have control. The price of SAPIEN 3 is mainly based on its global pricing and public information.
- As VenusA-Plus has recently been approved by the NMPA in November 2020, as of the Latest Practicable Date the price of VenusA-Plus was not publicly available.

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The following table summarizes key clinical trial data of major TAVI products in China and globally under clinical trial or commercialization.

Company	Product	30-days Mortality Rate ¹	30-days Major (Disabling) Stroke ¹	1-year Mortality Rate ¹	1-year Major (Disabling) Stroke ¹	1-year Moderate to Severe PVL Rate	1-year Major Vascular Complications	2-year Mortality Rate ¹	2-year Major (Disabling) Stroke ¹	3-year Mortality Rate ¹	3-year Major (Disabling) Stroke ¹
	VitaFlow™	0.9%	0.0%	2.7%	0.0%	0.0%	2.7%	4.5%	0.0%	10.9%	1.8%
	VitaFlow™ II	5.0%	0.0%*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	VenusA-Valve	5.0%	1.0%	5.9%	1.0%	4.2%	5.9%	8.9%	1.0%	12.9%	1.0%
	VenusA-Plus	4.8%	1.6%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	J-Valve	4.7%	0.0%	5.6%	2.0%	1.1%	N/A	9.1%	2.0%	10.8%	N/A
	SAPIEN 3 (U.S. Trial)	2.2%	0.9%*	14.4%	2.4%*	2.7%	N/A	N/A	N/A	N/A	N/A
	SAPIEN 3 (China Trial)	0.0%	2.0%*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	TaurusOne	1.7%	NA	6.7%	N/A	1.0%	4.2%	N/A	N/A	N/A	N/A
	TaurusElite	N/A	NA	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Note:

1. The data is from pivotal clinical trial of corresponding products and not head-to-head clinical results. VitaFlow™ (N=110), VitaFlow™ II (N=60), VenusA-Valve (N=101), VenusA-Plus(N=62), J-Valve (N=107), TaurusOne (N=120), SAPIEN 3 China Trial (N=50), U.S. Trial (N=583)

*: The data marked with * represent the incidences of disabling stroke.

For details, see “Industry Overview.”

Development Plan

Observing the market potential of TAVI technology, we began to develop our TAVI product in 2010, aiming to provide innovative medical solutions for severe aortic valve patients through its innovative features. VitaFlow™ received the NMPA marketing approval in July 2019 and was commercialized in China in August 2019. As of July 31, 2020, we had sold a total of 872 units of VitaFlow™. Going forward, we will strategically expand our distributor network for VitaFlow™. For details of our marketing strategies, see “—Sales and Marketing.” We also plan to initiate our first post-approval clinical trial of VitaFlow™ in 2021 to further evaluate the long-term safety and efficacy of our product. The post-approval clinical trial plans to enroll 100 patients, which will be conducted at seven trial sites. As required by the relevant PRC laws and regulations, the protocol of the post-approval clinical trial will follow substantially the same clinical protocol of the pre-approval clinical trial.

We are also evaluating the opportunities to market our VitaFlow™ overseas, especially in emerging markets that recognize the NMPA marketing approval. In July 2020 and November 2020, VitaFlow™ was registered in Argentina and Thailand, respectively, and we also plan to register VitaFlow™ in Russia in the next two years.

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Material Communications with NMPA

VitaFlow™ has been recognized as an innovative medical device by the NMPA in August 2016 and is eligible for an expedited approval process. We commenced the pivotal clinical trial for VitaFlow™ in China in June 2014. Since then, we have had two rounds of official communications with the NMPA through scheduled meetings. In these communications, NMPA and us mainly discussed about the design of VitaFlow™, especially the use of bovine pericardium and the applicable laws, regulations and guidelines in relation to product registration. We have had no material difficulty in addressing comments of the NMPA during such communications. Following such communications, we submitted to the NMPA the registration application for VitaFlow™ in January 2018 and obtained the marketing approval in July 2019.

Other than the above, we have not had any material regulatory communications with the NMPA for VitaFlow™, and we are not aware of any material concern from the NMPA in connection with VitaFlow™. As of the Latest Practicable Date, no material adverse change had occurred with respect to our marketing approval for VitaFlow™.

WE CANNOT GUARANTEE YOU THAT WE CAN SUCCESSFULLY MARKET VITAFLOW™ PRODUCT OVERSEAS ON A TIMELY MANNER, IF AT ALL.

VitaFlow™ II—Our Core Product

VitaFlow™ II is our second-generation TAVI product. The key upgrade is that the delivery system of VitaFlow™ II is equipped with a retrievable function. We have completed a Registration Clinical Trial in relation to VitaFlow™ II and submitted the registration application for VitaFlow™ II to the NMPA in October 2020. The application was accepted by the NMPA in November 2020 and is currently under review. We currently expect we will complete the registration of VitaFlow™ II in China by the end of 2021. In addition, we are conducting a pivotal clinical trial in relation to VitaFlow™ II in Europe. As of the Latest Practicable Date, we had enrolled 20 patients for such clinical trial in Europe. According to Frost & Sullivan, VitaFlow™ II was the only TAVI product developed in China that had commenced clinical trial in Europe as of the Latest Practicable Date. For the years ended December 31, 2018 and 2019 and the seven months ended July 31, 2019 and 2020, the research and development expenditures (including capitalized development costs and research and development costs recognized in profit or loss) incurred for VitaFlow™ II, our Core Product, were RMB46.1 million, RMB52.9 million, RMB40.8 million and RMB15.7 million, respectively, accounting for 41.6%, 40.5%, 50.1% and 31.0% of our total research and development expenditures, respectively, during the same period.

Product Structure and Operational Procedure

Similar to VitaFlow™, VitaFlow™ II consists of a PAV, a motorized and retrievable delivery system and certain procedural accessory. The PAV adopts the same design with VitaFlow™. The key upgrade lies in the delivery system, where the capsule of VitaFlow™ II includes a distal flare, enabling the physician to retrieve the PAV if it is not placed accurately at the designated position provided the deployment does not exceed 75% of the maximal deployment range. The retrievable function will help increase the accuracy of positioning the PAV, which will further improve the overall success rate of the TAVI procedure. VitaFlow™ II also includes our first-generation tip-

preshaped super stiff guidewire as part of its offering. The tip-preshaped super-stiff guidewire will feature high guidewire rail support and smooth transition, in order to reduce the risks of vascular damage or ventricular perforation. The tip-preshaped super stiff guidewire will only be registered and offered as part of VitaFlow™ II and will not be registered as a standalone product in China.

The operational procedure of VitaFlow™ II is similar to VitaFlow™. If the deployment of PAV has not exceeded 75% of the maximal deployment range, the physician may recapture the valve into the capsule by simply pressing the “retrieve” button on the motorized handle. A manual handle for retrieval is also available as a backup option. The physician may retrieve for up to three times.

Clinical Trial

We have completed the Registration Clinical Trial in relation to VitaFlow™ II in China. We are also conducting a pivotal clinical trial in Europe for the application of CE Mark. As of the Latest Practicable Date, we had enrolled 20 patients and completed TAVI procedures on all of them. We plan to submit the application for CE Mark registration in 2021, which will be partially supported by the clinical data from the Registration Clinical Trial in China.

Overview of the Registration Clinical Trial in China

From January 2018 to March 2019, 60 patients were enrolled in the Registration Clinical Trial and we performed TAVI procedure on all of them. The Registration Clinical Trial in relation to VitaFlow™ II is a prospective, multi-center and single-arm clinical trial in China, aiming to assess the safety and efficacy of VitaFlow™ II. The NMPA had confirmed that they had no objection if we applied for the marketing approval of VitaFlow™ II based on the clinical trial outcome from the Registration Clinical Trial. The primary endpoint of the Registration Clinical Trial is the all-cause mortality rate at 30 days after implantation. The endpoint is self-reported by each trial site and then adjudicated by a clinical endpoint committee of the lead research institution.

The Registration Clinical Trial is conducted at 13 clinical trial sites, with Zhongshan Hospital of Fudan University as the leading research institution. In October 2020, we submitted the registration application for VitaFlow™ II to the NMPA, which was supported by the Registration Clinical Trial results. In November 2020, registration application was accepted by the NMPA and is currently under review.

Study Protocol and Design of the Registration Clinical Trial

Set forth below are the patient inclusion criteria for the Registration Clinical Trial in relation to VitaFlow™ II in China.

- the age of the patient is 70 years old or above;
- the patient is diagnosed with severe native aortic stenosis;
- the patient is classified as class II or above under the NYHA Classification;
- the patient has a life expectancy of at least 12 months after implantation;
- the patient is deemed to be anatomically eligible for TAVI procedures; and

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- the patient is prohibitive or considered to have a high surgical risk for SAVR by a least two cardiothoracic surgeons

Safety Results

During the 30-day follow-up period, none of the patients experienced a major stroke and there were three mortality cases observed. As reviewed and adjudicated by the clinical endpoints committee, none of the mortality cases were related to the function of VitaFlow™ II. The following table summarizes the key safety results we obtained from the Registration Clinical Trial.

<u>Clinical endpoints</u>	<u>30 days (N=60)</u>
All-cause mortality	5.0%(3)
Disabling stroke	0.0%(0)
Major vascular complication	1.8%(1)

Efficacy Results¹

VitaFlow™ II adopts the same design with VitaFlow™, except for the retrievable function of the delivery system. We have observed a 100% success rate in relation to the retrievable function, as well as a 100% device success rate. In addition, we had also observed a significant improvement in patients' cardiac function, measured by the NYHA Classification. Prior to the TAVI implantation, none of the patients were classified as class I and only 18.3% of the patients were classified as class II under the NYHA Classification, which significantly improved to 19.3% and 68.4% at 30-day follow-up evaluation, respectively. The following table illustrates the class status of our patients under NYHA Classification at the follow-up time indicated.

<u>NYHA Classification</u>	<u>Pre-procedure (N=60)</u>	<u>Discharge (N=58)</u>	<u>30 days (N=57)</u>
Class I	0.0%	0.0%	19.3%
Class II	18.3%	34.5%	68.4%
Class III	35.0%	41.4%	12.3%
Class IV	46.7%	24.1%	0.0%

Clinical Trial in Europe

We are in the process of conducting a prospective and single-arm pivotal clinical trial in Europe, evaluating safety, performance and efficacy of VitaFlow™ II. According to Frost & Sullivan, VitaFlow™ II was the only TAVI product developed in China that had commenced clinical trial in Europe as of the Latest Practicable Date.

We intend to enroll 258 patients and we had enrolled 20 patients and performed TAVI procedures on all of them as of the Latest Practicable Date. As an industrial norm, the EMA will take into consideration the clinical trial data obtained in other countries that are obtained in clinical trials accordance with international guidelines as supporting data for CE Mark registration. In general, the patient inclusion criteria are similar to that of the Registration Clinical Trial, with modification to reflect indications for TAVI procedures and regulatory requirements in Europe. The primary endpoint is the all-cause mortality rate at 12 months after implantation. Secondary endpoints mainly include the successful recapture rate for the retrievable function of the delivery system, rate of stroke, new

¹ All efficacy data presented below are based on number of patients who survived at the follow-up time.

pacemaker implantation, coronary obstruction, vascular complication, PVL, valve performance and changes in physical function and quality of life.

Market Opportunity and Competition

According to Frost & Sullivan, in China there were not yet any commercialized domestically-developed second-generation TAVI product candidates and VitaFlow™ II was one of the only three second-generation TAVI product candidates under or beyond clinical trial stage in China. Most of the first-generation TAVI products only provide basic functions whereas second-generation TAVI products generally include upgrade functions, such as the retrievable delivery system. We believe VitaFlow™ II will be a competitive product in the market, considering our unique design adopted from VitaFlow™ as well as the new retrievable function.

In 2019, over 80% of the global TAVI procedures were completed in developed countries. In 2019, there were approximately 66,800 TAVI procedures performed in the U.S., approximately 6,800 TAVI procedures performed in Japan and approximately 52,100 performed in other developed countries. Among these countries, developed countries in Europe present significant opportunities for foreign medical device companies as these countries are regulated under the same EMA-administered regulatory framework where medical devices bearing the CE Mark can be marketed in these countries. In addition, foreign medical device manufacturers may use clinical trial data obtained in clinical trials that comply with the international standards to support the CE Mark application, which makes the registration pathway more efficient and cost-effective.

