OVERVIEW

Founded in 1994, we have been dedicated to the research, development, manufacture and commercialization of interventional medical devices primarily targeting structural heart diseases, with a track record spanning over two decades. We are a leading interventional medical device provider in China for CHD, a major field of application for structural heart diseases, in terms of market share in China's CHD occluder products market in 2021, with a broad portfolio of marketed and pipeline products, according to the F&S Report. We are the largest manufacturer of CHD occluder products and the related procedural accessories in China, with a market share of 38.0% in terms of revenue recognized for the sales in China in 2021, according to the same source*. Our PFO occluder products and LAA occluder products target cardioembolic stroke and related symptoms, another major field of application for structural heart diseases, which are among a handful of commercialized products to capture the significant market opportunities. We have also cultivated the most comprehensive product portfolio of heart valve product candidates in China to access the enormous market potential treating valvular diseases, the largest field of application for structural heart diseases which remains generally untapped in China, according to the F&S Report.

As of the Latest Practicable Date, we had a comprehensive product portfolio of 20 marketed occluder products and nine occluder product candidates as well as 21 major heart valve product candidates**. All of our products are developed in-house. As of the same date, we also had an expansive collection of intellectual property rights including 229 registered patents and 55 pending patent applications in China as well as 14 patents under application in the United States and the European Union.

Our Adoption of Biodegradable Technology

We spearhead the research and development of biodegradable technology. We have accumulated extensive know-how and experience in biodegradable technology, from material selection to meet various occluder performance requirements, structural design to ensure secure and firm occluder clamping, and controlled biodegradation to facilitate the tissue repair process, to proprietary product processing techniques, including biodegradable wire mesh technology, heat molding technology, vacuum drying and sterilization control technology, and water-proof packaging technology, to enhance occluder performance and validity. We have collaborated with Fuwai Yunnan Cardiovascular Hospital (雲南省阜外心血管病醫院) in completing the world's first fully biodegradable VSD occluder implantation in February 2018 during its clinical trial, which marked a breakthrough in the field of fully biodegradable occluders globally, according to the F&S Report. Our fully biodegradable MemoSorb® VSD

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* In China, domestic CHD manufacturers dominated the market with a combined market share of approximately 91.5% in 2021, according to the F&S Report.

** Our key products include MemoPart® ASD Occluder I, MemoCarna® ASD Occluder III, MemoSorb® VSD Occluder IV, and MemoLefort® LAA Closure Occluder I. Our key product candidates include (1) our biodegradable occluder product candidates, which comprise MemoSorb® ASD Occluder IV, MemoSorb® PFO Occluder II, and LAA Closure Occluder II, and (2) our transcatheter aortic valve replacement ("TAVR") system, transapical mitral valve clip repair ("TMVr-A") system and transfemoral mitral valve clip repair ("TMVr-F") system (collectively, the transcatheter mitral valve repair ("TMVr") systems). We may not be able to successfully develop and market the product candidates for their applications.

Occluder IV was approved by the NMPA in February 2022, and our other biodegradable occluder products were in R&D stage as of the Latest Practicable Date. Compared with traditional metal occluders, biodegradable occluders are designed to degrade over time into carbon dioxide and water, according to the F&S Report. We believe biodegradable occluders provide patients with additional future treatment options, as they would not be permanent implants in the human body, benefiting all patients receiving occluder implants. However, biodegradable occluders may not be suitable for patients with certain pre-existing conditions, such as diabetes, because biodegradable occluders may fully degrade before achieving complete closure of structural heart defects for patients with diabetes due to the related dysfunction.

Our Product Portfolio

The interventional medical device market targeting structural heart diseases consists primarily of three major fields of application, i.e., CHD, cardioembolic stroke, and valvular diseases, according to the F&S Report. The market size of China's interventional medical device market targeting structural heart diseases grew from RMB0.4 billion in 2017 to RMB2.0 billion in 2021 at a CAGR of 48.3%, and is expected to reach RMB10.4 billion in 2025 at a CAGR of 51.0%, according to the same source. As of the Latest Practicable Date, we were the only provider in China with a product portfolio covering all of the three fields. We categorize our product portfolio broadly into two major segments, i.e., occluder products and heart valve products. As of the Latest Practicable Date, we had a comprehensive product portfolio of (1) 20 marketed occluder products and nine occluder product candidates, including primarily various (i) CHD occluder products and (ii) PFO occluder products and LAA occluder products for prevention of cardioembolic stroke and other related symptoms, including migraine, peripheral arterial embolism, and decompression sickness, and (2) 21 major heart valve product candidates, including primarily aortic valve and mitral valve product candidates. Our occluder products have achieved broad market recognition since the initial launch of our first-generation CHD occluder products in 2003.

CHD. We have developed a wealth of occluder products targeting common types of CHD, including primarily ASD, VSD, and PDA. According to the F&S Report, considering the high incidence rates of patients, with approximately 0.9% of the overall newborn population in China suffering from CHD in 2021, the market size of China's CHD occluder products market is expected to increase from RMB426.4 million in 2021 to RMB659.0 million in 2025 at a CAGR of 11.5%. The market size of the global CHD occluder products market is expected to increase from US$223.2 million in 2021 to US$299.0 million in 2025 at a CAGR of 7.6%. As the largest manufacturer of CHD occluder products in China in terms of revenue recognized for the sales in China in 2021 with a market share of 38.0%, we believe we are well positioned to leverage favorable market trends and gain greater market share in this significant market. As of the Latest Practicable Date, we had obtained 13 NMPA registration certificates for Class III medical devices and valid CE Marks for eight of our CHD occluder products and related procedural accessories. We continue to promote the research and development of our biodegradable technology. Our biodegradable VSD occluder product obtained the NMPA approval in February 2022, and our biodegradable ASD occluder product candidate was in the clinical trial stage as of the Latest Practicable Date, which is expected to receive NMPA approval in the second quarter of 2024.

Cardioembolic stroke. We have commercially launched our first generation LAA occluder product in June 2020 and first generation PFO occluder product in August 2012. China's cardioembolic stroke occluder products market has significant growth potential. According to the F&S Report, the market size of China's cardioembolic stroke occluder products market is expected to increase from RMB0.6 billion in 2021 to RMB2.4 billion in 2025 at a CAGR of 38.5%; and the market size of the global cardioembolic stroke occluder products market is expected to increase from US$1.1 billion in 2021 to US$2.0 billion in 2025 at a CAGR of 16.7%. As of the Latest Practicable Date, we had obtained one NMPA registration certificate for Class III medical devices for our first generation LAA occluder product and one CE Mark for our first generation PFO occluder product. Our first generation LAA occluder product, launched in June 2020, had demonstrated therapeutic effects in clinical trials with a 100% operation success rate and reached an LAA closure rate of 97.6% after 12 months following the operation, with no probability of post-operative ischemic stroke. Specifically, operation success rate refers to the probability of successful implantation of the LAA occluder without death, which indicates safety, and LAA closure rate refers to the probability of successful implantation of the LAA occluder without dislodging, which indicates efficacy, according to the F&S Report. We expect our biodegradable PFO occluder product candidate to be among the first PFO biodegradable occluder products to be registered in China, according to the F&S Report. As of the Latest Practicable Date, our biodegradable PFO occluder product candidate was in the registration preparation process with the NMPA, and our biodegradable LAA occluder product candidate was in the stage of type inspection in China.

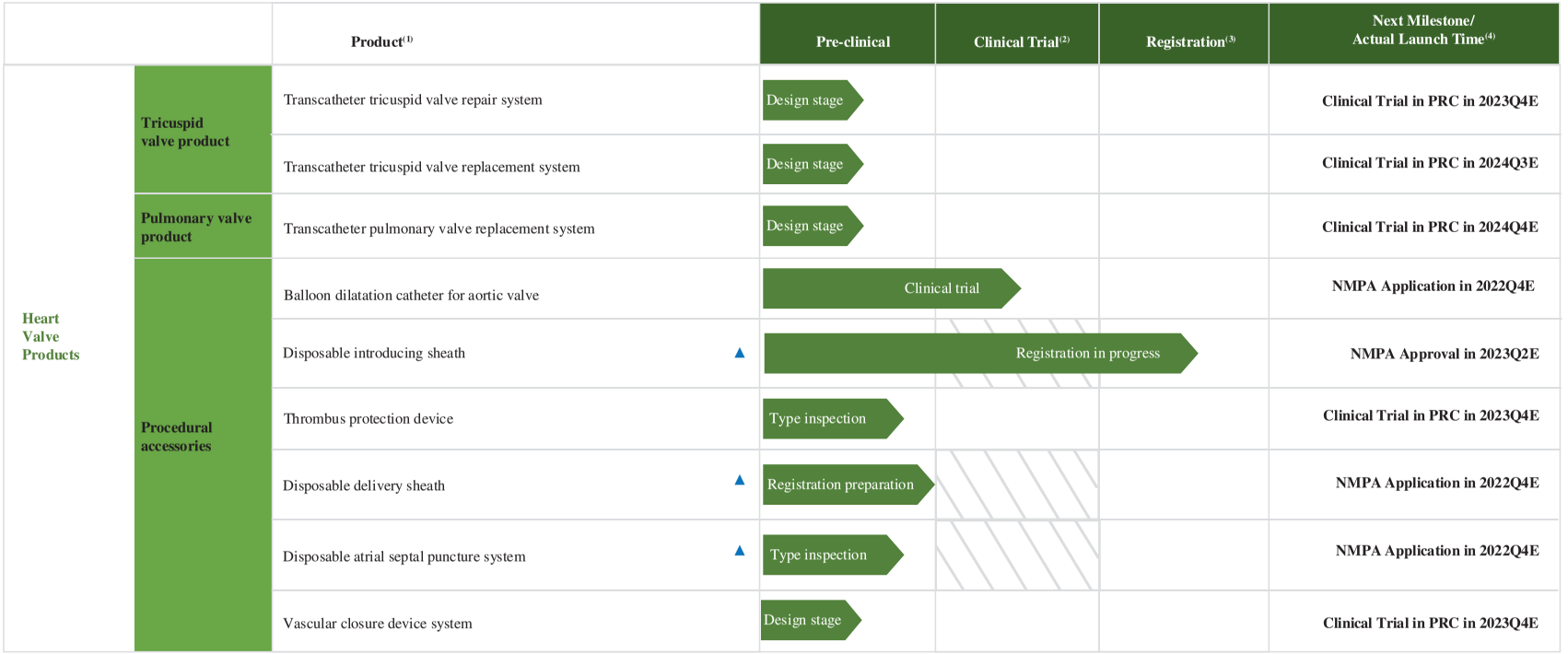
Valvular diseases. We have cultivated a comprehensive pipeline of interventional heart valve product candidates covering all the major valvular diseases, including primarily aortic valve diseases, mitral valve diseases and tricuspid valve diseases. According to the F&S Report, the market size of China's valvular disease interventional device market is expected to increase from RMB1.0 billion in 2021 to RMB7.9 billion in 2025 at a CAGR of 69.8%, and the global market is expected to grow from US$7.1 billion in 2021 to US$14.5 billion in 2025 at a CAGR of 19.7%. Our TAVR system, which was in the clinical trial stage as of the Latest Practicable Date, is expected to be 100% deployable, retrievable and repositionable before being detached from the delivery system, and such features were not present in any commercialized TAVR systems in China as of the Latest Practicable Date, according to the F&S Report. Our mitral valve product candidates include the TMVCRS, the TMVr-A system, and the TMVr-F system. As of the Latest Practicable Date, our TMVr-A system, which was in the clinical trial stage, was among only seven domestic products of similar properties and for similar indications in the clinical trial stage, according to the F&S Report. As of the same date, our TMVCRS was in the clinical trial stage. According to the F&S Report, China's TMVr market is expected to grow from RMB39.9 million in 2021 to RMB1.6 billion in 2025 at a CAGR of 152.0%, and the global market is expected to grow from US$0.9 billion in 2021 to US$2.5 billion in 2025 at a CAGR of 29.3%. As of the Latest Practicable Date, we had one heart valve product candidate in the registration process with the NMPA, one in the registration preparation process with the NMPA, four in the clinical trial stage, six in the type inspection stage and nine in the design stage.