In addition, TAVI markets in developing countries are still under-penetrated but have high potential for future growth. In general, these countries do not require additional domestic clinical trials for medical devices that have already obtained marketing approval from other developed countries or regions (such as the FDA approval and the CE Mark) and/or its country of origins. In 2019, there were approximately 20,400 TAVI procedures performed in developing countries excluding China, which is expected to grow at a CAGR of 22.5% to approximately 68,700 in 2025.

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As of the Latest Practicable Date, there were over ten TAVI products that obtained CE Mark. Currently, commercialized TAVI products in Europe are mainly manufactured by international medical device companies, such as Edwards Lifesciences, Medtronic, Boston Scientific and Abbott. According to Frost & Sullivan, VitaFlow™ II was the only product with a motorized delivery system and the only TAVI product developed in China among all the TAVI products under clinical trial or commercialization in Europe as of the Latest Practicable Date. The following table illustrated major TAVI products under clinical trial or commercialization in Europe as of the Latest Practicable Date.

Product	Edwards Lifesciences				Medtronic			Boston Scientific		Abbott	bluesail+	BIOTRONIK	MicroPort
	SAPIEN	SAPIEN XT	SAPIEN 3	SAPIEN 3 Ultra	Core Valve	Evolut R	Evolut Pro	Lotus Edge	ACURA TE neo	Portico	Allegra	Biovalve	VitaFlow™ II
Stage	Commercialized											Clinical Trial	Clinical Trial
Approval Time (CE Mark)	2007	2010	2014	2018	2011	2014	2017	2016	2014	2012	2017	-	-
Expanding Mechanism ¹	BE	BE	BE	BE	SE	SE	SE	ME	SE	SE	SE	SE	SE
Leaflet Material ²	BP	BP	BP	BP	PP	PP	PP	BP	PP	BP	BP	PP	BP
Vascular Approach ³	TF/TA	TF/TA	TF/TA	TF	TF	TF	TF	TF	TF/TA	TF	TF	TF	TF
Retrievability	-	-	-	-	-	+	+	+	-	+	+	-	+
Motorized Handle	-	-	-	-	-	-	-	-	-	-	-	-	+

Notes:

1. BE refers to balloon-expandable mechanism. SE refers to self-expanding mechanism. ME refers to mechanically-expanding mechanism.
2. BP refers to bovine pericardium. PP refers to porcine pericardium.
3. TF refers to transfemoral approach. TA refers to transapical approach.

For details, see “Industry Overview.”

Development plan

We commenced the feasibility study of VitaFlow™ II in May 2015. In January 2018, we commenced the Registration Clinical Trial for VitaFlow™ II. We completed TAVI implantation on all the patients enrolled in the Registration Clinical Trial in March 2019 and completed the 30-day follow-up evaluation in April 2019. In October 2020, we submitted the registration application for VitaFlow™ II to the NMPA, which was supported by the Registration Clinical Trial results. The registration application was accepted by the NMPA in November 2020 and is currently under review. We currently expect we will complete the registration of VitaFlow™ II in China by the end of 2021. We will complete a five-year follow-up study on the patients enrolled in the Registration Clinical Trial to demonstrate the long-term safety and efficacy of VitaFlow™ II, support our future academic promotion activities and benefit our R&D of next-generation TAVI product.

As of the Latest Practicable Date, we were in the process of conducting the pivotal clinical trial in relation to VitaFlow™ II in Europe for CE Mark registration. As the CE Mark application for VitaFlow™ II will be based on the 12-month follow-up evaluations of the Registration Clinical Trial

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in China and the data we will obtain from the planned clinical trial in Europe, we plan to submit the application for CE Mark by the end of 2021. We also plan to register VitaFlow™ II primarily in countries that recognize the NMPA marketing approval or the CE Mark, such as Argentina, Brazil, India, South Korea, Thailand and Russia, among others, provided we successfully obtained marketing approval from NMPA and/or the CE Mark.

Material Communications with NMPA and EMA

We commenced the Initial Clinical Trial for VitaFlow™ II in China in January 2018. VitaFlow™ II has been recognized as an innovative medical device by the NMPA in December 2018 and is eligible for an expedited approval process. In December 2019, we had a face-to-face conference with the NMPA to discuss the regulatory pathway of VitaFlow™ II and the applicable clinical trial data to be submitted for product registration. The NMPA confirmed that they had no objection if we applied for the marketing approval of VitaFlow™ II based on clinical trial outcome from the Registration Clinical Trial.

We submitted the application for the pivotal clinical trial in Europe in June 2018 and commenced the pivotal clinical trial in December 2018. We had several rounds of discussion with the notified body, which is administered by the EMA in Europe before the clinical trial commenced with respect to the clinical trial design and we had no material difficulty in addressing their comments during such communications.

Other than the above, we have not had any material regulatory communications with the NMPA or the EMA for VitaFlow™ II, and we are not aware of any material concern from the NMPA or the EMA in connection with VitaFlow™ II.

WE CANNOT GUARANTEE YOU THAT WE CAN SUCCESSFULLY DEVELOP AND MARKET VITAFLOW™ II IN CHINA AND OVERSEAS ON A TIMELY MANNER, IF AT ALL.

Other TAVI Products

As of the Latest Practicable Date, we were designing our third-generation self-expanding TAVI products, which will make further improvements to the prosthetic aortic valves of VitaFlow™ and VitaFlow™ II. In addition to the innovative features of VitaFlow™ and VitaFlow™ II, the prosthetic aortic valve of our third generation self-expandable TAVI product will adopt a novel design of the valve with our self-developed upgraded anti-calcification technology. The frame of the prosthetic aortic valve will also reserve space for future coronary intervention.

The third-generation self-expandable TAVI product is designed to benefit larger patient group, especially those with low to intermediate surgical risks. All of the upgraded features will enhance the durability of the prosthetic aortic valve, as a result making is more suitable for those patients. Although as of the Latest Practicable Date, TAVI treatment was only approved for patients who were not suitable for surgeries and patients with high surgical risks in China, it is expected that TAVI procedures will be approved for patients with low to intermediate surgical risks in China in the future, according to Frost & Sullivan, which is also in line with the trend in the United States.

In order to expand our product portfolio and to tap into the balloon-expandable TAVI product market, we are also in the process of designing our first balloon-expandable TAVI product. Our first

balloon-expandable TAVI product will also adopt the self-developed upgraded anti-calcification technology. To date, there is only one balloon-expandable TAVI product under commercialization stage in China, namely the SAPIEN 3 of Edwards Lifesciences, which received its NMPA marketing approval in June 2020.

For more information on the opportunity and competitive landscape in the TAVI market, see “Industry Overview” and “—Our Product Portfolio—Aortic Valve Products” for details,

WE CANNOT GUARANTEE YOU THAT WE CAN SUCCESSFULLY DEVELOP AND MARKET OUR THIRD-GENERATION TAVI PRODUCT OR OUR FIRST BALLOON-EXPANDABLE PRODUCT IN CHINA AND OVERSEAS ON A TIMELY MANNER, IF AT ALL.

Mitral Valve Product

According to Frost & Sullivan, mitral valve disease is one of the most prevalent heart valve diseases. Mitral regurgitation, being the most common type of mitral valve disease, is the most prevalent among all valvular heart diseases, representing 45.4% of all the patients suffering from valvular heart diseases in 2019. Mitral valve replacement or repair performed with extracorporeal circulation in open-chest surgery is the standard treatment for severe mitral regurgitation. Most of the TMV technologies focus on placement and fixation in the native mitral annulus and left ventricle, which is likely to cause an obstruction on the left ventricular outflow tract, impair function of the left ventricle and lead to device embolization. Currently, global TMV market is still in a relatively early stage with only six approved TMV repair and one approved TMV replacement product globally. As of the same date, only one TMV repair product had been approved by the NMPA. We believe the unmet medical demands provide room for TAVI players to mimic experience and clinical trial experiences on the TAVI market to tackle mitral regurgitation.

We are strategically positioned in the TMV market with robust pipeline mitral valve products, covering TMV repair and TMV replacement targeting mitral regurgitation. As of the Latest Practicable Date, we had five ongoing preclinical trial pipeline products, covering all mainstream viable TAVI treatment options for mitral regurgitation

TMV Repair

- Amend

We invested in and collaborated with ValCare, a medical device company organized in the U.S. with an Israeli subsidiary on a TMV repair pipeline product—Amend. As of the Latest Practicable Date, Amend was undergoing a feasibility study on human beings and had completed the first phase of its first-in-human MRCT in Israel and Europe. The purpose of the first-in-human MRCT is to evaluate the product safety and efficacy on human bodies and to obtain data for the initiation of clinical trials. Amend adopts an innovative semi-rigid, D-shaped ring with unique anchoring capabilities that emulates the current annuloplasty rings used in open-chest surgeries, which will be delivered via a catheter into the mitral annulus in a minimally-invasive procedure. Amend will maintain the original mitral valve’s structural integrity, and as a result improves its long-term performance. The design of the ring also makes Amend compatible with various delivery approaches, including transseptal or transapical approach. We have recently entered into a Master Distribution Agreement with ValCare

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under which, subject to and pending upon the execution of a mutually agreed upon agreement for the territory of China and certain other preconditions set forth in the Master Distribution Agreement, we shall be granted with exclusive distribution rights in relation to Amend in China. For details, see “—Collaboration with Third Parties.”

- *In-house developed TMV repair product*

We are currently conducting an early-stage design of edge to edge TMV repair product, which will adopt a transseptal approach.

TMV Replacement

- Corona

We are also collaborating with ValCare in relation to a TMV replacement product—Corona. As of the Latest Practicable Date, Corona was undergoing animal studies. The purpose of the animal studies is to verify the product design and to obtain preliminary safety and efficacy data. Corona is specifically designed to fit inside the Amend D-shaped repair ring. Corona and Amend together provide a valve-in-ring solution for patients that are ineligible for TMV repair and Corona can either be implanted alongside Amend or at a later stage after TMV repair is performed using Amend. The unique four-leaflet valve of Corona is also designed to improve its coaptation and sealing efficacy. We have recently entered into a Master Distribution Agreement with ValCare under which, subject to and pending upon the execution of a mutually agreed upon agreement for the territory of China and certain other preconditions set forth in the Master Distribution Agreement, we shall be granted with exclusive distribution rights in relation to Corona in China. For details, see “—Collaboration with Third Parties.”

- AltaValve

We invested in 4C Medical, which is developing an innovative TMV replacement medical device, AltaValve. As of the Latest Practicable Date, AltaValve was undergoing an early human feasibility study. The purpose of the early-stage human feasibility study is to obtain preliminary product safety and efficacy data on human bodies. AltaValve’s supra-annular fit and atrial-only fixation are designed to overcome the concerns of anchoring and fixation difficulties present in existing TMV technologies. Further, AltaValve leaves the left ventricle the geometry intact and therefore reduces the risks of LVOT obstruction and damage. AltaValve can be implanted through transseptal or transapical approach, which is suitable for the vast majority of patients suffering from mitral regurgitation. We enjoy the exclusive distribution rights in relation to AltaValve and manufacturing rights in relation to the delivery system of AltaValve in China. For details, see “—Collaboration with Third Parties.”

- *In-house developed TMV replacement product*














We are conducting animal studies on our in-house developed TMV replacement pipeline product. Our unique design of this product is expected to reduce the risks of LVOT obstruction and damage while preserving the ventricle function. The pipeline product has a thin diameter of 32 Fr, which has the potential to cause less vascular damage during delivery. As of the Latest Practicable Date, we had observed positive results during a three-month follow-up animal study.

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Market Opportunity and Competition

For patients with severe mitral regurgitation, the current standard treatment is mitral valve replacement or repair with extracorporeal circulation through open-chest surgery. TMV repair and TMV replacement have emerged as two potential alternative treatment options for severe MR in patients with prohibitive or high surgical risks. However, treatments for mitral valve disease have several inherent biomechanical challenges, including the complexity of mitral valve diseases, the position and structure of mitral valve, the stringent requirements of the stent, the saddled shape of the mitral annulus and the proneness to structural damage. Currently, most of the TMV technologies focus on placement and fixation in the native mitral annulus and left ventricle, which is likely to cause obstruction on the LVOT, impair function of the left ventricle and lead to device embolization.

According to Frost & Sullivan, the TMV market is still at an early stage with significant growth potential. Global TMV market is expected to reach US\$17.4 billion (or RMB117.0 billion) by 2030 and eventually grow to three or four times of the global TAVI market. As of the Latest Practicable Date, there were only seven TMV repair or replacement products that had received FDA approval, CE Mark or the NMPA approval, including six TMV repair products and one TMV replacement products. MitraClip, which was approved by the NMPA in June 2020, was the only TMV product that has been approved in the United States, Europe and China. In January 2020, Tendyne TMV replacement product was approved by the EMA, becoming the first TMV replacement product worldwide that obtained marketing approval. As of the Latest Practicable Date, there was only one TMV repair product, namely ValveClamp by Hanyu Medical that had commenced clinical trial in China. The following chart illustrates commercialized TMV repair/replacement products worldwide as of the Latest Practicable Date.

Transcatheter Mitral Valve Repair and Replacement Products							
							
Product	Tendyne	MitraClip	CARILLON Mitral Contour System	NeoChord DS1000	Cardioband	PASCAL	MPAS Implant
							
FDA Approval	—	2013	—	—	—	—	—
CE Mark	2020	2008	2009	2013	2015	2019	2016
NMPA Approval	—	2020	—	—	—	—	—
Approach	Replacement (High or Extreme risk)	Edge to Edge Repair	Indirect Annuloplasty	Chordal Repair	Direct Annuloplasty	Edge to Edge Repair	Direct Annuloplasty
Access	Transapical	Transfemoral & Transseptal	Right internal jugular vein	Transapical	Transfemoral & Transseptal	Transfemoral & Transseptal	Transfemoral

WE CANNOT GUARANTEE YOU THAT WE CAN SUCCESSFULLY DEVELOP AND MARKET OUR MITRAL VALVE PRODUCT IN CHINA ON A TIMELY MANNER, IF AT ALL.

Tricuspid Valve Products

Tricuspid valve disease mainly consists of tricuspid regurgitation (“TR”) and tricuspid stenosis. TR is the inability of the tricuspid valve to close completely that causes blood to flow from the right ventricle to the right atrium during systole. The prevalence of TR globally had reached 49.6 million in

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2019, with a CAGR of 2.1% from 2015 to 2019, and is estimated to reach 55.9 million patients in 2025. The prevalence of TR in China had reached 9.1 million in 2019 and is estimated to grow to 9.9 million in 2025. However, due to the difficulties in developing effective treatments and challenges in performing surgeries for tricuspid valve disease, to date there are only three commercialized TTV repair products in Europe, none of which had been approved in the U.S. or China.

We are collaborating with ValCare on a TTVR product, Trivid, to tack tricuspid valve diseases. As of the Latest Practicable Date, Trivid was undergoing early-stage design. We have recently entered into a Master Distribution Agreement with ValCare under which, subject to and pending upon the execution of a mutually agreed upon agreement for the territory of China and certain other preconditions set forth in the Master Distribution Agreement, we shall be granted with exclusive distribution rights in relation to Trivid in China. For details, see “—Collaboration with Third Parties.” In addition, we are also conducting early-stage design of our in-house developed edge to edge repair TTV product.

WE CANNOT GUARANTEE YOU THAT WE CAN SUCCESSFULLY DEVELOP AND MARKET OUR TRICUSPID VALVE PRODUCT IN CHINA ON A TIMELY MANNER, IF AT ALL.

Procedural Accessories and Surgical Valve

Our product portfolio also includes several in-house developed procedural accessories which are compatible with our TAVI products. As of the Latest Practicable Date, we had successfully launched our first-generation Alwide™ balloon catheter and Alpass™ catheter sheath as part of our VitaFlow™ offering and we had submitted the registration material for our second-generation Alwide™ balloon catheter to the NMPA, which was accepted by the NMPA and is currently under their review. We are also in the process of designing or verifying other procedural accessory pipeline products. Our procedural accessories can help physicians handle the challenges in performing TAVI procedures and therefore we believe has the potential to shorten the learning curve for TAVI procedures for our TAVI products, and can improve the safety and accessibility of TAVI procedures using our products. According to Frost & Sullivan, we are the only medical device company in China that has a comprehensive offering in-house developed complementary TAVI procedural accessories.

Launched Procedural Accessories

As part of the VitaFlow™ offerings, we launched our first-generation balloon catheter (Alwide™) and catheter sheath (Alpass™) in China in August 2019. These procedural accessories are registered and offered as part of VitaFlow™ and are not registered as standalone products in China. During the Track Record Period, all of our procedural accessories were sold as part of VitaFlow™ and were used during the implantation of VitaFlow™. For details, see “—Aortic Valve Products—VitaFlow™—Our Key Product—Product Structure—Procedural accessories.”

Pipeline Procedural Accessories and Surgical Valve

As of the Latest Practicable Date, we had certain procedural accessories and one surgical replacement product at different stages of development. As we had observed the significant market demands for procedural accessories including balloon catheter and catheter sheath, we intend to develop and register our pipeline procedural accessories as separate products to further expand our

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product portfolio. Our second-generation Alwide™ balloon catheter is currently under review by the NMPA for product registration. The second-generation Alwide™ balloon catheter is designed to provide improved compliance ability and burst pressure. Under the current PRC regulatory regime, the expandable sheath is exempted from the clinical trial requirement in China and we also plan to apply for exemption from clinical trial for our future generation balloon catheter products. We plan to submit the registration material for our second-generation Alpass™ catheter sheath to the NMPA by the end of 2021. We also have one surgical replacement product under early-stage development. After our procedural accessories and surgical replacement product receive the NMPA approval, we also plan to apply for CE Marks for these products. The table below illustrates the key features and stage of development of our pipeline procedural accessories and surgical replacement product as of the Latest Practicable Date.

Product	Stage of Development	Key features/upgrades
Second-generation Alwide™ balloon catheter	Registration	Improved compliance ability and burst pressure.
Third-generation Alwide™ balloon catheter	Verification	The capability of being fixed to the valve annulus to burst severe calcification during TAVI procedure
Second-generation Alpass™ catheter sheath	Verification	Improved lubricity with various models available
Expandable sheath	Design	Reducing access complications
Embolic protection device	Design	Designed to protect the brain during TAVI procedures
Surgical replacement product	Design	The surgical replacement product will adopt the new anti-calcification technology and a more durable valve design.

WE CANNOT GUARANTEE YOU THAT WE CAN SUCCESSFULLY DEVELOP AND MARKET OUR PROCEDURAL ACCESSORIES AND SURGICAL VALVE IN CHINA ON A TIMELY MANNER, IF AT ALL.

OUR PLATFORM

Since our inception, we have developed a medical device platform focusing on valvular heart disease, which lays the foundation for our research and development, clinical trial and manufacturing. Our platform has enabled us to achieve synergy in the research, development, clinical trial and manufacturing in accordance with our stringent quality management system. For example, members of our manufacturing team are involved at the verification stage of product development to ensure a smooth transition from clinical trials to commercial manufacturing and members from our clinical trial team are involved in the early-stage R&D to ensure that the product design addresses the potential regulatory focus and concerns in the clinical trial stage. Feedbacks we gathered from clinical trials are also reported to the R&D team for product upgrading.

In-house Research & Development

R&D Team and Advisory Board

R&D is crucial to our growth. We have built a core R&D team with key technology expertise in areas including, among others, biological material, suturing technique, structure design and processing

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technique. Our R&D team is led by Mr. Chen Guoming, who has been in charge of our R&D activities since we were at incubation stage and has been leading the R&D of our TAVI products, VitaFlow™ and VitaFlow™ II, as well as other pipeline products. As of the Latest Practicable Date, our R&D team had approximately 50 team members, approximately two-thirds of whom possess a master's or higher degree in relevant fields and approximately one-third of whom had overseas education background with bachelor's or higher degree. All of our in-house R&D team members are based in Shanghai.

As of the Latest Practicable Date, we had signed up with three globally well-known researchers and practitioners as members of our international scientific advisory board. Our international scientific advisory board has provided insights, guidance and recommendations for our R&D team. From time to time, we hold meetings with these advisors to discuss the R&D progress of our pipeline products as well as the latest market trends in valvular heart disease treatment. As of the Latest Practicable Date, we were not aware of any conflict of interest between any member of our international scientific advisory board and us. Certain information about the members of our advisory board are set out below:

- ***Dr. Nicolo Piazza.*** Dr. Piazza is an assistant professor in the Cardiology Division and Attending at McGill University Health Center. Dr. Piazza's clinical and research activities focus on valvular heart disease with particular interests in aortic and mitral valve diseases. Dr. Piazza also served as director roles amongst several major international healthcare conferences on valvular heart diseases, including Transcatheter Valve Therapeutics, PCR London Valves, PCR Asia/Chengdu Valves and Heart Valve Society Meeting.
- ***Dr. Thomas Modine.*** Dr. Modine serves at the department of pulmonary and cardiovascular medicine at Lille University Hospital in quality of hospital practitioner and is a consultant professor at Shanghai Jiaotong University. His research interests are in aortic valve complex, bioengineering, beating heart surgery, hybrid approaches, and TAVI and TMV repair/replacement technologies.
- ***Dr. Darren Mylotte.*** Dr. Mylotte is a cardiologist at Galway University Hospital in Ireland. Dr. Mylotte completed an Irish cardiology specialist training and completed a Ph.D. thesis on TAVI at Thorax Center in the Netherlands. He has an extensive publication record in interventional cardiology and has co-authored several cardiology textbooks. He is a fellow of the European Society of Cardiology. Dr. Mylotte is a member of the editorial board of Euro Intervention and a reviewer for several high-impact cardiology journals.

In 2018 and 2019 and the seven months ended July 31, 2020, our research and development costs were RMB44.7 million, RMB96.7 million and RMB38.2 million, respectively. We expect that our research and development costs will increase in line with the increased level of research and development activities of our pipeline products in the future.

Product Design and Preclinical Development

Product Design

Our R&D team is divided into three R&D groups, namely the frame group, the valve group and the delivery system group. Each group focuses on the research and development of new technology

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and materials related to that group that has the potential to be applied to our product portfolio. For the design and development of a pipeline product, we established a project team which consist of members from each R&D group. The project team will hold regular meetings to discuss R&D progress in each group, the latest market trends as well as detailed analysis of similar products manufactured by our competitors. We believe this working mechanism enables each R&D group to closely follow and meet our in-house R&D needs as well as the market trends while separately focus on the R&D of their respective fields. Through this working mechanism, we have been able to develop innovative designs for each of the valve tissue, PET skirt, frame and handle in VitaFlow™.

The design and development of our pipeline products typically involve four phases: design planning, design realization, design evaluation and design verification. We commence manufacturing only after the process goes beyond the design verification stage.

- ***Design planning.*** We first analyze market trends, regulatory requirements and existing products or products in related therapeutic areas and formulate a preliminary product protocol. The product protocol addresses the clinical demands of physicians, taking into consideration of clinical trial feasibility and potential feasibility.
- ***Design realization.*** We transform the product protocol into engineering requirements by using our internal manual and then develop the components according to the engineering requirements. The ultimate goal at this stage is to realize the assembled product with the desired function and performance.
- ***Design evaluation.*** After design planning, we conduct an internal design evaluation to evaluate the safety and efficacy of the sample product and to ensure the product design satisfies the applicable regulatory requirements.
- ***Design verification.*** At the design verification stage, the quality control department conducts several verification tests, covering safety, efficacy, function, operability and reliability of the pipeline product. Only pipeline products that can pass the design verification can proceed with clinical trials.

Preclinical Animal Studies

To evaluate the functions safety and efficacy of our product and pipeline products in a cost-effective way with controllable risk exposures, we typically perform a preclinical animal study before our products reaching clinical trial stage. We collaborate with third parties, including our Controlling Shareholder, to conduct animal studies. See “Connected Transactions – Continuing Connected Transactions” for our collaboration with the MicroPort Group in relation to preclinical animal studies.