The following chart summarizes the development stage of our products and major product candidates as of the Latest Practicable Date.

	Product[1]		Pre-clinical	Clinical Trial[2]	Registration[3]	Next Milestone/ Actual Launch Time[4]
Occluder Products[5]	Atrial septal defect occluder	MemoPart® ASD Occluder I (Double-rivet)	●	Launched	Launched	NMPA Approval in 2003 CE Mark in 2012
		MemoPart® ASD Occluder II (Single-rivet)		Launched	Launched	CE Mark in 2012
		MemoCama® ASD Occluder III (Oxide Coating)	●	Launched	Launched	NMPA Approval in 2020Q2 CE Application in 2022Q4E
		MemoSorb® ASD Occluder IV (Biodegradable)	○	Clinical trial		NMPA Application in 2023Q2E
	Ventricular septal defect occluder	MemoPart® VSD Occluder I (Double-rivet)		Launched	Launched	NMPA Approval in 2003 CE Mark in 2012
		MemoPart® VSD Occluder II (Single-rivet)		Launched	Launched	CE Mark in 2012
		MemoCama® VSD Occluder III (Oxide Coating)		Launched	Launched	NMPA Approval in 2021Q3 CE Application in 2023Q1E
		MemoSorb® VSD Occluder IV (Biodegradable)	●	Launched	Launched	NMPA Approval in 2022Q1
	Patent ductus arteriosus occluder	MemoPart® PDA Occluder I (Double-rivet)		Launched	Launched	NMPA Approval in 2003 CE Mark in 2012
		MemoPart® PDA Occluder II (Single-rivet)		Launched	Launched	CE Mark in 2012
		MemoCama® PDA Occluder III (Oxide Coating)		Launched	Launched	NMPA Approval in 2021Q2 CE Application in 2023Q2E
	Patent foramen ovale occluder	MemoPart® PFO Occluder I (Double-rivet/ Single-rivet)		Launched	Launched	CE Mark in 2012
		MemoSorb® PFO Occluder II (Biodegradable)	○	Registration preparation		NMPA Application in 2022Q3E

	Product[1]		Pre-clinical	Clinical Trial[2]	Registration[3]	Next Milestone/ Actual Launch Time[4]
Occluder Products[5]	Left atrial appendage occluder	MemoLefort® LAA Closure Occluder I	●	Launched		NMPA Approval in 2020Q2
		LAA Closure Occluder II (Biodegradable)	○	Type inspection		Clinical Trial in PRC in 2022Q4E
	Interatrial shunt device	Interatrial shunt device I		Clinical trial		NMPA Application in 2023Q4E
		Interatrial shunt device II (Biodegradable)		Design stage		Clinical Trial in PRC in 2023Q3E
		Interatrial shunt device III (Radiofrequency ablation shunt device)		Type inspection		Clinical Trial in PRC in 2023Q4E
		Radiofrequency ablation device (Device)		Type inspection		Clinical Trial in PRC in 2023Q4E
	Vascular plug	MemoPart® Plug I (Double-rivet)		Launched		CE Mark in 2012[6]
		MemoPart® Plug II (Single-rivet)		Launched		CE Mark in 2012[6]
		MemoFlex® Plug III (Double-waist)		Clinical trial		NMPA Application in 2023Q4E
	Procedural accessories	MemoPart® interventional delivery system I		Launched		NMPA Approval in 2007 CE Mark in 2012
		Interventional delivery system II (Integrated)		Launched		NMPA Approval in 2018Q3 CE Mark in 2024Q2E
		Delivery system		Launched		NMPA Approval in 2021Q4
		Integrated interventional delivery system for Plug III	◀	Launched		NMPA Approval in 2021Q4
		Interventional delivery system (Biodegradable)	◀	Launched		NMPA Approval in 2022Q2
		MemoPart® Snare I		Launched		NMPA Approval in 2007 CE Mark in 2016
		Snare II (Multiple-loop Snare)	◀	Design stage		NMPA Application in 2022Q3E

	Product[1]		Pre-clinical	Clinical Trial[2]	Registration[3]	Next Milestone/ Actual Launch Time[4]
Heart Valve Products	Aortic valve products	Transcatheter aortic valve replacement ("TAVR") system	○	Clinical trial		NMPA Application in 2023Q4E
		Artificial heart valve with polymer leaflets for transcatheter implantation	Design stage			Clinical Trial in PRC in 2024Q4E
		Transcatheter aortic valve stenosis therapy system	Type inspection			Clinical Trial in PRC in 2023Q4E
		Pulsed acoustical generator	Type inspection			Clinical Trial in PRC in 2023Q4E
		Transcatheter aortic valve system (balloon dilation)	Type inspection			Clinical Trial in PRC in 2024Q4E
		Aortic valve perfusion system	Design stage			Clinical Trial in PRC in 2024Q4E
	Mitral valve products	Transapical mitral valve repair system (chordal) ("TMVCRS")	Clinical trial			NMPA Application in 2024Q3E
		Transapical mitral valve clip repair system ("TMVr-A")	○	Clinical trial		NMPA Application in 2023Q4E
		Transcatheter annulus repair system	Design stage			Clinical Trial in PRC in 2023Q4E
		Transfemoral mitral valve clip repair system ("TMVr-F")	○	Type inspection		Clinical Trial in PRC in 2022Q4E
		Transcatheter mitral valve replacement ("TMVR") system	Design stage			Clinical Trial in PRC in 2024Q4E
		Transcatheter papillary muscle repair system	Design stage			Clinical Trial in PRC in 2024Q4E



● Key products are (1) products that contributed the majority of our revenue in the Track Record Period and/or (2) products that we believe to have strong market potential.

○ Key product candidates are product candidates that we believe to have strong market potential and/or technological innovations.

▲ Among our products candidates, these devices are exempted from clinical trial requirements in accordance with the Newly Supplemented and Revised Catalogue of Medical Devices Exempted from Clinical Trials issued on December 13, 2019, and the Catalogue of Medical Devices Exempted from Clinical Trials (the Second Revised) issued on January 14, 2021.

(1) Our occluder products, including ASD occluder products, VSD occluder products, PDA occluder products, PFO occluder products and LAA occluder products, are designed to treat the respective heart defects. Our interatrial shunt device ("IASD") product candidates are designed to reduce left atrial hypertension. Our vascular plugs are designed for rapid vessel occlusion. Our heart valve product candidates, including aortic valve product candidates, mitral valve product candidates, tricuspid valve product candidates and pulmonary valve product candidate, are designed to treat the respective valvular diseases. Our portfolio of products and product candidates also includes occluder related procedural accessories and heart valve related procedural accessories.

(2) We plan to commence overseas clinical trial process for various product candidates. Specifically, we plan to commence clinical trial for the following product candidates: MemoSorb® ASD Occluder IV in the European Union and the United States in the fourth quarter of 2024; MemoSorb® VSD Occluder IV in the European Union and the United States in the fourth quarter of 2022 and the fourth quarter of 2023, respectively; MemoSorb® PFO Occluder II in the European Union and the United States in the fourth quarter of 2024; MemoLefort® LAA Occluder I in the European Union in the fourth quarter of 2022; interventional delivery system for biodegradable

occluders in the European Union and the United States in the fourth quarter of 2022 and the fourth quarter of 2023, respectively; TAVR system in the European Union in the fourth quarter of 2024; TMVr-A system in the European Union and the United States in the fourth quarter of 2025; and balloon dilatation catheter for aortic valve in the European Union in the fourth quarter of 2024. In addition, we plan to initiate clinical trial for LAA Closure Occluder II and IASD II in the European Union and the United States after 2025.

(3) Our MemoSorb® ASD Occluder IV, MemoSorb® PFO Occluder II, LAA Closure Occluder II, IASD I, IASD III, TAVR system, TMVCRS, TMVr-A system, TMVr-F system and transcatheter tricuspid valve repair system are eligible for the Green Path for Innovative Medical Device based on our preliminary assessment. Our LAA occluder products, biodegradable occluder product candidates and heart valve product candidates are generally subject to clinical trials upon commercialization for continued evaluation of efficacy and safety.

(4) "NMPA Approval" refers to the receipt of the registration certificate from the NMPA; "CE Mark" refers to the receipt of the CE Mark, which is required for products to be marketed in the European Union; "NMPA Application" refers to the application for the registration certificate with the NMPA; "CE Application" refers to the application for the CE Mark; and "E" following the years and quarters represents our current estimation. Registration certificates for medical devices in China are valid for five years and must be renewed by filing renewal applications with the NMPA or its local branches six months prior to the expiration date. CE Marks are also generally valid for five years and must be renewed by filing renewal applications with relevant CE notified bodies for conformity assessment. As of the Latest Practicable Date, we had attained valid CE Marks for nine of our products pursuant to the Medical Device Directive of the European Union (the "MDD"), all of which were granted in April 2021 and valid through May 2024 in accordance with the transition period permitted under the new Medical Device Regulation of the European Union (the "MDR"). We plan to make MDR applications going forward to renew existing, or apply for new, CE Marks.

Overseas market to which that our products were sold during the Track Record Period primarily comprises Russia, Brazil, Indonesia, India, Columbia, Pakistan, Egypt, Kazakhstan and Italy, where we have undergone the local registration process for each country and we relied on CE Marks during the registration process for each country except for Russia, Brazil and Columbia, where CE Marks are not mandatory. CE Marks are required for products sold within the European Economic Area, and the CE notified bodies designated by member states of the European Economic Area to assess the conformity of products before being placed on the market are competent authorities governing the CE certification procedure. In other countries, imported medical devices need to undergo their respective registration processes governed by local medical products administration or the equivalent regulatory agency prior to sale.

(5) "Double-rivet" refers to the design feature that massages and fixes the occluder with two rivets each on one of the two outward-facing sides of the occluder; "single-rivet" refers to the design feature that massages and fixes the occluder with a single rivet on the outward-facing side of the right disc of the occluder; and "double-waist" refers to the design feature that uses two waists (instead of one) to connect the discs of the occlusion device in order to increase the occlusion area and improve adaptation to vascular diseases.

(6) The CE Marks for our MemoPart® Plug I and MemoPart® Plug II expired in April 2021, and we had terminated related sales upon the expiration. We voluntarily chose not to renew such CE Marks considering the insignificant revenue contribution of vascular plug products during the Track Record Period, the time and expenses involved in renewing the CE Marks, and more importantly, the promising research and development progress of MemoFlex® Plug III, which we expect to have greater market potential based on a review of market conditions.

All of our products and product candidates are or are designed to be Class III medical devices. None of our medical devices was included under the centralized procurement regime in China during the Track Record Period and up to the Latest Practicable Date. As of the Latest Practicable Date, 13 of our marketed products in China are covered by medical insurance scheme at the provincial level*. Whether a product is included in the medical insurance reimbursement coverage may impact the prices our end customer pay for our products. However, medical insurance reimbursement coverage has no direct impact on the pricing of our products to our customers, including primarily distributors and hospitals. Such pricing is generally determined by the public prices, which are determined through the public tender processes organized by the procurement platforms.

Our Platform

We have established a comprehensive and synergistic platform with strong research and development, manufacture and commercialization capabilities, which contributes to our sustainable growth.

Research and development. We have established research and development centers in Beijing and Shanghai and have developed in-house expansive and evolving portfolio of intellectual property rights relating to our products, product candidates and technologies, including 228 registered patents and 55 pending patent applications in China as of the Latest Practicable Date. We have received numerous awards and accolades, including the second prize of the National Science and Technology Progress Award (國家科學技術進步獎二等獎), the first prize of the Shanghai Science and Technology Award (上海市科學技術一等獎) and the first prize of the Shanghai Medical Technology Award (上海市醫學科技一等獎). We maintain continuous collaboration with hospitals, research institutions and KOLs to ensure that our research and development progress is capable of addressing the evolving needs of patients and physicians. During such collaboration, we lead the research and development process of our products. Specifically, we completed the world's first fully biodegradable VSD occluder implantation in February 2018 during its clinical trial, which marked a breakthrough in the field of fully biodegradable occluders globally, according to the F&S Report. We have also collaborated with a prominent medical institution in China in the research and development of our TAVR system which is expected to be 100% deployable, retrievable and repositionable before decoupling from the delivery system. In addition, we have collaborated with the

* Specifically, our MemoPart® ASD Occluder I, MemoPart® VSD Occluder I, MemoPart® PDA Occluder I, MemoPart® interventional delivery system I, MemoPart® Snare I and interventional delivery system II were eligible for medical insurance reimbursement in all the provinces, autonomous regions and municipal cities in China. Our MemoCarna® ASD Occluder III, MemoCarna® PDA Occluder III, MemoLefort® LAA Closure Occluder I, MemoCarna® VSD Occluder III, integrated interventional delivery system for Plug III, delivery system and interventional delivery system (biodegradable) were subject to medical insurance reimbursement in certain provinces in China, such as Shanghai, Tianjin, Jiangsu province, Anhui province, Guangdong province, Guangxi Zhuang autonomous region, Fujian province, Yunnan province, Guizhou province, Liaoning province, Henan province, Shandong province, Gansu province, Shaanxi province, Xinjiang Uygur autonomous region, Inner Mongolia autonomous region, Zhejiang province, Tibet autonomous region, Shanxi province, Beijing, Hebei province, Heilongjiang province, Sichuan province, Chongqing, Qinghai province, Jiangxi province, Hainan province, Hunan province, Hubei province and Ningxia Hui autonomous region.

National Engineering Research Center for Biomaterials (國家生物醫學材料工程技術研究中心) to conduct research on biodegradable materials, through which we have optimized biodegradable product design and strengthened our techniques in degradation rate control, which plays a key role in the development of our biodegradable occluder product and product candidates. As of the Latest Practicable Date, we had 30 major product candidates at various development stages, including our biodegradable occluders and heart valve product candidates, which we expect to compete favorably in the market with their unique designs and advanced features. In addition, we had accumulated considerable experience in product registration and launch in the European Union and attained valid CE Marks for nine of our products as of the Latest Practicable Date.

Manufacture. We have accumulated expertise and established practice protocols, which serves to ensure the precision, efficiency and safety of our manufacturing process. We conduct substantially all the key manufacturing procedures in-house except for sterilization. We believe our manufacturing capabilities have served to maintain effective quality control and cost control. Our quality control team participates in our daily operations, such as product design and development, raw material supply and procurement, product manufacturing and delivery, and after-sales follow-ups, to ensure the quality management of our products. We have also established a three-tier quality control system based on (1) domestic medical device laws and regulations, (2) EU medical device laws and regulations as well as (3) the relevant international quality authentication standard to monitor all aspects throughout the product lifecycle.

Commercialization. We have a proven track record of commercializing 13 products in China and 11 products overseas both by ourselves and through historical collaboration with the Retained Lepu Medical Group. Consistent with industry practice, we sell our products both directly to hospitals and through distributors covering all provinces, municipalities and autonomous regions in China. As of June 30, 2022, we had established a nationwide network of 288 distributors covering 878 hospitals. In China, we generally operate a single-layer distribution system which allows us to understand and manage the market demand. We historically collaborated with the Retained Lepu Medical Group to sell our products overseas. See "Connected Transactions — Non-Exempt Continuing Connected Transactions" and "— Sales, Distribution and Marketing — Sales Arrangements." We believe direct distribution arrangement with such distributors allows for more control over our overseas distributor networks and better understanding of overseas market demands. We have also built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution.

Our business grew rapidly during the Track Record Period. Our revenue increased by 27.3% from RMB116.5 million in 2019 to RMB148.2 million in 2020, and further increased by 50.1% to RMB222.6 million in 2021. Our revenue increased by 12.5% from RMB111.0 million in the six months ended June 30, 2021 to RMB124.8 million in the six months ended June 30, 2022. Our net profit increased by 32.5% from RMB51.9 million in 2019 to RMB68.8 million in 2020. Our net profit decreased by 14.6% to RMB58.7 million in 2021. Our net profit

decreased by 41.9% from RMB41.8 million in the six months ended June 30, 2021 to RMB24.3 million in the six months ended June 30, 2022. Our net profit margin was 44.6%, 46.4%, 26.4%, 37.6% and 19.4% in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively.

COMPETITIVE STRENGTHS

We believe the following competitive strengths have contributed to our success and differentiated us from our competitors.

Pioneer specializing in interventional medical devices targeting structural heart diseases, with a leading position in CHD treatment and early-mover advantages in cardioembolic stroke prevention

We have been dedicated to the research, development, manufacture and commercialization of interventional medical devices primarily targeting structural heart diseases, with a track record spanning over two decades. We are a leading interventional medical device provider in China for CHD in terms of market share in China's CHD occluder products market in 2021, with a broad portfolio of marketed and pipeline products, according to the F&S Report. We are the largest manufacturer of CHD occluder products and the related procedural accessories in China, with a market share of 38.0% in terms of revenue recognized for the sales in China in 2021, according to the same source. In China, domestic CHD manufacturers dominated the market with market share of approximately 91.5% in 2021, with the remaining approximately 8.5% occupied by international CHD manufacturers.

As of the Latest Practicable Date, we had a comprehensive occluder product portfolio of 20 marketed occluder products and nine occluder product candidates, including primarily (1) various CHD occluder products and (2) PFO occluder products and LAA occluder products for prevention of cardioembolic stroke and related symptoms. In particular, in respect of CHD, our occluder products target a series of conditions for patients of all ages, including ASD, VSD, and PDA, the common types of CHD. The total number of CHD procedures performed in 2021 was approximately 52,800, among which approximately 52.6% were for patients under age 18. The total number of CHD procedures performed in 2030 is expected to grow to 85,259, among which approximately 61.0% is expected to be for patients under age 18. As of the Latest Practicable Date, we had obtained 13 NMPA registration certificates for Class III medical devices and valid CE Marks for eight of our CHD occluder products and related procedural accessories. We have also developed a robust product pipeline to achieve a more extensive product offering. See "— Our Products."