Before commencing animal studies, we first formulate a detailed animal study protocol which specifies the goals and requirements for animal studies. We then send the protocol to the testing institution to evaluate the feasibility and the cost related to such studies. After the protocol is agreed upon, we prepare the product and the relevant surgery protocol. The testing institution is responsible for the preparation and monitoring of animals during and after performing animal surgeries. We also assembled a team of experienced product engineers, who are capable of performing procedures on animals themselves. As a result, we believe we are well-positioned to identify potential risks and improve our products through animal studies. As of the Latest Practicable Date, we had three experienced product engineer that can independently perform animal surgeries.

Clinical Trials

We have a dedicated clinical operation team responsible for the day-to-day management of the clinical trials of our pipeline products. Our regulatory affair and clinical trial department are responsible for the clinical trial design, preparation of the necessary documents, selection of qualified clinical trial sites and the monitoring of clinical trials to ensure that clinical trials comply with the clinical trial protocol and GCP.

We normally select 10-20 trial sites for each clinical trial. We require clinical trial sites to be registered with the NMPA. We evaluate the number of valvular heart disease patients, the research experiences of the hospitals and the number of clinical trials carried out at the relevant departments of the hospitals to ensure that sufficient resources at trial sites will be allocated to our clinical trials. We only select reputable and experienced physicians as PIs for our clinical trials. The clinical trial for VitaFlow™ took only eleven months from the first patient enrollment to completing TAVI procedures on all the patients, which, according to Frost & Sullivan, is significantly shorter than that of clinical trials of other TAVI products in China.

The leading PI for the clinical trial for VitaFlow™ and VitaFlow™ II in China was Dr. Ge Junbo. Dr. Ge is an academician of the Chinese Academy of Sciences and the chief of cardiology department of Zhongshan Hospital of Fudan University, who performed the first TAVI procedure in China as early as 2010. We keep communication with all the PIs participating the clinical trials, including Dr. Ge, to better understand the clinical performance of our products and to address the issues arising from the clinical trials promptly. We believe their views and advices from clinical perspective are not only valuable for our product registration in China, but also benefit us in the design of upgraded products.

In line with industry practice, during the Track Record Period, we engaged certain industry-leading CROs, to provide certain services in the clinical trials for our TAVI products in China and overseas, including preparing ethical committee application at each hospital, assisting in revising the study protocol and design, managing and monitoring the implementation of clinical trials, collecting and keeping records of patients' information and providing progress or summary reports. In addition, during the Track Record Period, we also engaged certain industry-leading SMOs, who are primarily responsible for assisting researchers to complete certain supporting duties in relation to the ongoing clinical trials, including collecting source data and scheduling patient's follow-up evaluations, among others. We also engaged one clinical statistic center for data collection and data analysis for each clinical trial.

We select our CROs and SMOs based on various factors, including service quality, capability, reputation, cost-effectiveness and research experience in cardiovascular interventional therapy. We normally enter into master service agreements with our CROs or SMOs with a detailed scope of work for each study or trial, establishing specific and detailed metrics on working methods, procedures, standards and timelines to further ensure the quality of the outcomes. We will organize periodic meetings with such CROs and SMOs and ask them to prepare reports from time to time. We monitor the CROs and SMOs to ensure they perform their duties with a standard in line with our protocols and industry benchmark to safeguard the integrity of the data collected from the trials and studies. All the clinical trial results are stored on an online electronic data capture (EDC) system, which is only

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accessed by our responsible employees and the employee of the CRO/SMO that is in charge of the clinical trial.

Key terms of our service agreement with CROs and SMOs are summarized below.

- *Services.* CROs and SMOs provide us with services related to clinical trials in certain phases as specified in the agreement or work order.
- *Term.* CROs and SMOs are required to complete the work on a project basis and within the prescribed time limit.
- *Payments.* We are required to make payments to the CROs or SMOs by installments according to milestones of respective services during the clinical trials.
- *Intellectual property rights.* Intellectual property arising from the clinical trials conducted by the CROs or SMOs are exclusively owned by us.
- *Confidentiality.* The CROs and SMOs are required to keep confidential any information, documents, materials or data relating to our products and clinical trials and shall promptly return all of the above upon the expiration of the agreements.
- *Dispute resolution.* In the event of any disputes related to the enforcement of any agreement during the clinical trial, both parties shall negotiate amicably. If an agreement cannot be reached, the parties have the right to sue.

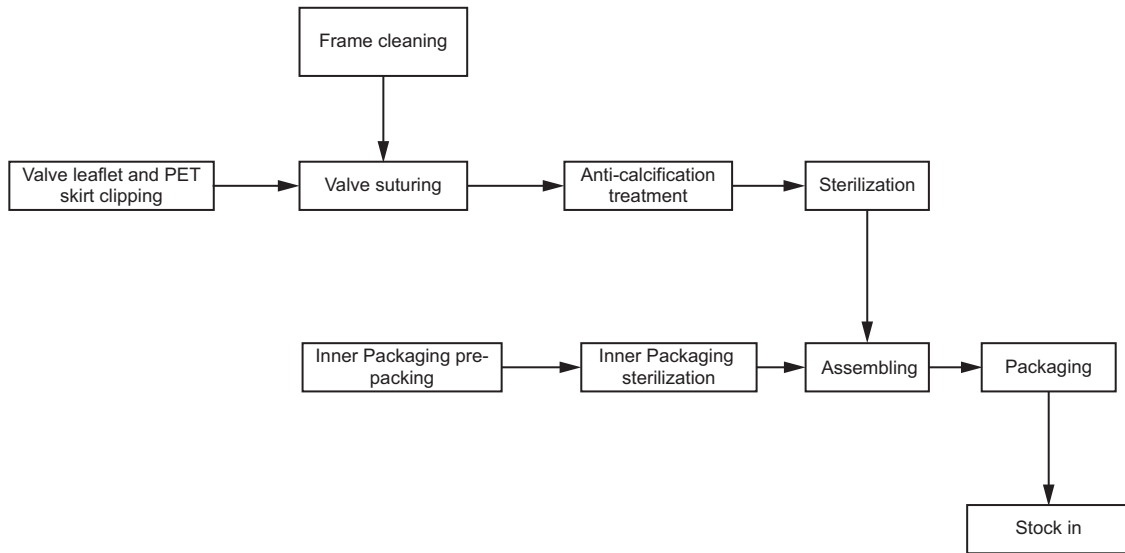
Manufacturing

Production Process

We commenced commercial manufacturing of VitaFlow™ and marketed procedural accessories shortly after we received the NMPA marketing approval in July 2019. Key manufacturing steps, including valve suturing, are performed at a cleanroom that complies with the classification of ISO Class 7 cleanness standards. All of the manufacturing processes are conducted by our in-house manufacture team.

PAV

Set forth below is an illustrative flowchart for the production process of the PAV of VitaFlow™.



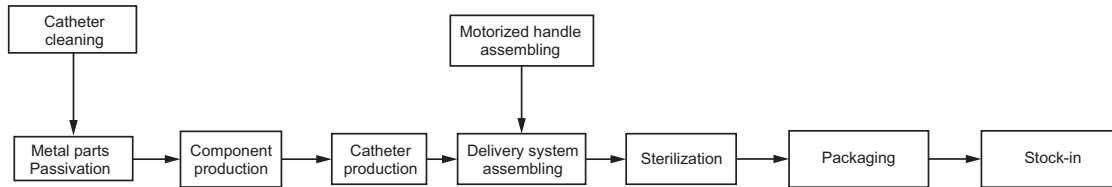
The following is a brief description of the key steps in our manufacturing process of PAV.

- ***Valve leaflet and PET skirt clipping.*** After cleaning and heating procedures, the valve leaflets and PET skirts will be cut into required shapes and sizes by laser cutting machines.
- ***Valve suturing.*** After the nitinol frame is properly cleaned, we commence the suturing process. To address the challenges in suturing bovine pericardium due to its added thickness and the design of the double-layer PET skirt, we adopt a unique suturing technology which enables VitaFlow™ to achieve the thinnest delivery system among our competitors. Suturing must be done manually by experienced technicians as it requires significant know-how in assessing the thickness and hardness of bovine pericardia.
- ***Anti-calcification.*** We adopt our in-house developed proprietary “VITAL-X” anti-calcification technology to treat the valve to complete valve anti-calcification.
- ***Sterilization and assembly.*** We sterilize the semi-finished PAV with our unique chemical processing technology. Afterwards, we assemble the semi-finished PAV with packaging and accessories.
- ***Quality inspection.*** We conduct quality inspections after each key step during the manufacturing process. If any flaw is detected, the semi-finished PAV would be placed to the previous step to be revoked or scrapped, as appropriate. After the product is assembled and packaged, we will conduct a final inspection of the product.

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Delivery System

Set forth below is an illustrative flowchart for the production process of the delivery system of VitaFlow™.

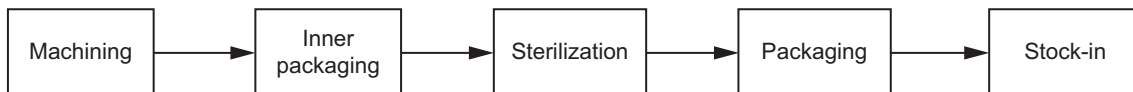


The following is a brief description of the key steps in our manufacturing process of the delivery system:

- **Component production.** We first clean the catheter and passivate the metal parts, and then use the processed materials to manufacture the key components of the catheter.
- **Catheter production.** We assemble the components to form the catheter module.
- **Delivery system assembly.** We assemble the catheter module and the motorized handle, which will form the delivery system.
- **Sterilization and packaging.** We sterilize the delivery system, label and add an outer package to the sterilized delivery system.
- **Quality inspection.** We conduct quality inspections for each key step during the manufacturing process. If any flaw is detected, the semi-finished product would be placed to the previous step to be revoked or scrapped, as appropriate.

Procedural Accessories

Set forth below is an illustrative flowchart for the production process of our procedural accessories.



Manufacturing Team

We have built a strong manufacturing team to transit our products from clinical trials to commercial production seamlessly. Our manufacturing team is led by Mr. Fu Xiaokang, who has abundant experience in manufacturing management with us as well as with other international leading medical device companies. As of the Latest Practicable Date, we had over 90 manufacturing personnel. We train our manufacturing personnel to make sure they are skilled in the manufacturing process and techniques and comply with our internal quality control requirements as well as applicable laws and regulations in China. Each manufacturing personnel is required to complete such training and pass the internal assessment before commencing manufacturing seamlessly. Manufacturing prosthetic aortic valves is a complex and demanding process. Suturing the bovine pericardium to the frame, a key step in the manufacturing process, must be done manually by experienced technicians, which currently cannot be replaced by machines as it requires significant know-how in assessing the

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thickness and hardness of bovine pericardia. As of July 31, 2020, we had over 30 full-time technicians that are capable of completing the suturing task. We believe our manufacturing team enables us to adjust our production activity quickly to respond to changes in market demand for our products.

Manufacturing Facilities and Production Capacity

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. We lease the Nanhui Facility from an Independent Third Party and the Zhangjiang Facility from the MicroPort Group. For details, see “Connected Transactions.” As of the Latest Practicable Date, Zhangjiang Facility was primarily used for research and development of our pipeline products and Nanhui Facility was primarily used for commercial production of VitaFlow™. We also engaged a third party to construct 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, which will significantly enhance our production capacity.

The following table sets forth the production capacity, actual production volume and utilization rate in relation to the commercial manufacturing of VitaFlow™ during the Track Record Period.

	For the years ended December 31,		For the seven months ended July 31,
	2018	2019	2020
VitaFlow™			
Production capacity ⁽¹⁾ (units per year)	—	613	1,281
Actual production volume (units)	—	528	808
Utilization rate ⁽²⁾ (%)	—	86.2%	63.1%

- (1) Production capacity refers to the theoretical maximum units of products that our manufacturing facilities and our manufacturing team can produce during the months that we had been in commercial manufacturing after we obtained the marketing approval of VitaFlow™ in July 2019. Our production capacity is based on the assumption that it takes an average of 14 and 12.5 hours per person to produce one PAV in 2019 and the seven months ended July 31, 2020, respectively; and each person works 44 hours per week and 52 weeks per year. The increase of our production capacity in 2020 was primarily attributable to the increased number of qualified workers for suturing and the fact that we had improved our suturing technology to reduce the hours taken for suturing per person, as valve suturing is the most crucial step in the manufacturing of VitaFlow™.
- (2) Utilization rate equals actual production volume divided by production capacity. The utilization rate for the seven months ended July 31, 2020 was lower than that of the year ended December 31, 2019, primarily due to the impact of the COVID-19 pandemic.