We have marketed PFO and LAA occluder products, which prevent cardioembolic stroke and related symptoms, including migraine, peripheral arterial embolism, and decompression sickness. According to the F&S Report, as the major interventional medical devices targeting cardioembolic stroke, PFO and LAA occluder therapies are still at an emerging stage with their first adoption in China in 2014, much later than drug treatment. As of the Latest Practicable Date, there were only eight players in China that had marketed PFO and/or LAA occluder

products, according to the same source. As a result of the growing number of patients and a relatively low penetration rate of such therapies in China, being approximately 42.4% for PFO occluder products and approximately 5.9% for LAA occluder products in 2021, the market size of China's PFO occluder products market is expected to increase from RMB187.1 million in 2021 to RMB370.0 million in 2025 at a CAGR of 18.6%, and the market size of China's LAA occluder products market is expected to increase from RMB0.5 billion in 2021 to RMB2.1 billion in 2025 at a CAGR of 43.2%, according to the same source. In addition, the market size of the global PFO occluder products market is expected to increase from US$189.2 million in 2021 to US$432.2 million in 2025 at a CAGR of 22.9%, and the market size of the global LAA occluder products market is expected to increase from US$0.9 billion in 2021 to US$1.9 billion in 2025 at a CAGR of 20.3%, according to the same source. As of the Latest Practicable Date, we had launched our first-generation PFO occluder product with one CE Mark and first-generation LAA occluder product with one NMPA registration certificate for Class III medical devices. Our newly launched LAA occluder product has demonstrated therapeutic effects in clinical trials with a 100% operation success rate and reached an LAA closure rate of 97.6% after 12 months following the operation, with no probability of post-operative ischemic stroke. As of the Latest Practicable Date, our biodegradable LAA occluder product candidate was in the stage of type inspection, designed to degrade over time into carbon dioxide and water upon the completion of endothelial repair. We believe we are well-positioned to capitalize on the significant growth potential in these fast-growing and under-penetrated markets, leveraging our early-mover advantages, advanced product features (such as the ease of use, effective closure and safety record), and established sales channels for CHD occluder products.

Advanced biodegradable technology to capture significant market demand for sought-after therapeutic and safety benefits

We are a forerunner in the adoption of biodegradable technology in occluder products, according to the F&S Report. As of the Latest Practicable Date, we were the only provider of biodegradable occluder product which was commercialized in the global market, according to the same source. We have accumulated extensive know-how and experience in biodegradable technology, from material selection to meet various occluder performance requirements, structural design to ensure secure and firm occluder clamping, and controlled biodegradation to facilitate the tissue repair process, to proprietary product processing techniques, including biodegradable wire mesh technology, heat molding technology, vacuum drying and sterilization control technology, and water-proof packaging technology, to enhance occluder performance and validity.

Compared with traditional metal occluders, biodegradable occluders are designed to degrade over time into carbon dioxide and water upon completion of endothelial repair, according to the F&S Report. Our design for biodegradable occluder product and product candidates not only ensures effective autologous tissue closure but also minimizes potential compression and wear on surrounding tissues caused by metal implants, which lowers the risk of long-term complications. In addition, we believe it leaves available for patients additional future treatment options, especially transseptal procedures, as the biodegradable occluders

would not be a permanent implant in the human body, benefiting all patients receiving occluder implants, and in particular, to children who constitute the majority of patients suffering from CHD and also expect a significantly longer remaining life span and better life quality, according to the F&S Report.

We remain focused on upgrading our occluder products with biodegradable technology. Our fully biodegradable MemoSorb® VSD Occluder IV was approved by the NMPA in February 2022. Our other occluder candidates featuring biodegradable materials have advanced to various pre-launch stages. As of the Latest Practicable Date, our biodegradable ASD occluder product candidate was in the clinical trial stage, our biodegradable PFO occluder product candidate was in the registration preparation process with the NMPA, and our biodegradable LAA occluder product candidate was in the stage of type inspection.

Most comprehensive product portfolio of heart valve product candidates with early-mover advantages in mitral valve product candidates in China

We have cultivated a comprehensive pipeline of interventional heart valve product candidates covering all of the major valvular diseases, including primarily aortic valve diseases, mitral valve diseases, and tricuspid valve diseases. We have assembled a specialized in-house research and development team with extensive expertise in heart valve products, which allows us to develop products with unique designs and notable preclinical research results. As of the Latest Practicable Date, we had nine pending patent applications in China for our heart valve product candidates.

According to the F&S Report, China's valvular disease interventional device market is still at its emerging stage with limited commercialized products in the market, with the market size expected to increase from RMB1.0 billion in 2021 to RMB7.9 billion in 2025 at a CAGR of 69.8%, and the number of TMVr operations to be performed is expected to grow from approximately 190 in China with a penetration rate of 0.002% for the TMVr operations in 2021 approximately 9,970 and 0.08% by 2025. We have the most comprehensive product portfolio of heart valve product candidates in China, with 21 major product candidates as of the Latest Practicable Date, and we are among the few early-movers that initiated the research and development of product candidates targeting mitral valve diseases, according to the same source.

Our mitral valve products under development, designed for delivery via transapical and/or transfemoral access, include primarily the TMVCRS, TMVr-A system, and TMVr-F system. As of the Latest Practicable Date, our TMVr-A system, which was in the clinical trial stage, was among only seven domestic products of similar properties and for similar indications in the clinical trial stage, according to the F&S Report. As of the same date, our TMVCRS was in the clinical trial stage and our TMVr-F system was in the stage of type inspection. We plan to submit registration application with the NMPA for TMVCRS in the third quarter in 2024, submit registration application with the NMPA for TMVr-A system in the fourth quarter of 2023, and initiate the clinical trial for TMVr-F system in the fourth quarter of 2022 in China and submit registration application with the NMPA in the fourth quarter of 2024.

The upper clamping arms of our TMVr-A and TMVr-F systems are independently controllable by manipulating a pulling wire, with each of the clamping arms holding one of the mitral valve leaflets. The central spacer in between the two upper clamping arms of our TMVr-A and TMVr-F systems is coated with PET skirt to fill the internal space and further reduce the regurgitation. Our TMVr-A system is designed to be paired with one of the thinnest delivery sheaths to minimize potential damage to the heart. Furthermore, our TMVr-A system can be delivered through a straight-forward transapical delivery, allowing better manipulation and handling of the system and reduced handling time. Our TMVr-A system is also deployable under the guidance of ultrasound, without the need for radiation during the procedure. The higher level of control and operability, as compared to other existing competing products, serves to reduce the duration and difficulty of TMVr procedures, which we believe will be a key competitive edge of our TMVr-A system.

As of the Latest Practicable Date, we had conducted research and development for a wide range of product candidates targeting aortic valve diseases, including our TAVR system, transcatheter aortic valve system (balloon dilation), artificial heart valve with polymer leaflets for transcatheter implantation, transcatheter aortic valve stenosis therapy system, and pulsed acoustical generator.

China's TAVR system is expected to grow from RMB0.9 billion in 2021 to RMB4.9 billion in 2025 at a CAGR of 52.0%, according to the F&S Report. The number of TAVR operations to be undertaken in China annually is expected to grow from 6,600 in 2021 to 43,000 in 2025 at a CAGR of 59.6%, according to the same source. Our TAVR system, which was in the clinical trial stage as of the Latest Practicable Date, is expected to be 100% deployable, retrievable and repositionable before decoupling from the delivery system, and such features are not present in any commercialized TAVR systems in China as of the Latest Practicable Date, according to the F&S Report. Those features allow physicians multiple attempts to adjust the position of the TAVR system during the procedure, which may significantly improve the overall procedure success rate and lower the risk of post-operative complications, according the same source. As of the Latest Practicable Date, our TAVR system was one of 10 domestic TAVR systems that entered into clinical trial stage. The results from animal studies for our TAVR system have demonstrated anticipated loading, positioning, releasing and retrieving performance. We also completed the type inspection by the NMPA in December 2020. We had initiated the clinical trial as of the Latest Practicable Date and expect to submit registration application with the NMPA in the fourth quarter of 2023.

Validated platform backed by strong research and development and manufacturing capabilities

Strong product research and development capability is the cornerstone of our validated, industry-leading platform. As of the Latest Practicable Date, we had obtained a total of 14 NMPA registration certificates for Class III medical devices and valid CE Marks for nine of our products. Our research and development capability also enables us to build an expansive and evolving product pipeline. As of the Latest Practicable Date, we had 30 major product candidates in our pipeline, of which one was in the registration process with the NMPA, two in the registration preparation process with the NMPA, seven in clinical trials, nine in the type inspection stage, and 11 in the product design stage.

We have built our research and development team with technological expertise in various areas, primarily including nitinol shape memory cutting and braiding techniques, animal source material processing techniques, biodegradable material controlled release techniques, suturing techniques, and structure design and processing techniques. As of the Latest Practicable Date, our research and development team had a total of 78 members, with approximately 39.7% holding a master's or higher degree in relevant fields. We have developed a significant portfolio of intellectual property rights in relation to our technologies and products. As of the Latest Practicable Date, we had 229 registered patents and 55 pending patent applications in China. We have received numerous awards and accolades, including the second prize of the National Science and Technology Progress Award (國家科學技術進步獎二等獎), the first prize of the Shanghai Science and Technology Award (上海市科學技術一等獎), and the first prize of the Shanghai Medical Technology Award (上海市醫學科技一等獎). Our in-house team closely monitors technological advancements and industry trends globally, to actively facilitate the iterative innovations and value exploration of our existing technologies and products.

We maintain continuous collaboration with hospitals, research institutions and KOLs to ensure that our research and development progress is capable of addressing the evolving needs of patients and physicians. We retain the ownership of substantially all of the technologies, patented and unpatented, developed from such collaborations. We have also collaborated with a prominent medical institution in China in the research and development of our TAVR system which is expected to be 100% deployable, retrievable and repositionable before decoupling from the delivery system. In addition, we have collaborated with the National Engineering Research Center for Biomaterials (國家生物醫學材料工程技術研究中心) to conduct research on biodegradable materials, through which we have optimized biodegradable product design and strengthened our techniques in degradation rate control, which plays a key role in the development of our biodegradable occluder product and product candidates.

We have solid manufacturing capabilities supported by our experienced production team, advanced manufacturing facilities, and strict quality control standards. We have applied our core technologies, such as nitinol braiding and heat processing, to optimize the blocking effect of our occluder products. For our heart valve product candidates, we have independently implemented a valve leaflet processing procedure using our animal source material processing platform and a valve frame processing procedure using our nickel-titanium alloy platform, both of which were developed in-house. We also conduct substantially all the key manufacturing procedures in-house except for sterilization. We believe our manufacturing capabilities have served to maintain effective quality control and cost control. We strictly adhere to industry norms for our medical device production quality management and strive to maintain stable production and quality control teams and supply chains to ensure stable production of consistently high-quality products. Our quality control team participates in our daily operations, such as product design and development, raw material supply and procurement, product manufacturing and delivery, and after-sales follow-ups, to ensure the quality management of our products. We have also established a three-tier quality control system based on (1) domestic medical device laws and regulations, (2) EU medical device laws and regulations as well as (3) the relevant international quality authentication standard to monitor all aspects throughout the product lifecycle.