The machines we use for manufacturing our products mainly include laser welding machine, and ultrasonic cleaners. We purchase such machinery from reputable suppliers. We have established a comprehensive maintenance system for our machinery. Since the commencement of our manufacturing and up to the Latest Practicable Date, we had not experienced any material or prolonged interruptions of our manufacturing due to equipment or machinery failure.

COLLABORATION WITH THIRD PARTIES

To closely follow the emerging technologies for the treatment of valvular heart disease, in addition to our in-house research and development efforts, we also evaluate the opportunities to collaborate with other medical device companies for in-licensing their products in China. As of the

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Latest Practicable Date, we had collaborated with ValCare and 4C Medical in relation to our TMV pipeline products. Through our collaboration with them, we are granted the exclusive distribution rights in China with respect to the three TMV repair/replacement products and one TTV repair products, enabling us to further enrich our product offerings in the significantly untapped TMV and TTV markets in China. For details, see “—Our Product Portfolio.”

ValCare

ValCare is a pre-revenue medical device company organized in the U.S. with an Israeli subsidiary, primarily focusing on minimally invasive therapies treating mitral and tricuspid valve diseases. For details, see “History, Development and Corporate Structure—Strategic Investments.”

On July 15, 2020, we entered into a master distribution agreement with ValCare, pursuant to which we shall be granted the exclusive right to market and distribute Amend, Corona, and Trivid in mainland China, Hong Kong, Taiwan, India, South Korea, Indonesia, Malaysia, Thailand and Singapore (“**Master Distribution Agreement**”), subject to and pending upon the execution of a mutually agreed upon local agreements for each territory and certain other preconditions set forth in the Master Distribution Agreement. Pursuant to the Master Distribution Agreement, all of the intellectual properties in relation to Amend, Corona and Trivid shall remain the sole and exclusive property of ValCare. Set forth below is the summary of the key terms of the Master Distribution Agreement.

- **Term.** 15 years.
- **Product.** Amend, Corona, and Trivid, including upgrades, modifications, alterations or derivatives to these products provided that the key features of these products remain unchanged.
- **Distribution arrangement.** During the term of the Master Distribution Agreement, subject and pending upon the execution of a mutually agreed upon local agreements for each territory and certain other preconditions set forth in the Master Distribution Agreement, we shall be appointed as the exclusive distributor to distribute the products specified in this agreement in mainland China, Hong Kong, Taiwan, India, South Korea, Indonesia, Malaysia, Thailand and Singapore (“**Territory**”). We may also, at our sole discretion, appoint sub-distributors to distribute such products within any portion of the Territory.
- **Non-compete.** We agreed that during the term of the Master Distribution Agreement, we will not, directly or indirectly, engage with, represent, work for or provide services to or for the benefit of any business entity or individual for the sale, lease or otherwise provision of products within the Territory that are similar to Amend, Corona and Trivid.
- **Future products.** During the term of the Master Distribution Agreement, if ValCare would like to distribute or sell any other future product in the Territory, ValCare shall notify us in writing with such intent. We then may provide ValCare with an offer for the distribution of such future products and such offer shall only lapse in the event that a definite distribution agreement is not entered into by us and ValCare within six month from the date of the delivery of the aforementioned notice.

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- **China local agreement.** Under the Master Distribution Agreement, ValCare and us are obliged to enter into a mainland China local agreement, pursuant to which we will undertake to commence the NMPA registration process for each of the Amend, Corona and Trivid by no later than the second anniversary of completion of the early feasibility study conducted by ValCare, including commencement of the clinical trials in China in relation to these products. We will also pay ValCare a one-time non-refundable milestone payment upon we commenced the NMPA registration process for *Amend*. In return, ValCare will share with us all necessary documents relating to product design and R&D for the NMPA registration process.
- **Training.** ValCare will provide up to a mutually agreed number of days for training to our personnel in connection with the marketing, sale and support of Amend, Corona and Trivid. We will bear all training related costs. We also undertake that only trained and certified personnel will have access to these products.
- **Warranties.** ValCare warrants that the products shall be free from defects in workmanship and materials until the application expiration date. ValCare will be responsible for replacement of defective products covered by this warranty unless such defect was as a result of improper handling, shipment, storage or use.
- **Intellectual property.** All of the intellectual properties in relation to Amend, Corona and Trivid shall remain the sole and exclusive property of ValCare. We will be granted by ValCare a non-transferable, non-sublicensable license for the sole purpose of assembly, distribution, marketing and support of these products and existing trademarks for these products in China.
- **Other jurisdiction rights.** We have the right to cause ValCare to enter into good faith negotiations for local agreements in countries/regions other than mainland China for product registration in such country/region within one months after any of Amend, Corona and Trivid receives the CE Mark or the FDA approval. If, prior to any of the product receiving the CE Mark or the FDA approval, ValCare is approached by a third party wishing to enter into a distribution agreement in any portion of the Territory, we shall have the right to enter into negotiations towards the execution of a local agreement for the specific product in that portion of Territory. Such right shall lapse in the event that a definite distribution agreement is not entered into by us and ValCare within six month from the date of the delivery of the aforementioned notice.

4C Medical

4C Medical is a company incorporated in Delaware and engaged in the research and development of the mitral and tricuspid valve devices in the United States. For details, see “History, Development and Corporate Structure—Strategic Investments—Investment in 4C Medical.” In conjunction with our initial investment in 4C Medical, we entered into a distribution and manufacturing agreement with 4C Medical in September 2018, (the “**Distribution and Manufacturing Agreement**”) pursuant to which we are granted the exclusive right to distribute AltaValve in mainland China, Hong Kong, Macau and Taiwan. Under the Distribution and Manufacturing Agreement, we may also seek to manufacture the delivery system of AltaValve

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(excluding the valve itself), provided it is successfully registered with the NMPA through the locally-manufactured product pathway. Set forth below is the summary of the key terms of the Distribution and Manufacturing Agreement.

- **Term.** Seven years, which will be automatically renewed for a successive term of one year following the expiration of the initial term, subject to termination by 4C Medical upon 90 days notice at the end of the initial term or any renewal term and subject to the termination clause below.
- **Product.** AltaValve human mitral valve replacement medical device product (“AltaValve”), including the valve and the delivery system, as well as any upgrades which will generate next and subsequent generation AltaValve product.
- **Product registration.** 4C Medical and we shall make a good faith effort to register AltaValve with the NMPA under the locally-manufactured product pathway, in the event of which AltaValve will be registered under our name. Otherwise, AltaValve will be registered under the name of 4C Medical if the NMPA does not accept the registration under our name and the product shall be registered as an imported product.
- **Clinical trial.** We are responsible for all administrative costs, clinical trials required to obtain the NMPA registration certificate and 4C Medical shall provide all necessary data and documents to support the NMPA pre-approval and post-approval process. Together with 4C Medical, we will commence the process to obtain the NMPA registration certificate (including clinical trials) as soon as possible, but in no event shall the enrollment of the first mitral valve disease patient in the China clinical trial commence earlier than the date on which 4C Medical has obtained both FDA and PMDA registration certificate for AltaValve.
- **Manufacturing arrangement.** We may, upon written notice to 4C Medical, seek to manufacture the delivery system of AltaValve (excluding the valve itself) following the successful registration of AltaValve through the locally-manufactured product pathway.
- **Distribution arrangement.** We are appointed as the exclusive distributor to market, promote, distribute and sell AltaValve in mainland China, Hong Kong, Macau and Taiwan, and 4C Medical shall not, directly or indirectly, supply AltaValve to any other party within such territory during the term of the Distribution and Manufacturing Agreement. We may at our sole discretion, engage sub-distributors to market, promote, distribute and sell the product in such territory.
- **Training.** Once AltaValve is registered with the NMPA, we may request 4C Medical, at its cost and expenses to provide up to five days of initial on-site training for us, which shall be materially comparable with the standard 4C Medical supply to its employees and clinician customers in the U.S. The training shall cover the operation, function, use, frequently asked questions and troubleshooting of AltaValve. We may request 4C Medical to provide additional training at our cost and expense after such initial training.
- **Purchase price and annual minimum volume.** The purchase price and annual minimum volume shall be determined within 90 days prior to the date of registration of AltaValve at the NMPA. Payment shall be made within 60 days after receipt of the product.

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- **Adverse event.** In the event that there is any adverse event caused by AltaValve, we will immediately notify 4C Medical and upon our request, 4C Medical will give us reasonable assistance to deal with such events, including providing professional advice, preparing and providing test reports, data, results or any other documents and costs incurred by us in relation to such events shall be borne by 4C Medical. 4C Medical shall be responsible for the compensation paid to customers in connection with or arisen out of any personal injury or property damage caused by such adverse events to the extent that such adverse events are caused by material defects of AltaValve or 4C Medical's failure to cause the product to meet product specifications.
- **Intellectual property.** 4C Medical shall exclusively enjoy all intellectual property rights in relation to AltaValve and 4C Medical, except that we are granted a non-exclusive, non-transferable and royalty-free right and license to use the trademark, service marks, trade names, logos or other words or symbols identifying AltaValve in the territory during the term of the agreement.
- **Termination.** The Distribution and Manufacturing Agreement can be terminated by either party in the event of (i) bankruptcy of the other party; (ii) material breach by the other party, which has not been remedied within thirty days of the non-breaching party's written request; (iii) force majeure event and (iv) that 4C Medical no longer makes AltaValve available. The agreement can also be terminated by 4C Medical (i) if there is a change of control in Shanghai MicroPort Medical; or (ii) there is a change of control in 4C Medical on or after the second anniversary of the date that AltaValve received the NMPA registration.
- **Non-compete.** We are not subject to non-competition obligations under the Distribution and Manufacturing Agreement.

SALES AND MARKETING

We adopt an academic marketing approach to introducing our products to the market. We also organized extensive promotional activities with KOLs, physicians, hospitals and medical associations to enhance our brand awareness and establish a quality physician base. Our academic marketing and promotion activities primarily include participating in medical conferences and industry exhibitions, holding and assisting hospital seminars and training sessions. We also invite physicians to attend hospital seminars training sessions, or procedure simulations to get them familiarized with our TAVI products and to increase the number of qualified physicians and eligible hospitals for TAVI procedures. As of the Latest Practicable Date, our sales and marketing team had over 40 personnel. Our sales and marketing team was led by Mr. Wu Guojia, who had over six years of experience at the cardiology department of a hospital and over 16 years of experience at leading international cardiovascular medical device companies such as Boston Scientific. For details, see "Directors and Senior Management." We also have a training team within the sales and marketing team, which is responsible for introducing our products and technologies at educational symposia.

We actively participate in medical conferences and industry exhibitions in the cardiac or cardiovascular fields. We believe these activities provide us with great opportunities to introduce our TAVI products to physicians, especially to get them familiarized with our unique designs such as the

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bovine pericardium leaflets, the double-layer PET skirt and the motorized delivery system. In 2019, we introduced VitaFlow™ through lectures or case studies seminars at over 11 industry-leading academic conferences, including the PCR-CIT China Chengdu Valves Conference (成都國際心臟瓣膜病介入治療會議), China Valve (Hangzhou) Conference (杭州國際心臟瓣膜病介入治療會議), China Structure Week (中國結構周) and Association of Asia Valvular Heart Disease China Forum (心外科學會亞洲心臟瓣膜病學會中國論壇). During the Track Record Period, we were one of the few Chinese companies that had presented case study at international leading academic conferences, including PCR London and the SOLACI conference (also known as the Latin American Society of Interventional Cardiology). These academic presences enable us to introduce TAVI technology and our product to a wider hospital group.

According to Frost & Sullivan, the TAVI market in China is highly concentrated with respect to hospitals, with the Top 20 TAVI Hospitals playing an important role in the market. It is expected that 73.5% of the TAVI in China will be performed at the Top 20 TAVI Hospitals in 2020. We focus on penetrating these hospitals as the first step of our marketing strategy. In order to gain a higher market share in these hospitals, we maintained interaction and communication with KOLs from these hospitals from time to time. We invite these KOLs to carry out clinical studies for our pipeline products and post-marketing clinical studies. We also provide certain in-sale services during TAVI implantation using VitaFlow™, such as product unpacking and assembly and providing assistance during the TAVI procedure, in order to familiarize physicians with our product and its innovative features. We believe the views and endorsement of these KOLs are valuable to our market penetration and future product upgrade. As of the Latest Practicable Date, we successfully penetrated 18 out of the Top 20 TAVI Hospitals.

Currently, there are strong demands for qualified hospitals with an experienced TAVI operation team to support the growth of China's TAVI market. Supported by our penetration in the Top 20 TAVI Hospitals and presence at industry leading conferences, we believe we are well-positioned to penetrate eligible hospitals for TAVI procedure that lack TAVI experiences. We organize hospital seminars and training sessions at eligible hospitals for TAVI procedures in China. We also invite experienced TAVI practitioners, especially leading physicians in this area to facilitate the training process. As of July 31, 2020, we had organized approximately 90 hospital seminars and training sessions in 24 provinces and over 50 cities in China. With our frequent participation in academic conferences and close interaction with physicians and hospitals, as of the Latest Practicable, TAVI procedures using VitaFlow™ had been performed at over 120 hospitals in China and no incidence of major postoperative complication had been observed.

CUSTOMERS

We currently have one in-house developed commercialized product, VitaFlow™, for which we received the NMPA marketing approval in July 2019. During the Track Record Period, all of our revenues were generated from the sale of VitaFlow™ in China. Going forward, we will gradually expand our sales for VitaFlow™ throughout China. In July 2020 and November 2020, we successfully registered VitaFlow™ in Argentina and Thailand, respectively and we also plan to enter overseas markets that recognize the NMPA marketing approval, such as Thailand and Russia in the next two years. We submitted the registration application for VitaFlow™ II to the NMPA in October 2020, which was accepted in November 2020 and is currently under review. In addition, we plan to apply for

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the CE Mark of VitaFlow™ II by the end of 2021. Afterwards, we plan to enter overseas markets that recognize the NMPA marketing approval or the CE Mark, such as Argentina, Brazil, Thailand, South Korea, Russia and India for VitaFlow™ II provided we successfully obtained the relevant marketing approval in China or Europe.

In line with the medical device industry norm, we adopt a distributorship model and we do not sell our products directly to hospitals. During the Track Record Period and up to the Latest Practicable Date, all of our VitaFlow™ products are sold through distributors. As of July 31, 2020, we had 19 distributors. In addition, our distributors may from time to time, engage sub-distributors to assist them, penetrating a broader network of eligible hospitals for TAVI procedures. Under the distribution agreements with our distributors, we require our distributors to seek our written consent before engaging sub-distributors. In 2019 and the seven months ended July 31, 2020, we had six and twelve sub-distributors that had sold VitaFlow™ to hospitals. We adopt the distributorship model primarily because through this model, we are able to expand hospital coverage and promote our products to a larger hospital group in a cost-effective manner, while we focus on research and development activities.

We generally sell our products at ex-factory prices to our distributors in China. We take into account a number of factors in determining our ex-factory prices, which primarily include our costs and expenses, historical procurement amount from the distributor and hospital coverage of the distributor. Currently there is generally no special tender or bidding process or price guidance set on TAVI procedures and related products for enterprises by the PRC government and our sales efforts primarily focus on obtaining provincial settlement code at each provinces in China, which will enable us to sell our products at hospitals in such provinces. As of the Latest Practicable Date, TAVI procedures using VitaFlow™ had been performed at over 145 hospitals, most of which are Class IIIA hospitals located at tier-one and tier-two cities.

In addition, with respect to our overseas strategies, we plan to engage local agent or distributor to assist us to penetrate local markets. We normally select local distributor/agent based on their relevant experiences in the territory, especially whether they have access to eligible hospitals for TAVI procedures. As of the Latest Practicable Date, we had engaged a local distributor in Argentina. Pursuant to the distribution agreement, the local distributor is engaged as our exclusive distributor for VitaFlow™ in Argentina. The local distributor is obliged not to distribute any product similar or equal to VitaFlow™. The agreement also sets out a fixed purchase price and the minimum purchase amount for the distributor. Under the agreement, we will be responsible for product manufacturing and product delivery to Argentina. The local distributor is obliged to, at its own expense and consistent with our sales policies, conduct marketing activities in Argentina, including keeping regular contact with local hospitals. The local distributor shall also submit quarterly market research information to us, which will set out their selling performance in Argentina. Going forward, we plan to engage one local distributor or agent in the territory. The distribution agreement has a term of three years. Our sales and marketing team will provide training to the Argentine distributors and may also provide trainings to hospitals in Argentine if necessary. We plan to engage one local distributor for each overseas jurisdiction we plan to enter on similar commercial terms with the one in Argentina if these terms are achievable.

During the Track Record Period, substantially all of our revenue was derived from the sale of our VitaFlow™, which was commercialized in China in August 2019. In 2018, 2019 and the seven

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months ended July 31, 2020, the aggregate sales to our five largest customers were nil, RMB14.9 million and RMB28.2 million, representing nil, 69.4% and 58.2% of our total revenue, respectively. Sales to the largest customer in 2018, 2019 and the seven months ended July 31, 2020 were nil, RMB5.8 million and RMB10.6 million, representing nil, 27.1% and 21.8% of our total revenue, respectively. All of our five largest customers during the Track Record Period were our distributors, who are Independent Third Parties.

Selection of Distributors

Our sales and marketing department is mainly responsible for the selection of suitable distributors for our business and able to contribute to our business growth. We normally select distributors who can effectively work with us to promote our VitaFlow™ at local hospitals and who have established and maintained skills, experiences and resources to help us execute our business strategies.

During the selection of distributors, we first evaluate their qualifications. Our distributors are required to possess the requisite business licenses and permits to sell medical devices in China. We will also evaluate factors including (i) experience in marketing and sales of medical devices and high-value medical consumables; (ii) primary sales channels and hospital coverage; and (iii) marketing strategies to promote our products. We also engage a third-party company to conduct background checks on all the distributors that have passed our internal qualification evaluations. We only choose to enter into distribution agreements with distributors who have passed our background check. We re-review the qualifications of our distributors when our distribution agreements with them are due for renewal. We also review the sales performance of such distributors before renewal.

As a large part of communications with hospitals and after-sale service is conducted by our distributors, we provide technical training to our distributors and assess their knowledge and capability. The training mainly covers product information, medical knowledge such as the surgical process, and eligible customer analysis. The assessment is divided into a basic level (G1) and a professional level (G2). All front-line business personnel of our distributors involved in our business is required to complete our training and pass the G1 assessment. The business personnel who have passed the G1 assessment with three or more years of working experience in the medical device industry are required to pass the G2 assessment. We also adopt robust measures and selection criteria to manage the anti-bribery and anti-corruption risks involved with our distributors. Our agreements with our distributors will set out anti-bribery and anti-corruption obligations for the distributors. In the event that there is any breach of these obligations, we are entitled to terminate the distribution agreement and claim reimbursement for all the associated losses. For details, see “—Risk Management and Internal Control.”

Rights and Obligations of Distributors

We enter into a distribution agreement with each distributor, which set out key rights and obligations. We require such distributors not to sell TAVI products of our competitors. The key terms of our distribution agreements with our distributors are summarized below.

- *Duration.* Distribution agreements we entered into in 2019 at the initial stage after VitaFlow™ was commercialized typically have a term of three to five months and will be

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automatically renewed for six months. Starting from 2020, we typically enter into distribution agreements for one-year.

- *Exclusivity.* The distributors are authorized to sell our products only within the designated geographic regions and hospitals and are prohibited to sell outside their respective territories. Our distributors are also prohibited from selling competing products in the designated geographic regions and hospitals.
- *Sub-distributors.* Our distributors shall not procure sub-distributors without our written consent.
- *Minimum purchase volume.* We typically set a minimum purchase volume with the distributor, which is subject to review and amendment upon renewal of distribution agreement. The minimum purchase volume serves as annual sales goals instead of strict purchase requirements.
- *Obligations.* Our distributors are obligated to, among other things, (i) comply with the relevant laws and regulations, (ii) keep inventory and usage records of all products, and (iii) store the product appropriately in accordance with the instructions set out in the product manual.
- *Pricing and payment.* We set out the selling prices to our distributors in the purchase orders and the distributors shall make payments in full on the next business day after receiving our notice of the confirmation to the purchase orders. We may from time to time offer certain distributors a price discount on a case-by-case basis in light of their historical procurement amount and respective hospital coverage.
- *Credit term.* Except for two distributors in 2020, 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.
- *Delivery.* We are responsible for transporting our products to the distributor and bearing the costs of transportation.
- *Product return.* In line with the industry practice, we do not allow our distributors to return products unless there are quality defects or in the event of a product recall. Generally, we are not responsible for product sale or return once our products are sold to the distributors.
- *Confidentiality.* Distributors are required to keep confidential any information relating to our business and shall not disclose the confidential information to any third parties within the term of the agreement and five years after its termination.
- *Termination.* Each party has the right to terminate the agreement if the other party breaches the terms and conditions therein. In the event of termination, we may allow the distributor to return up to 15% of their inventories.

We require all the distributors to place orders under our online ordering system, which enables our sales and marketing department to provide real-time supervision so that we can have a good understanding of each distributor's sales network, the demand and needs of hospitals they cover and

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their procurement practices. In particular, for substantially all of our distributors, we require them to make full payment prior to product shipments, except for two distributors to whom we granted a credit term of 10 business days starting from June 2020 and approximately 30 days starting from October 2019, respectively. The credit terms we granted to these distributors are in light of their historical procurement amount and their respective hospital coverage. We closely track our receivables settlement with these distributors and we will immediately discuss with such distributor if there is any late payment. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any late settlement with respect to our trade receivables that would have a material and adverse impact on our business. Considering that above, we believe our risk exposure to the recoverability of trade receivables from our distributors is very limited and our credit management policy is appropriate.

Distributor Inventory Management

Our distributors generally place orders with us based on actual demand from hospitals. During the Track Record Period, most of our distributors place two to three orders per month and we will normally ship our products the next business day upon we receive the payment in relation to the order in full. We believe that we are able to ensure that our sales to distributors reflect genuine market demand for our products and to prevent channel-stuffing, in consideration of the following measures and conditions.

- *Close monitoring.* We track the order and implantation of our products through an online ordering system. Our distributors are required to confirm the receipt on the online ordering system promptly after receiving our products. Leveraging our online ordering system, we believe we have a good understanding of our distributors' sales network, the demand and need of hospitals they cover and distributors' procurement practices.
- *Credit term.* We require all of our distributors to make full payment to us before we make shipment, 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, in light of their historical procurement amount and hospital coverage. We believe that this will require our distributors to effectively manage their cash flow and ensure that orders are made based on actual demand. Going forward, we will only grant credit terms to major distributors on a case-by-case basis based on our assessment.
- *Inventory check.* We regularly organize inventory checks upon our distributors. If the data on our online ordering system does not match the actual stock of distributors, we have the right to implement measures including terminating the distributorship with such distributor.
- *Implantation data.* We gather information from hospitals to monitor the hospital implantation data of VitaFlow™ and we believe this will enable us to better understand the actual demands of our products. We will take the implantation data into consideration when negotiating the minimum purchase volume under the distribution agreement.
- *Strict product return policy.* We typically do not allow distributors to return any products unless there are quality defects or there is a product recall. During the Track Record Period, no distributor returned any product.

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- Distributor independence.* During the Track Record Period, to the best of our Directors' knowledge, all of our distributors were Independent Third Parties, and none were controlled by our current or former employees. During the Track Record Period, we did not provide any material advance or financial assistance to our distributors. To the knowledge of our Company, (i) there is no other relationship or arrangement (family, business, financing, guarantee or otherwise in the past or present) between (a) each of our distributors and sub-distributors during the Track Record Period, and (b) our Group, our Directors, Shareholders and senior management and their respective associates as of the Latest Practicable Date; and (ii) our Group, our Directors, shareholders and senior management and their respective associates have never financed, directly or indirectly, our Group's distributors and sub-distributors for the purchase of our products during the Track Record Period and up to the Latest Practicable Date.

Number of Distributors

After VitaFlow™ received the NMPA marketing approval in July 2019, we started to engage distributors. The table below sets forth the changes in the number of distributors during the Track Record Period.