Extensive distributor network and effective academic promotion and marketing capability

We have a proven track record of commercializing 13 products in China and 11 products overseas both by ourselves and through historical collaboration with the Retained Lepu Medical Group. Leveraging our extensive network of distributors and effective academic promotion and marketing capability, our products reached 878 hospitals in China as of June 30, 2022, including 503 Class III Grade A hospitals. We believe we can leverage our established sales network to market our product candidates, as we have established our reputation among cardiologists, distributors, and most importantly, patients over the years. We believe our industry-leading sales channels and growing penetration in hospitals serve to solidify our competitive edge in the market, which will allow us to cross-sell existing products and rapidly ramp up the future sales of our product candidates. With these considerable early-mover advantages, we believe we are well-positioned to capture the upside potential when commercializing our product candidates for cardioembolic stroke and valvular diseases. Consistent with industry practice, we sell products both directly to hospitals and through our extensive network of distributors covering all provinces, municipalities and autonomous regions in China.

We generally operate a single-layer distribution system in China which allows us to understand and manage the market demand. We are selective in engaging distributors and have developed longstanding and stable business relationships with most of our major distributors. We also historically collaborated with the Retained Lepu Medical Group to sell our products to 41 countries and regions outside China. Through gradual termination of our cooperation with the Retained Lepu Medical Group for the distribution of our products overseas, as of September 30, 2021, we had entered into distribution agreements with overseas distributors directly, except for India. See "Connected Transactions — Non-Exempt Continuing Connected Transactions" and "— Sales, Distribution and Marketing — Sales Arrangements." We have built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution.

We market our products to hospitals through academic promotion and marketing, including product introduction, technical training, surgical assistance and live surgery broadcast, and have established research and clinical collaboration and training relationships with numerous hospitals, physicians and KOLs. We actively participate in medical conferences and industry exhibitions and host meetings and seminars to introduce our products to physicians. We believe that such meetings and conferences are key opportunities for us to showcase our products and product candidates and can increase our market recognition.

Experienced and visionary senior management team with strong support from our shareholder

Our management team has been intimately involved in the medical device industry for decades, with in-depth industry knowledge, extensive managerial and operational experience, and long-term focus and commitment, to drive our current accomplishment. Our core management team members have worked collaboratively for more than eight years in introducing the state-of-the-art interventional medical devices targeting structural heart diseases to the domestic market and advance favorable industry development in China. Our management team has played a vital role in our strategic development, efficient clinical planning of our products, and marketing network cultivation. Dr. CHEN Juan, our Executive Director, chairman of the Board of Directors and general manager, has over 20 years of extensive industry and management experience mainly in the medical device and healthcare industry. Dr. Chen is a leading figure in the medical device industry in Shanghai and is the co-inventor of 17 invention patents. Ms. ZHANG Yuxin, our Executive Director, vice general manager and senior engineer, is the head of our research and development department. Ms. Zhang has more than 10 years of medical device research and development experience and is the co-inventor of more than 30 patents. Ms. Zhang won the second prize of the 2012 Beijing Science and Technology Award (北京市科學技術獎二等獎) from the Beijing Municipal People's Government. Ms. ZHANG Xiani is our deputy general manager responsible for sales and marketing affairs, with more than 10 years of experience in the healthcare industry. Ms. Zhang has acute market sense with strong operational capabilities. We are also constantly driven by our corporate culture of pursuing excellence, which we believe has helped to reinforce our market position and brand recognition.

In addition to our seasoned management team, we have also benefited from strong support from Lepu Medical, one of our Controlling Shareholders, which is a well-known public company listed on the Shenzhen Stock Exchange (stock code: 300003). Lepu Medical has established a renowned reputation among physicians, which we believe could support our continued growth with its market recognition and industry resources.

GROWTH STRATEGIES

We intend to pursue the following strategies to further grow our business.

Promote the development and clinical trial progress of our product candidates

As of the Latest Practicable Date, we had seven product candidates undergoing clinical trial. We plan to continue to advance the development and promote the clinical trial progress of our product candidates in the following fields.

Valvular diseases. For our heart valve product candidates, we will continue to advance the development of our aortic valve product candidates and mitral valve product candidates, especially our TMVCRS, TMVr-A system, and TMVr-F system targeting mitral valve diseases, to achieve comprehensive coverage in the treatment of mitral valve regurgitation. According to the F&S Report, the number of TMVr operations to be performed is expected to grow from approximately 190 in China with a penetration rate of 0.002% for the TMVr operations in 2021 and approximately 9,970 and 0.08% by 2025. In addition, the number of TMVr operations performed and the penetration rate of TMVr operations globally were 27,700 and 0.3% in 2021, respectively. Leveraging the experience accumulated from developing our transcatheter biological aortic valve product candidates, we will develop more products with similar functions through our leaflet processing platform and nickel-titanium alloy platform. Specifically, we commenced clinical trial for our TMVCRS in February 2022. For our TMVr-A system, which was in the clinical trial stage in China as of the Latest Practicable Date, we plan to initiate the clinical trial in both the European Union and the United States in the fourth quarter of 2025, and for TMVr-F system, we plan to initiate the clinical trial in the fourth quarter of 2022 in China, and overseas clinical trial in both the European Union and the United States in the fourth quarter of 2025. We also intend to use sonic balloon technology that delivers ultrasound shockwaves to break up calcified plaques in patients with aortic artery disease to further develop non-implanted transcatheter aortic valve products to enrich our product coverage treating valvular diseases.

Cardioembolic stroke. We will continue to promote the research and development of our biodegradable PFO occluder product candidate and LAA occluder product candidate. According to the F&S Report, there were 4.5 million people suffering from cardioembolic stroke in China in 2021. According to the same source, in 2021, the penetration rate of PFO occluder products in China was 42.4%; and the penetration rate of LAA occluder products in China was 5.9%, compared to 44.9% in the United States and 14.6% in Europe. We believe we are well-positioned to capitalize on the significant growth potential in these fast-growing and under-penetrated markets, leveraging our early-mover advantages, advanced product features (such as the ease of use, effective closure and safety record), and established sales channels for CHD occluder products. As of the Latest Practicable Date, our biodegradable PFO occluder product candidate was in the registration preparation process with the NMPA, and we plan to initiate overseas clinical trial in both the European Union and the United States in the fourth quarter of 2024. For our LAA occluder product candidate, we expect to initiate overseas clinical trial for our first generation LAA occluder product candidate in the European Union in the fourth quarter of 2022; and we expect to initiate the clinical trial for our biodegradable LAA occluder product candidate in the fourth quarter of 2022 in China, and overseas clinical trial in both the European Union and the United States thereafter.

CHD. We will leverage our established market advantages to quickly achieve the commercialization of our occluder product candidates with oxide coating or using biodegradable materials. We will also continue to promote the development of our biodegradable occluder product candidates. As of the Latest Practicable Date, our biodegradable ASD occluder product candidate was in the clinical trial process in China, and we plan to initiate overseas clinical trial in both the European Union and the United States in the fourth quarter of 2024. For our biodegradable VSD occluder product, we plan to initiate overseas clinical trial in the European Union in the fourth quarter of 2022 and in the United States in the fourth quarter of 2023.

In 2022, we obtained the NMPA approval for our biodegradable VSD occluder in February 2022 and the NMPA approval for our interventional delivery system for biodegradable occluders in May 2022. From 2023 to 2024, we plan to launch 14 new products, including our biodegradable ASD occluder product candidate, biodegradable PFO occluder product candidate, TAVR system, and TMVr-A system, which are in various pre-launch stages. In addition, we have several product candidates currently at the product design and development stage, including artificial heart valve with polymer leaflets for transcatheter implantation and TTVRS. We aim to advance these product candidates to the clinical trial and registration stage rapidly to retain early-mover advantages among competitors.

Continue to enhance research and development capabilities

We will continue to develop new technologies and focus on the core technologies and product development targeting structural heart diseases to broaden our product portfolio to target a greater spectrum of heart diseases. Leveraging our in-depth industry knowledge, we have developed product candidates which we believe have significant market potential, and we will continue to promote the research and development of these and other product candidates, including the transcatheter heart valve product candidates for artificial valve leaflets. Furthermore, we will continue to develop our biodegradable technology in various aspects, including material innovation, structural design, controlled biodegradation and product processing, to optimize the biodegradable properties with enhanced product functions and features. We believe our biodegradable technology, as applied to our occluder product and product candidates, will drive industry transformation, which in turn positions us well to capitalize on the significant market opportunities.

We will further enhance our research and development capabilities to solidify our leading position in the industry. We intend to recruit approximately 70 to 100 staff responsible for research and development activities and registration of our medical devices. We will provide more training resources and learning opportunities for our core technical personnel, improve their technical skills, and offer more competitive compensation packages to maintain sufficient human resources for product development and future growth. In addition, we may strategically collaborate with academic institutions or medical associations on developing new products in the field of CHD occluder products, PFO occluder products and LAA occluder products targeting cardioembolic stroke and related symptoms, and heart valve products, to broaden our product portfolio.

Expand brand exposure and market share in China

We will expand our sales and marketing team and explore potential marketing channels. We plan to recruit approximately 100 to 150 sales and marketing personnel to continue to expand our sales network in China. In addition, we plan to continue to build our brand reputation among doctors and patients. We will continue to implement academic promotion activities to solidify and strengthen our network of research institutions, hospitals, physicians and KOLs, obtain valuable feedback from industry experts, and promote brand awareness and influence in the industry and academia, which we believe are crucial to our ability to increase the sales of our products and launch our product candidates. Furthermore, we plan to build a product display and training center at our headquarters, where we will showcase product samples and offer training sessions to physicians and hospitals to explain the implementation of our products so that they will become more familiar with our products and brand. Through such interactions, we believe we can help physicians enhance procedural and clinical proficiency and promote the brand awareness of our products.

Additionally, we intend to further enhance our sales and marketing capabilities through enhanced management of our distributors. We plan to provide more technical training sessions for product information and know-how to our distributors and more frequently assess their knowledge and performance so that they will gain deeper understanding for the features and advantages of our products, facilitating their recommendation and promotion of our products to hospitals and physicians. We also intend to establish a sales and marketing center at our headquarters to promote more frequent communications among our sales and marketing staff and our distributors to identify market opportunities, formulate and execute more targeted commercialization and distribution strategies, and plan for more effective academic promotion and marketing activities.