	<u>For the year ended December 31,</u>		For the seven months ended
	<u>2018</u>	<u>2019</u>	July 31, 2020
As of the beginning of the period	—	—	12
Additions of new distributors	—	15	11
Termination of existing distributors ^{Note}	—	3	4
As of the end of period	—	12	19

In 2019 and the seven months ended July 31, 2020, we terminated a total of three and four distributors, respectively. Revenue generated from these distributors represented 6.2% and 6.3% of our revenue during each respective period. We terminated these distributors primarily because we strategically shifted our marketing strategy and penetration plan with respect to the hospitals they were covering and accordingly we considered these distributors were not suitable for us, and to a lesser extent, because we terminated the overlapping distributors with the Retained Group. For details, see “Relationship with Our Controlling Shareholders—Independence of Our Group from Our Controlling Shareholders—Sales and Marketing.”

Pricing

We generally adopt a patient-oriented pricing and commercialization strategy which we believe can achieve the balance between patients' affordability and market demands. We have conducted extensive market research with KOLs, hospitals, physicians and patients as well as regulatory bodies before product pricing and have taken into account various factors in product pricing, such as feedbacks collected from these parties, possibility of inclusion in the medical insurance reimbursement list in China as well as prices of our competitors. 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. Considering patients' affordability in China and in order to gain a

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higher market share in China's TAVI market and to better position our products for future admission into the medical insurance reimbursement list, the price of VitaFlow™ is significantly lower than our competitors in China, despite VitaFlow™ having achieved positive clinical trial results with respect to all-cause mortality rate and post-operative complications. In general, VitaFlow™ is priced at approximately RMB196,000 per unit under the public wholesale tender scheme in China as of the Latest Practicable Date. With its competitive price, we believe VitaFlow™ has the potential to become one of the first TAVI products to be admitted into the medical insurance reimbursement list in China. We will adopt similar pricing strategy for VitaFlow™ II after it is commercially launched. We plan to apply for admission of VitaFlow™ and VitaFlow™ II in the medical insurance reimbursement scheme in China once available. For risks associated with our pricing strategy, see "Risk Factors—Risks Relating to Commercialization and Distribution of our Products—Our pricing strategy and downward change in pricing of our products may have a material adverse effect on our business and results of operations" for details. We also offer competitive prices to our distributors. To incentivize our distributors, we may negotiate with certain distributors for price discount on a case-by-case basis in light of their hospital coverage and historical procurement amount. We believe our patient-oriented pricing model can significantly benefit the large patient pool eligible for TAVI procedures, which in turn, can drive our business growth.

After-sale Service

After our products are sold and implanted, we also conduct certain follow-up services, including distributor training and assessment, product maintenance and performance follow-up with physicians and patients. We conduct follow-up discussions with the physicians who used our TAVI products post-TAVI procedures to better understand the key advantages and weaknesses of our TAVI products, which we believe provide us the opportunity not only to improve our product design in the future, but also to strengthen product loyalty and lay the foundation for further cooperation. The information we collected from after-sale product performance follow-up also form a strong basis for our future academic promotion activities. In addition, we may also conduct post-marketing clinical trials and follow-up studies for a period of up to five years after the TAVI procedure is completed. We also provide channels for complaints regarding our products. During the Track Record Period and up to the Latest Practicable Date, we have not received any product complaint that needed to be reported to the NMPA. During the Track Record Period and up to the Latest Practicable Date, we had not recalled any product due to quality issues.

RAW MATERIALS AND SUPPLIERS

Our principal raw materials for the manufacturing of TAVI products are bovine pericardium and nitinol components, which are generally procured on an as-needed basis. To ensure the quality of our principal raw materials, we only procure bovine pericardium and nitinol components from selected suppliers that can satisfy our stringent raw material requirements. The bovine pericardium we used in our R&D activities and the commercial manufacturing of VitaFlow™ are imported from one qualified supplier in Australia, where bovine pericardium has not been affected by BSE. As we only obtained the license for import of bovine pericardium for commercial production effective from April 2019 and the license for import of bovine pericardium for R&D effective from April 2020, we only started to procure bovine pericardium directly from such supplier for R&D and commercial production immediately after we obtained the respective importing license. Accordingly, prior to obtaining such

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licenses certain of the bovine pericardium we used were procured from the MicroPort Group, who purchased bovine pericardium from the Australian supplier and then sold to us at the same price and normal commercial terms. Considering that there are also other bovine pericardium suppliers in China and overseas that can satisfy our stringent quality requirements, we believe we are able to source bovine pericardium from other suppliers if our relationship with the current Australian bovine pericardium supplier is materially adversely affected. Our nitinol components are mainly procured from Germany. See “Risk Factor—Risks Relating to Manufacture and Supply of our Products—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.”

With respect to the bovine pericardium, we had entered into a master purchase agreement for a period of two years with the supplier based in Australia, which is automatically renewable for another two years unless any party disagrees. Pursuant to this agreement, we are obliged to purchase 800 pieces of bovine pericardium valves each year at a fixed price set out therein, which will be subject to adjustment every year. The master purchase agreement also sets out the detailed specifications of the bovine pericardium and we are entitled to reject any bovine pericardium that does not comply with such specifications. The supplier also guarantees that the bovine pericardium shall be free from defects in material and workmanship for one year from our acceptance of such products. With respect to nitinol components, we had entered into a purchase agreement with a supplier based in Germany for a period of one year and the purchase agreement sets forth detailed specifications of the nitinol products.

We have formulated detailed quality standards for bovine pericardium and nitinol components, covering both technical specifications and regulatory compliance aspects. We normally enter into a quality assurance agreement with such suppliers together with the purchase agreement, which sets out our quality standards and inspection procedures. We keep a qualified supplier list and we only procure bovine pericardium and nitinol components from such qualified suppliers. We conduct supplier audit, which includes documentation inspection and/or on-site inspection for all the suppliers. Upon receiving the raw material shipments, we retain the right to reject or return based on our inspection results. We assess the performance of our qualified suppliers annually on criteria such as quality of supplies, service and timeliness of delivery. In response to the COVID-19 pandemic, we generally kept a higher level of inventories. For bovine pericardium, we will anticipate the forecasted consumption for the next two to three months and will adjust our purchases accordingly. We did not experience, and do not expect our supply chain to be materially and adversely affected by the COVID-19 pandemic.

In 2018, 2019 and the seven months ended July 31, 2020, purchases from our five largest suppliers amounted to RMB45.6 million, RMB63.7 million and RMB37.9 million, accounting for 51.8%, 42.1% and 47.9% of our total purchases, respectively, and purchases from our largest supplier amounted to RMB24.8 million, RMB23.9 million and RMB13.8 million, accounting for 28.2%, 15.8% and 17.5% of our total purchases for the same period, respectively. Except for the MicroPort Group, all of our five largest suppliers during the Track Record Period are Independent Third Parties. We generally have maintained a business relationship with such suppliers for over three years. Save as disclosed above, none of our Directors, their associates or any of our current Shareholders (who, to the knowledge of our Directors, own more than 5% of our share capital) has any interest in any of our five

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largest suppliers that are required to be disclosed under the Listing Rules. The following table sets forth the details of our five largest suppliers for the period indicated.

For the year ended December 31, 2018

<u>Supplier</u>	<u>Purchase amount (RMB in thousands)</u>	<u>Percentage of total purchase</u>	<u>Goods/services procured</u>
MicroPort Group	24,808	28.2%	Technical services, rentals, raw materials and animal study services
Supplier A	8,941	10.1%	Nitinol components
Supplier B	6,411	7.3%	Animal experiment
Supplier C	2,878	3.3%	Catheter products
Supplier D	2,543	2.9%	Molding
Total	45,581	51.8%	

For the year ended December 31, 2019

<u>Supplier</u>	<u>Purchase amount (RMB in thousands)</u>	<u>Percentage of total purchase</u>	<u>Goods/services procured</u>
MicroPort Group	23,857	15.8%	Technical services, rentals, raw materials and animal study services
Supplier E	12,274	8.1%	Bovine pericardium
Supplier A	12,075	8.0%	Nitinol components
Supplier B	9,554	6.3%	Animal experiment
Supplier F	5,954	3.9%	Air-ticketing
Total	63,714	42.1%	

For the seven months ended July 31, 2020

<u>Supplier</u>	<u>Purchase amount (RMB in thousands)</u>	<u>Percentage of total purchase</u>	<u>Goods/services procured</u>
Supplier E	13,848	17.5%	Bovine pericardium
Supplier A	10,174	12.8%	Nitinol components
MicroPort Group	6,637	8.4%	Technical services, rentals, bovine pericardium and other raw materials and animal study services
Supplier G	3,775	4.8%	Catheter products
Supplier H	3,474	4.4%	Nitinol components
Total	37,908	47.9%	

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INVENTORY

Our inventory mainly includes raw materials, work in progress and finished products. We have established an inventory management system that monitors each stage of our warehousing process. We evaluate our inventory level on a weekly basis for our raw materials. Considering that most of our bovine pericardia for manufacturing VitaFlow™ are imported from Australia, we generally keep a higher inventory level for bovine pericardium to minimize the administrative costs associated with the importing process. Our VitaFlow™ has a shelf life of one year and is sold on a first-in-first-out basis. Warehouse personnel is responsible for the storage and distribution of raw materials. Raw materials are separately stored in different areas of the warehouse according to their storage condition requirement, properties, usage and batch number. During the Track Record Period, we did not experience any material shortage of inventory.

QUALITY MANAGEMENT

Quality control and quality assurance are crucial for us, and we endeavor to ensure the quality of our operations through a comprehensive quality management system, which was formulated in accordance with the GMP standard as required by the NMPA and ISO13485:2016 standard, covering substantially every aspect of our operations including product design, supply chain and manufacturing, among others.

We have established a comprehensive set of quality control and quality assurance procedures to monitor our manufacturing process to ensure it to comply with relevant regulatory requirements and our internal quality requirements. We select our suppliers based on a strict set of criteria and we regularly conduct supplier audits which include documentation inspection and/or on-site inspection on such qualified suppliers to make sure our requirements are being consistently met. Key steps of our manufacturing process must be conducted in cleanrooms that comply with the classification of ISO Class 7 cleanness standards. We regularly validate facilities, equipment, manufacturing processes and production parameter to ensure that our processes, methods, programs and equipment work properly. In addition, we have a monitor system that can provide real-time monitoring of our manufacturing environment, especially special requirements such as humidity, temperature and differential pressure. We conduct inspection on raw materials, including work-in-progress in accordance with our quality management standards. Finished products are subject to strict inspection and test before sale. We require responsible personnel for each manufacturing step to keep records on inspection results and we also conduct a final review on related inspection and test records to determine whether a specific product can be released for sale. Products that do not meet our quality standards are destroyed or otherwise disposed of in accordance with the relevant environmental control requirement. We analyze the data and feedback we received from our distributors and hospitals as we believe such data and feedback are crucial in the development of our next-generation product.

INTELLECTUAL PROPERTY

As a medical device company focusing on innovative solutions for valvular heart diseases, intellectual property rights are crucial to our business and we are committed to the development and protection of our intellectual properties.

As of the Latest Practicable Date, we owned 98 patents in China, including 23 invention patents, 68 utility models and seven industry designs. As of the same date, we also had 82 pending patent

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applications in China, including 72 invention patents and 10 utility models. To facilitate our strategy to enter overseas market, we also owned 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. During the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings in respect of, and we had not received notice of any material claims of infringement of, any intellectual property rights that are threatened or pending, in which we may be a claimant or a respondent. For details, see “Appendix IV — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights.”

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The table below lists the material patents and patent applications of our Core Product, VitaFlow™ II, and our first commercialized product, VitaFlow™ as of the Latest Practicable Date.