Furthermore, we will leverage our established network of distributors to commercialize our existing and future product candidates. We plan to initiate the promotion of these products in Class III Grade A hospitals, the top-tier hospitals where we have a broad network of influential physicians and KOLs as well as an extensive distributor coverage. Our products reached 878 hospitals in China, including 503 Class III Grade A hospitals, as of June 30, 2022. We believe this is a cost-effective manner to ramp up sales of new products at the initial launch stage. We also plan to gradually penetrate into lower-tier hospitals to expand our sales coverage.

Expand our global footprint by increasing product development and commercialization and broadening overseas sales channels

We plan to expand our sales and increase our brand recognition in global markets. We generated revenue from the Retained Lepu Medical for products sold overseas of RMB7.8 million, RMB28.0 million, RMB10.2 million, RMB8.5 million and RMB0.6 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, accounting for 6.7%, 18.9%, 4.6%, 7.7% and 0.5% of our total revenue in the same periods, respectively. Depending on the market demand and conditions, we plan to commence necessary overseas clinical trial process for select product candidates and gradually complete overseas registration for our product candidates in target markets. We plan to purchase materials and equipment, conduct animal studies, clinical trials, inspections and registration, and engage local agencies and consultants for clinical trials and registration matters. We also intend to accelerate the commercialization of our biodegradable occluder product and product candidates and heart valve product candidates in overseas markets such as the European Union, Southeast Asia and the United States.

During the Track Record Period, our products were sold overseas to 44 countries and regions in Asia, Europe, America and Africa. We plan to collaborate with international distributors to cover overseas markets primarily consisting of the European Union, Southeast Asia and the United States in the next five years. As of September 30, 2021, we had terminated our cooperation with the Retained Lepu Medical Group for the distribution of our products overseas and entered into distribution agreements with overseas distributors directly, except for India. See "Connected Transactions — Non-Exempt Continuing Connected Transactions" and "— Sales, Distribution and Marketing — Sales Arrangements." We have built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution. We also plan to expand our own overseas business team to formulate and execute our business development strategy, establish overseas offices, participate in medical conferences and industry exhibitions and seek collaboration opportunities with local sales channels in select overseas markets.

Selectively pursue strategic investments and acquisitions

We plan to actively seek opportunities for strategic acquisitions or investments to strengthen our research and development capabilities, expand our product portfolio, and enhance our market position. The types of opportunities on which we intend to focus include, among others, (1) companies that offer products or product candidates which complement our product portfolio and that we do not currently produce; (2) companies that manufacture product components for occluder or heart valve products which can enhance our upstream supply, strengthen our bargaining power, and achieve potential synergies along the industry value chain; and (3) companies with advanced technologies or research and development capabilities that represent significant future growth opportunities, with which we can collaborate on technology and product development, registration and commercialization. We may consider acquisitions, in-licensing, or other forms of collaborations.

For investments and acquisitions related to products and product components, we intend to primarily consider domestic companies leveraging our in-depth understanding of China's interventional medical device market targeting structural heart diseases, which we believe will enable us to effectively identify suitable targets and execute our investment and acquisition strategies. For investments and acquisitions related to advanced technologies or strong research and development capabilities primarily in the field of biodegradable materials, we expect to focus mainly on overseas opportunities in countries and regions such as the United States and Europe, where more cutting-edge technologies and products related to interventional medical devices are under development, according to the F&S Report. As advised by our industry consultant based on its industry research as of the Latest Practicable Date, there were more than 40 companies in China and overseas markets which may be considered as potential targets for investment and acquisition, subject to further commercial consideration and assessment. Our Directors confirm that we had not identified any specific acquisition targets, formed any specific acquisition plans or entered into any agreements with potential targets as of the Latest Practicable Date.

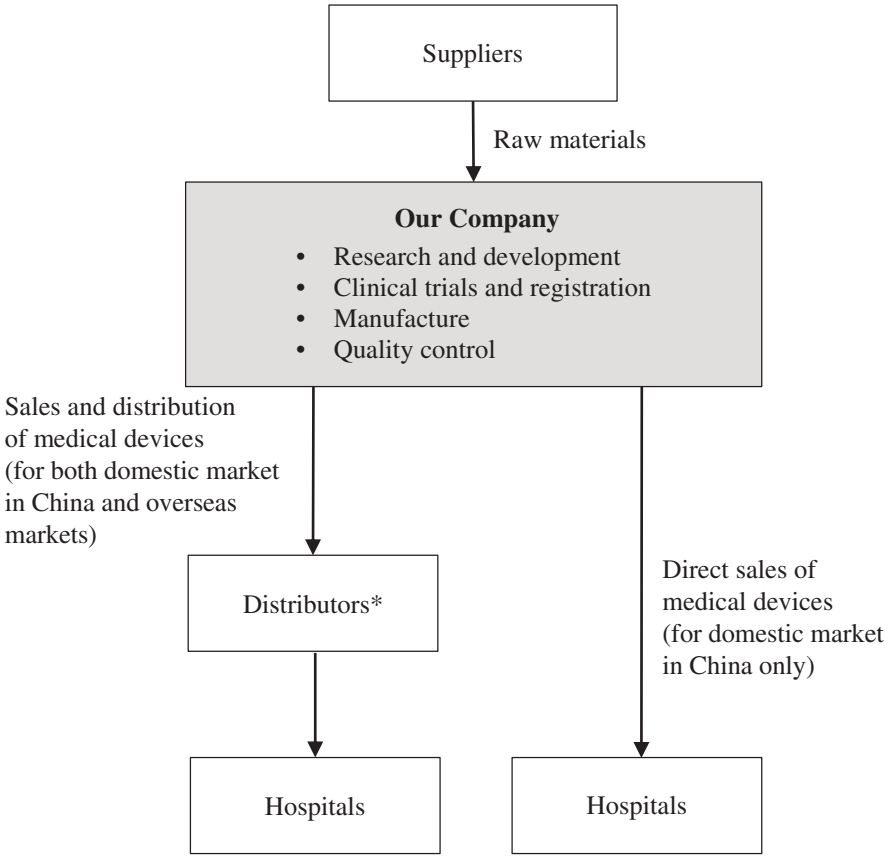
Expand our production capabilities to support future growth

In response to our increasingly rich product portfolio and growing demand for our products, we will continue to expand our production capacity by purchasing more machinery and equipment and installing new product lines. We plan to enhance the production capacity for our marketed products by purchasing more machinery and equipment. We also intend to install several new product lines, including production lines for biodegradable occluder product and product candidates with expected annual production capacity of approximately 8,000 to 10,000 units of occluder products and production lines for heart valve product candidates with expected annual production capacity of approximately 3,000 to 5,000 units of heart valve products.

Specifically, we plan to purchase additional machinery and assembly lines, automatic packaging and quality inspection equipment, as well as specific molds for our biodegradable occluder product and product candidates and heart valve product candidates. We also plan to recruit approximately 30 to 50 production personnel and provide training to our production personnel on the operation of new machinery and equipment, on the product knowledge, and on the manufacturing technique, skill and processes of new products. Additionally, we plan to expand and upgrade laboratories and manufacturing facilities. To facilitate our manufacturing activities, we plan to expand and upgrade our physics, chemistry, and micro-biology laboratories. We also plan to renovate our manufacturing facilities, refine our clean air-conditioning and purified water systems, and build additional ancillary facilities.

OUR BUSINESS MODEL

We have been dedicated to the research, development, manufacture and commercialization of interventional medical devices primarily targeting structural heart diseases, with a track record spanning over two decades. We have established a validated business model empowered by our technological capabilities and accumulated operational experience. Employees of different functional teams collaborate on our platform to guide the pathway for our products and product candidates from product design to sales and distribution. The following diagram illustrates our business model.



* We historically collaborated with the Retained Lepu Medical Group to distribute our products overseas. See "Connected Transactions — Non-Exempt Continuing Connected Transactions" and "— Sales, Distribution and Marketing — Sales Arrangements" for details.

OUR PRODUCTS

As of the Latest Practicable Date, we had a comprehensive portfolio of 50 products and major product candidates covering three key market segments in the interventional medical device industry targeting structural heart diseases, including primarily CHD, cardioembolic stroke and valvular diseases. We categorize our product portfolio into two major segments, i.e., occluder products and heart valve products. As of the Latest Practicable Date, we had developed a comprehensive product portfolio of occluder products and product candidates,

including primarily (1) various CHD occluder products and (2) PFO occluder products and LAA occluder products for prevention of cardioembolic stroke and related symptoms, including migraine, peripheral arterial embolism, and decompression sickness. As of the Latest Practicable Date, we had also conducted research and development for a wealth of heart valve product candidates, including primarily aortic valve and mitral valve product candidates. As of the same date, our business focused on occluder products and our heart valve product candidates in various pre-launch stages without marketed heart valve products. For a summary of our major products and product candidates as of the Latest Practicable Date, see "— Overview — Product Portfolio." For regulatory pathways for our commercialized products and product candidates, see "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices."

The following table sets forth a breakdown of our revenue by major product for the periods indicated.

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total
	(RMB in thousands, except for percentages)						*(Unaudited)*			
CHD occluder products	86,716	74.5	106,609	71.9	132,473	59.5	64,123	57.8	90,699	72.7
ASD occluder products[(1)]	56,058	48.1	69,677	47.0	99,809	44.8	47,791	43.1	71,270	57.1
VSD occluder products	19,322	16.6	22,076	14.9	19,771	8.9	9,958	9.0	10,287	8.2
PDA occluder products	11,336	9.8	14,856	10.0	12,893	5.8	6,374	5.7	9,142	7.3
Occluder related procedural accessories	28,912	24.8	32,004	21.6	41,568	18.7	18,385	16.6	27,060	21.7
Interventional delivery systems	17,036	14.6	18,418	12.4	25,296	11.4	11,161	10.1	18,216	14.6
Snares	11,876	10.2	13,586	9.2	16,272	7.3	7,224	6.5	8,844	7.1
PFO and LAA occluder products	474	0.4	9,524	6.4	48,457	21.8	28,424	25.6	6,980	5.6
PFO occluder products	474	0.4	1,201	0.8	4,307	1.9	1,175	1.1	3,215	2.6
LAA occluder products	–	–	8,323	5.6	44,150	19.8	27,249	24.6	3,765	3.0
Other products[(2)]	349	0.3	110	0.1	85	0.0	36	0.0	66	0.1
Total	116,451	100.0	148,247	100.0	222,583	100.0	110,968	100.0	124,804	100.0

(1) Revenue generated from MemoCarna® ASD Occluder III increased from RMB3.4 million in 2020 to RMB32.1 million in 2021, accounting for 2.3% and 14.4% of the total revenue in the same periods, respectively. The revenue increased from RMB13.1 million in the six months ended June 30, 2021 to RMB34.6 million in the six months ended June 30, 2022, accounting for 11.8% and 27.7% of the total revenue in the same periods, respectively.

(2) Other products primarily include vascular plugs and other ancillary products.

The following table sets forth a breakdown of the sales volume and average selling price of our product types for the periods indicated.

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Sales volume	Average selling price[1]	Sales volume	Average selling price[1]	Sales volume	Average selling price[1]	Sales volume	Average selling price[1]	Sales volume	Average selling price[1]
		(RMB)		*(RMB)*		*(RMB)*		*(RMB)*		*(RMB)*
							(Unaudited)			
CHD occluder products	27,377	3,167	26,544	4,016	29,095	4,553	14,062	4,560	19,613	4,624
Occluder related procedural accessories	37,292	775	36,404	879	44,789	928	20,541	895	28,163	961
PFO and LAA occluder products	1,029	460	854	11,152	3,070	15,784	1,470	19,336	1,045	6,679
Other products	469	744	292	377	894	96	199	182	581	114

(1) Calculated by dividing the revenue generated from the sales of a certain type of products by the related sales volume.

The average selling price for our CHD occluder products increased from RMB3,167 per unit in 2019 to RMB4,016 per unit in 2020 and further to RMB4,553 per unit in 2021, primarily due to (1) the launch of our MemoCarna® ASD Occluder III in May 2020, which started to generate revenue in the second half of 2020 with relatively higher pricing per unit compared to CHD occluder products of older generations due to its upgrade in product design and manufacturing process. Specifically, as a percentage of the total revenue generated from sales of CHD occluder products, sales of our MemoCarna® ASD Occluder III accounted for 3.1% and 24.3% in 2020 and 2021, respectively; and (2) the increase in pricing per unit for our CHD occluder products sold overseas through the Retained Lepu Medical Group from 2019 to 2020. See "Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement." See "Financial Information — Period to Period Comparison of Results of Operations." The average selling price for our CHD occluder products increased from RMB4,560 per unit in the six months ended June 30, 2021 to RMB4,624 per unit in the six months ended June 30, 2022, primarily due to the increased sales volume of our MemoCarna® ASD Occluder III and the launch of our MemoCarna® PDA Occluder III and MemoCarna® VSD Occluder III in mid-2021, all of which have relatively higher pricing per unit compared to CHD occluder products of older generations as a result of the upgrade in product design and manufacturing process.

The average selling price for our PFO and LAA occluder products increased from RMB460 per unit in 2019 to RMB11,152 per unit in 2020 and further to RMB15,784 per unit in 2021, primarily due to (1) the launch of our LAA occluder product in June 2020, which started to generate revenue in the second half of 2020 with relatively higher pricing per unit due to the relatively more complex structure and sophisticated manufacturing process used in

producing LAA occluder products; specifically, as a percentage of the total revenue generated from sales of PFO and LAA occluder products, sales of our LAA occluder product accounted for 87.4% and 91.1% in 2020 and 2021, respectively; and (2) the increase in pricing per unit for our PFO occluder products sold overseas through the Retained Lepu Medical Group from 2019 to 2020. See "Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement." See "Financial Information — Period to Period Comparison of Results of Operations." The average selling price for our PFO and LAA occluder products decreased from RMB19,336 per unit in the six months ended June 30, 2021 to RMB6,679 per unit in the six months ended June 30, 2022, primarily due to the decreased sales volume of our relatively higher pricing LAA occluder products as a result of our limited technical training and surgical assistance capabilities amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022, which were critical for the execution of the implantation of and therefore the related sales. Specifically, as a percentage of the total revenue generated from sales of PFO and LAA occluder products, sales of our LAA occluder product accounted for 95.9% and 53.9% in the six months ended June 30, 2021 and 2022, respectively.

During the Track Record Period, the selling prices of our products generally did not have significant differences compared to those of other similar products, which were produced by domestic and international companies in the market, according to the F&S Report.

The following table sets forth a breakdown of our gross profit and gross profit margin by product type for the periods indicated.

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin
	(RMB in thousands, except for percentages)									
							(Unaudited)			
CHD occluder products	81,383	93.9	101,752	95.4	125,109	94.4	60,894	95.0	85,269	94.0
Occluder related procedural accessories	20,863	72.2	24,207	75.6	31,780	76.5	14,232	77.4	18,419	68.1
PFO and LAA occluder products	273	57.6	7,070	74.2	40,635	83.9	23,934	84.2	5,771	82.7
Other products	313	89.7	84	76.4	21	25.8	24	66.7	24	36.1
Total	102,832	88.3	133,113	89.8	197,545	88.8	99,084	89.3	109,482	87.7

Our gross profit margin for CHD occluder products remained relatively stable during the Track Record Period. Our gross profit margin for occluder related procedural accessories increased gradually during the Track Record Period, primarily due to the greater economies of scale in manufacturing occluder related procedural accessories as a result of the large production volumes and streamlined and standardized manufacturing processes. The gross profit margin for occluder related procedural accessories decreased in the six months ended June 30, 2022, primarily due to the increased sales of our integrated intervention delivery system II, which requires more complicated manufacturing procedures. Our gross profit margin for PFO and LAA occluder products increased from 57.6% in 2019 to 74.2% in 2020 and further to 83.9% in 2021, primarily due to the launch of our LAA occluder products, which have relatively higher gross profit margin. The gross profit margin for PFO and LAA occluder products decreased slightly in the six months ended June 30, 2022, primarily due to an increase in the raw materials and consumables costs relating to our LAA occluder products caused by the regional resurgence of COVID-19 in China and overseas. In addition, our overall gross profit margin increased slightly from 2019 to 2020, primarily to due to the increase in pricing per unit for our products, especially our CHD occluder products sold overseas through the Retained Lepu Medical Group in 2020. See "Financial Information — Period to Period Comparison of Results of Operations."

Biodegradable technology in Occluder Products

We adopt biodegradable technology in occluder products. Compared with traditional metal occluders, biodegradable occluders are designed to degrade over time into carbon dioxide and water upon completion of endothelial repair, according to the F&S Report. Our design for biodegradable occluder product and product candidates not only ensures effective autologous tissue closure but also minimizes potential compression and wear on surrounding tissues caused by metal implants, which lowers the risk of long-term complications. In addition, we believe it leaves available for patients additional future treatment options, especially transseptal procedures, as the biodegradable occluders would not be a permanent implant in the human body.

We have accumulated extensive know-how and experience in biodegradable technology, including:

- *Material selection*. We have a comprehensive understanding of the properties of a variety of biodegradable materials to select appropriate biodegradable materials, including polylactic acid and polydioxanone, to meet the performance requirements of different product candidates.

- *Structural design*. With our understanding of the properties of biodegradable materials, we complement the mechanical performance of our biodegradable product candidates with unique structural design, including suturing, parachute-shaped lock and double-disk concave configuration, to ensure secure and firm clamping.

- *Controlled biodegradation*. We use rate-controlling technology to reconcile biodegradation process with tissue repair process, achieving a safe and controllable biodegradation performance for our product candidates.

- *Product processing*. We have developed a range of technologies for processing biodegradable occluder product and product candidates to ensure their performance and validity, including biodegradable wire mesh technology, heat molding technology, vacuum drying and sterilization control technology, and water-proof packaging technology.

We completed the world's first fully biodegradable VSD occluder implantation in February 2018 during its clinical trial, which marked a breakthrough in the field of fully biodegradable occluders globally, according to the F&S Report. Our fully biodegradable MemoSorb® VSD Occluder IV was approved by the NMPA in February 2022, and our other biodegradable occluder products were in R&D stage as of the Latest Practicable Date.

Occluder Products

Our occluder products have achieved broad market recognition since the initial launch of our first generation CHD occluder products in 2003. As of the Latest Practicable Date, we had a comprehensive portfolio of occluder products and product candidates targeting CHD and cardioembolic stroke.

We believe our occluder products have the following key advantages.

- *Effective closure rates.* Our devices have consistently been shown to be highly effective in closing structural heart defects. For example, clinical study reports in relation to our MemoCarna® ASD Occluder III have reported a closure rate of 98.1% after six months following the operation, and clinical study reports in relation to our MemoCarna® VSD Occluder III, MemoSorb® VSD Occluder IV, and MemoCarna® PDA Occluder III have reported 100.0% closure rates after six months following the operation.

- *Safe and precise delivery.* Our occluder products are delivered through our tailor-made delivery systems to ensure safe and precise delivery and release at the site of the defect to be closed. See "— Our Products — Occluder Products — Other Products — Procedural Accessories — Delivery System."

- *Minimally invasive.* Our occluder products are designed to be implanted through transapical or transfemoral procedures, serving to reduce surgical complications associated with invasive open-chest surgeries.

CHD Occluder Products

We have developed a wealth of occluder products targeting common types of CHD, including primarily ASD, VSD, and PDA. We were the largest manufacturer of CHD occluder products and the related procedural accessories in China, with a market share of 38.0% in terms of revenue recognized for the sales in China in 2021, according to the F&S Report.

According to the F&S Report, the market size of the global CHD occluder products market is expected to increase from US$223.2 million in 2021 to US$299.0 million in 2025 at a CAGR of 7.6%, and further to US$366.5 million in 2030 at a CAGR of 4.2% from 2025 to 2030. The market size of China's CHD occluder products market is expected to increase from RMB426.4 million in 2021 to RMB659.0 million in 2025 at a CAGR of 11.5%, and further to RMB765.8 million in 2030 at a CAGR of 3.1% from 2025 to 2030, according to the same source.

During the Track Record Period, we generated a majority of our revenue from sales of CHD occluder products. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we generated revenue from sales of CHD occluder products of RMB86.7 million, RMB106.6 million, RMB132.5 million, RMB64.1 million and RMB90.7 million, respectively, representing 74.5%, 71.9%, 59.5%, 57.8% and 72.7% of our total revenue for the same periods, respectively.

ASD Occluder Products

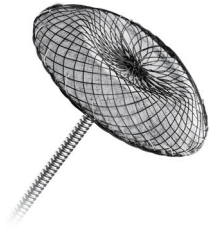
ASD is a type of congenital heart disease where there is a defect, or a hole, in the septum between the heart's left and right atria. In patients with ASD, blood travels across the hole from the left atrium to the right atrium, leading to the right side of the heart receiving extra blood and therefore bearing more than its normal workload. The increased amount of blood flows into the pulmonary arteries, which may also lead to complications such as obstructive pulmonary hypertension, Eisenmenger syndrome, arrhythmia and heart failure, which can be life-threatening in severe cases.