Name of Patent	Type of Patent	Registration Number/ Application Number	Owner/ Applicant	Status	Related Product(s)	Application	Registration	Expiration	Jurisdiction	Authority
						Date	Date	Date		
Implant delivery system	Invention patent	201210356246.3	MP CardioFlow	Granted	Delivery system of VitaFlow™ and VitaFlow™ II	September 21, 2012	November 25, 2015	September 20, 2032	China	CNIPA
Implant delivery system	Invention patent	13838923.4	MP CardioFlow	Granted	Delivery system of VitaFlow™ and VitaFlow™ II	April 20, 2015	November 13, 2019	April 19, 2035	Europe	EUIPO
Prosthesis heart valve	Invention patent	201310064011.1	MP CardioFlow	Granted	PAV of VitaFlow™ and VitaFlow™ II	February 25, 2013	June 15, 2016	February 24, 2033	China	CNIPA
Electric handle for implant delivery and delivery system	Invention patent	201310202016.6	MP CardioFlow	Granted	Delivery system of VitaFlow™ and VitaFlow™ II	May 27, 2013	May 25, 2016	May 26, 2033	China	CNIPA
Drive handle for conveying implant and conveying system	Invention patent	201510213801.0	MP CardioFlow	Granted	Delivery system VitaFlow™ II	April 29, 2015	August 24, 2018	April 28, 2035	China	CNIPA
Catheter set for implant delivery and delivery system	Invention patent	201510489321.7	MP CardioFlow	Granted	Delivery system and procedural accessories of VitaFlow™ and VitaFlow™ II	September 21, 2012	October 9, 2018	September 20, 2032	China	CNIPA
Electric handle for implant delivery and delivery system	Invention patent	14803859.9	MP CardioFlow	Pre-Granted ¹	Delivery system of VitaFlow™ and VitaFlow™ II	November 27, 2015	February 6, 2019	November 26, 2035	Europe	EUIPO

Name of Patent	Type of Patent	Registration Number/ Application Number	Owner/ Applicant	Status	Related Product(s)	Application Date	Registration Date	Expiration Date	Jurisdiction	Authority
Device and method for loading implant into delivery system	Invention patent	14857026.0	MP CardioFlow	Granted	Delivery system of VitaFlow™ and VitaFlow™II	May 31, 2016	December 5, 2018	May 30, 2036	Europe	EUIPO
Prosthesis heart valve	Intention patent	201611238574.8	MP CardioFlow	Applied	PAV of VitaFlow™ and VitaFlow™II	December 28, 2016	N/A	N/A	China	CNIPA
Cardiac valve delivery catheter and delivery system	Invention patent	201710682415.5	MP CardioFlow	Applied	Delivery system of VitaFlow™II	August 10, 2017	N/A	N/A	China	CNIPA
Delivery system for self-expanding prosthesis and prosthesis heart valve	Invention patent	201710743343.0	MP CardioFlow	Applied	Delivery system of VitaFlow™II	August 25, 2017	N/A	N/A	China	CNIPA

Note:

- As of the Latest Practicable Date, the European Patent Office had received an opposition filed by a third party after the patent was granted in February 2019 (“**Opposition Action**”). As of the Latest Practicable Date, we had filed our response to the opposition action and the European Patent Office has not issued rulings with respect to the Opposition Action. Accordingly, the status of the patent was designated as “pre-granted.” In the worst case scenario, if the European Patent Office ruled in favor of the opposition, we would still be able to commercialize VitaFlow™ II in Europe but would lose patent protection with respect to the motorized delivery system.

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COMPETITION

We operate in a rapidly changing market, resulting from technological advances and scientific discoveries. While we believe our robust R&D capabilities provide us with competitive advantages, we face potential competition with major international medical device companies as well as domestic medical device companies which are developing heart valve disease solutions. We compete primarily based on the clinical performance of our products and pipeline products, our ability to commercialize products, R&D capabilities and brand recognition.

For further details of our major competitors, see “—Our Product Portfolio” and “Industry Overview.”

EMPLOYEES

As of July 31, 2020, we had 299 employees. All of our employees are based in China. The table below sets forth our employees by function as of July 31, 2020.

<u>Functions</u>	<u>Number of Employees</u>
Management and administrative	25
Supply chain and manufacturing	132
R&D	47
Quality control	51
Sales and marketing	32
Regulatory affair and clinical management	12
Total	<u>299</u>

We recruit our employees through recruitment websites, recruiters, internal referrals and job fairs. For all of our employees, we will provide on-board training for them and we also provide periodic training or seminars to ensure their self-development.

In compliance with the relevant PRC laws and regulations, we entered into employment contracts with our employees to cover matters such as wages, benefits and grounds for termination. We enter into standard confidentiality agreements with all of our employees. We enter into non-compete agreements with employees of the departments that we consider crucial to our business, such as R&D, quality control, clinical trial registration, and key technicians. Such non-compete agreements prohibit the employees from competing with us, directly or indirectly, during his or her employment. When an employee leaves our Company, we assess whether he or she has access to our confidential information and if necessary requires the employee to enter into a non-compete agreement for up to two years after the termination of his or her employment. Our PRC Legal Advisers are of the view that these non-compete agreements are valid and legally binding under the PRC laws.

The remuneration package of our employees includes salary and bonus, which are generally based on their qualifications, industry experience, position and performance. We consider the remuneration package of our employees to be competitive among our domestic competitors. We make contributions to social insurance and housing provident funds as required by the PRC laws and regulations.

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Our employees are represented by labor unions. We consider our relationship with employees good. During the Track Record Period and as of the Latest Practicable Date, we did not experience any material labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

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 China, we maintain different types of insurance policies, such as personal accident insurance. We also maintain product liability insurance covering our clinical trials. Our Directors consider that our existing insurance coverage is sufficient for our present operations and in line with the industry practice in China. See “Risk Factors—Risks Relating to Our Operations—Our insurance coverage may not completely cover the risks relating to our business and operations” for details.

PROPERTIES

Our headquarters are located in Shanghai. As of the Latest Practicable Date, we did not own any properties and we leased a number of properties with an aggregate GFA of 8,426.19 square meters, one of which was leased from the MicroPort Group. The following table sets forth the details of our leased properties as of the Latest Practicable Date.

<u>Location</u>	<u>Use</u>	<u>GFA (sq. m.)</u>	<u>Expiry date</u>
Shanghai	Headquarters, R&D and manufacturing facility	2,906.95	December 31, 2022
Shanghai	Manufacturing and R&D	2,216.86	December 31, 2022
Beijing	Office	26.57	December 19, 2021, which is automatically renewable for one year upon expiration if no party objects
Beijing	Office	11	December 31, 2022, which is automatically renewable for one year upon expiration if no party objects
Chengdu	Office	164.81	June 30, 2022
Chengdu	R&D, office and manufacturing	3,100	December 31, 2024

For the first and the sixth leases set out above, certain of the premises are used as offices, which are inconsistent with the usage set out in the title certificate or other relevant permits. Our PRC Legal Advisers are of the view that the local authorities may require us not to use such properties as our offices. Considering that (i) as of the Latest Practicable Date, we had not received any penalty, objection, inquiry or investigation from the local authorities with respect to such properties; and (ii) these properties are located in Shanghai Zhangjiang Hi-Tech Park and Chengdu Tianfu

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International Biotech Park, respectively, where there are abundant unoccupied office premises for lease and we believe we would be able to relocate our office to a different site relatively easily if we are required by local authorities not to use such premises as offices, our Directors are of the view that the likelihood that our business or results of operations would be materially and adversely affected by this title defect is very remote.

As of the Latest Practicable Date, we had not completed lease registration with the relevant regulatory authorities for two of the six leases. Our PRC Legal Advisers are of the view that the non-registration of lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease for any delay in making these registrations. Therefore, we have the right to use such properties in accordance with the lease agreement but we may be subject to the risks of fines if the lease registration is not completed as required by the relevant local housing administrative authorities. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of the lease agreements.

According to section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this prospectus is exempted from compliance with the requirements of section 342(1)(b) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which require a valuation report with respect to all our Group's interests in land or buildings, for the reason that, as of July 31, 2020, we had no single property with a carrying amount of 15% or more of our total assets.

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

In respect of social responsibilities, we have entered into employment contracts with our employees in accordance with the applicable PRC laws and regulations. We hire employees based on their merits and it is our corporate policy to offer equal opportunities to our employees regardless of gender, age, race, religion or any other social or personal characteristics. We strive to provide a safe working environment for our employees. We have implemented work safety guidelines setting out safety practices, accident prevention and accident reporting procedures. Our employees responsible for manufacturing and quality control and assurance are required to hold relevant qualifications, as well as wear the proper safety gear when working. We conduct regular safety inspections and maintenance for our manufacturing facility.

We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees and communities. We have implemented company-wide environmental health and safety policies and operating procedures, covering waste treatment, process safety management, worker health and safety requirements and emergency planning and response. In particular, our operations involve the use of hazardous and flammable chemical materials. Our operations also produce hazardous wastes. We generally contract with third parties for the disposal of these materials and wastes. During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations in all material aspects and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations during the period.

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LICENSES AND PERMITS

We are subject to regular inspections, examinations and audits by local regulators including the Shanghai Medical Products Administration and are required to maintain or renew the necessary permits, licenses and certificates for our business. Our PRC Legal Advisers are of the view that, during the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from the relevant government authorities that are material for our business operations in China. The following table summarizes material licenses and permits we held as of the Latest Practicable Date. We plan to renew all the material license and permit upon its expiration.

<u>License/Permit</u>	<u>Holder</u>	<u>Grant date</u>	<u>Expiration date</u>
Medical Device Registration Certificate (醫療器械註冊證)	MP CardioFlow	July 10, 2019	July 9, 2024
Medical Device Manufacturing Certificate (醫療器械生產許可證)	MP CardioFlow	November 5, 2020	July 23, 2024
Internet drug information service qualification certificate (non operating) (互聯網藥品信息服務許可證)	MP CardioFlow	May 16, 2019	May 15, 2024
Medical Device Export-sale Certificate (醫療器械產品出口銷售證明)	MP CardioFlow	August 24, 2020	August 23, 2022

COMPLIANCE AND LEGAL PROCEEDINGS

We may be involved in legal proceedings in the ordinary course of business from time to time. During the Track Record Period and up to the Latest Practicable Date, none of us or our Directors were involved in any litigation, arbitration or administrative proceedings which could have a material adverse impact on our business, financial condition or results of operations. As of the Latest Practicable Date, we were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us or our Directors which may have a material and adverse impact on our business, financial condition or results of operations.

As advised by our PRC Legal Adviser, during the Track Record Period and as of the Latest Practicable Date, save as disclosed above, we had complied with the relevant PRC laws and administrative regulations in all material aspects.

RISK MANAGEMENT AND INTERNAL CONTROL

We are exposed to various risks during our operations and have established risk management systems with relevant policies and procedures that we believe are appropriate for our business operations. Our policies and procedures relate to the R&D, manufacture and commercialization of our products. To monitor the ongoing implementation of our risk management policies and corporate governance measures after the Listing, we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an audit committee to review and supervise our financial reporting process and internal control system. Our audit committee consists of three members, namely

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Mr. Jonathan H. Chou, who serves as chairman of the committee, Ms. Sun Zhixiang and Dr. Jiang Hualiang. For the qualifications and experience of these committee members, see “Directors and Senior Management;”

- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions and information disclosure;
- attend the training session by our Directors and senior management in respect of the relevant requirements of the Listing Rules and duties of directors of companies listed in Hong Kong; and
- provide regular anti-corruption and anti-bribery compliance training for our Directors and senior management in order to enhance their knowledge and compliance of applicable laws and regulations.

We have engaged an internal control consultant to review the effectiveness of our internal controls associated with our major business processes, identify deficiencies and improvement opportunities, provide recommendations on remedial actions and review the implementation status of these remedial actions. During the review process of our internal control consultant, certain internal control matters were identified and we have adopted corresponding internal control measures to improve on these matters. We have adopted the recommendations made by the internal control consultant and our internal control consultant has completed the follow-up procedures on our internal control system with regard to those actions taken by us in September 2020 and have not identified any material deficiencies in our internal control system.

In addition, as part of our risk management measures, we have implemented specific measures against corruption and bribery. We require our employees, especially those involved in procurement, distribution and sales, and other business functions which are more susceptible to bribery and corruptions, to abide by our compliance requirements, and make necessary representations and warranties to the Company. We also communicate our anti-bribery and anti-corruption principles to our distributors as well as the CMOs and SMOs we engaged for our clinical trial and require them to comply with our anti-bribery and anti-corruption principles. We have established a system of supervision that allows complaints and reports to be submitted to management regarding non-compliant behavior of our employees and external customers and suppliers.