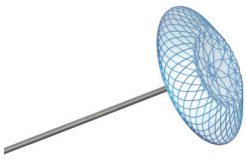
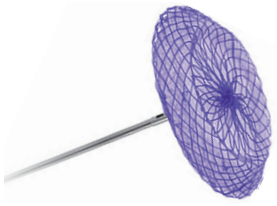
ASD occluder is a percutaneous transcatheter occlusion device intended for the closure of ASD. The first three generations of our ASD occluder products are self-expandable occlusion devices constructed with two discs made of braided nitinol wire mesh and a connecting waist. We utilize our physical kneading technique to ensure reliable wire connections without solder. Our ASD occluder products are sutured with PET flow-occluding fabric to aid closure. As of the Latest Practicable Date, we were developing our fourth generation ASD occluder product MemoSorb® ASD Occluder IV, which employs biodegradable materials instead of nitinol and PET. Our ASD occluder products come in various disc diameters and waist sizes, which allows physicians to select the most suitable one depending on the defect that the occluder is intended to close.

As of the Latest Practicable Date, we had launched three generations of ASD occluder products. MemoPart® ASD Occluder I, our first generation ASD occluder product, was approved by the NMPA in April 2003 and was granted the initial CE Mark in August 2012. MemoPart® ASD Occluder II, our second generation ASD occluder product, was granted the initial CE Mark in August 2012. MemoCarna® ASD Occluder III, our third generation ASD occluder product, was approved by the NMPA in May 2020. We plan to commence CE Mark application for MemoCarna® ASD Occluder III in the fourth quarter of 2022.

As of the Latest Practicable Date, we were developing our fourth generation ASD occluder product, MemoSorb® ASD Occluder IV, which is biodegradable. According to the F&S Report, occluders for septal defect treatment are usually made of non-degradable metallic and synthetic fabric materials. Compared with traditional metal occluders, biodegradable ASD occluders are designed to degrade over time into carbon dioxide and water upon completion of endothelial repair, according to the same source. Our design for biodegradable occluder product and product candidates not only ensures effective autologous tissue closure but also minimizes potential compression and wear on surrounding tissues caused by metal implants, which lowers the risk of long-term complications. In addition, we believe it leaves available for patients additional future treatment options, especially transseptal procedures, as the biodegradable occluders would not be a permanent implant in the human body, benefiting all patients receiving occluder implants, and in particular, to children who constitute the majority of patients suffering from CHD and also expect a significantly longer remaining life span and better life quality, according to the F&S Report. As of the Latest Practicable Date, our MemoSorb® ASD Occluder IV was in the clinical trial process, and we expect to submit application to the NMPA in the second quarter of 2023 and receive approval in the second quarter of 2024. We plan to commence clinical trial for MemoSorb® ASD Occluder IV in the European Union and the United States in the fourth quarter of 2024.

The following table illustrates the details of our ASD occluder products and product candidates.

Product Name	Key Features and Benefits	Product Structure
MemoPart® ASD Occluder I (Double-rivet)	• Nitinol material with biocompatibility and elastic deformation and recovery capability for secure and firm clamping • Double-rivet design	
MemoPart® ASD Occluder II (Single-rivet)	• Nitinol material • Single-rivet design to reduce metal implants and load to the heart • More flattened discs than the first generation product to improve endothelialization	

Product Name	Key Features and Benefits	Product Structure
MemoCarna® ASD Occluder III (Oxide Coating)	• Nitinol material • Single-rivet design: Datura-shaped braided mesh allowing more flattened discs to facilitate endothelialization while preserving a pathway for future transseptal treatments • Uniform and dense oxide coating produced under plasma treatment process to minimize the precipitation of nickel ions	
MemoSorb® ASD Occluder IV (Biodegradable) (product candidate)	• Biodegradable material • Single-rivet design • Patented mold locking structure to ensure secure and firm clamping • Platinum marker bands outside the biodegradable wire to enable precise positioning during the procedure	

We generated revenue of RMB56.1 million, RMB69.7 million, RMB99.8 million, RMB47.8 million and RMB71.3 million from the sales of our ASD occluder products in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 48.1%, 47.0%, 44.8%, 43.1% and 57.1% of our total revenue in the same periods, respectively.

VSD Occluder Products

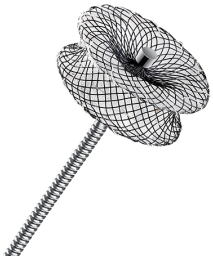
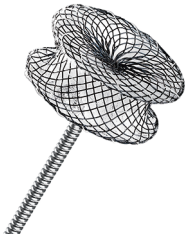
VSD is among the most common congenital heart diseases found in children and adults. The defect, or the hole, occurs in a patient's septum between the heart's left and right ventricles and allows blood to pass from the left ventricle to the right ventricle. The abnormal blood circulation increases the load of the right ventricle and lungs. Potential complications of VSD include heart failure, obstructive pulmonary hypertension and Eisenmenger syndrome.

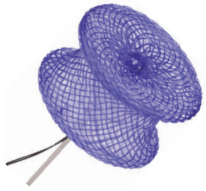
VSD occluder is a percutaneous transcatheter occlusion device intended for the closure of VSD. The first three generations of our VSD occluder products are self-expandable occlusion devices constructed with two discs made of braided nitinol wire mesh and a connecting waist. We utilize our physical kneading technique to ensure reliable wire connections without solder. Our VSD occluder products are sutured with PET flow-occluding fabric to aid closure. Our fourth generation fully biodegradable VSD occluder product, MemoSorb® VSD Occluder IV, which was approved by the NMPA in February 2022, employs biodegradable materials instead of nitinol and PET. Our VSD occluder products come in various disc diameters and waist sizes, which allows physicians to select the most suitable one depending on the defect that the occluder is intended to close.

As of the Latest Practicable Date, we had launched four generations of VSD occluder products. MemoPart® VSD Occluder I, our first generation VSD occluder product, was approved by the NMPA in December 2003 and was granted the initial CE Mark in August 2012. MemoPart® VSD Occluder II, our second generation VSD occluder product, was granted the initial CE Mark in August 2012. MemoCarna® VSD Occluder III, our third generation VSD occluder product, was approved by the NMPA in July 2021. We plan to commence CE Mark application for MemoCarna® VSD Occluder III in the first quarter of 2023.

MemoSorb® VSD Occluder IV, which is fully biodegradable, is the latest addition to our VSD occluder product family. Compared with traditional metal occluders, biodegradable VSD occluders are designed to degrade over time into carbon dioxide and water upon completion of endothelial repair. In addition, the biodegradable materials we use are designed to ensure a soft contact, which prevents potential compression and wear on surrounding tissues and greatly reduces the risk of atrioventricular block. Furthermore, the biodegradable nature leaves room for future treatment. In February 2018, we completed the world's first fully biodegradable VSD occluder implantation during its clinical trial, which marked a breakthrough in the field of fully biodegradable occluders globally, according to the F&S Report. We submitted the registration application to the NMPA for MemoSorb® VSD Occluder IV in January 2021 and obtained the NMPA approval in February 2022. We plan to commence clinical trial for MemoSorb® VSD Occluder IV in the European Union and the United States in the fourth quarter of 2022 and the fourth quarter of 2023, respectively.

The following table illustrates the details of our VSD occluder products.

Product Name	Key Features and Benefits	Product Structure
MemoPart® VSD Occluder I (Double-rivet)	• Nitinol material with biocompatibility and elastic deformation and recovery capability for secure and firm clamping • Double-rivet design	
MemoPart® VSD Occluder II (Single-rivet)	• Nitinol material • Single-rivet design to reduce metal implants and load to the heart	

Product Name	Key Features and Benefits	Product Structure
MemoCarna® VSD Occluder III (Oxide Coating)	• Nitinol material • Single-rivet design: Datura-shaped braided mesh allowing more flattened discs to facilitate endothelialization • Uniform and dense oxide coating produced under plasma treatment process to minimize the precipitation of nickel ions	
MemoSorb® VSD Occluder IV (Biodegradable)	• Fully biodegradable material • Single-rivet design • Patented mold locking structure to ensure secure and firm clamping	

We generated revenue of RMB19.3 million, RMB22.1 million, RMB19.8 million, RMB10.0 million and RMB10.3 million from the sales of our VSD occluder products in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 16.6%, 14.9%, 8.9%, 9.0% and 8.2% of our total revenue in the same periods, respectively.

PDA Occluder Products

PDA is one of the most common congenital heart diseases. As a normal fetal artery connecting the aorta and the pulmonary artery, ductus arteriosus allows blood to detour away from the lungs before birth. The ductus arteriosus usually narrows and closes within the first two to three weeks after birth, while the failed closure of ductus arteriosus is called a PDA. A PDA allows blood that should have traveled through the aorta to flow back into the lungs, causing heart failure, heart malformations and other complications.

A PDA occluder is a percutaneous transcatheter occlusion device intended for the closure of PDA. Our PDA occluder products are self-expandable occlusion devices made of braided nitinol wire mesh. Our PDA occluder is provided with a cylinder or a cone shape to fit the tube-shaped or funnel-shaped PDA, respectively, between which the cylinder-shaped PDA occluder is our unique design. The edge on the aorta side of the PDA occluder has a concave configuration to reduce occluder's intracardiac volume, therefore lowering the incidence of iatrogenic stenosis of the aorta. We utilize our physical kneading technique to ensure reliable wire connections without solder. PET flow-occluding fabric is sutured on the PDA occluders to aid occlusion. Like our other CHD occluder products, our PDA occluders also come in various dimensions.

As of the Latest Practicable Date, we had launched three generations of PDA occluder products. MemoPart® PDA Occluder I, our first generation PDA occluder product, was approved by the NMPA in April 2003 and was granted the initial CE Mark in August 2012. MemoPart® PDA Occluder II, our second generation PDA occluder product, was granted the initial CE Mark in August 2012. MemoCarna® PDA Occluder III, our third generation PDA occlude product, was approved by the NMPA in May 2021. We plan to commence CE Mark application for MemoCarna® PDA Occluder III in the second quarter of 2023.

The following table illustrates the details of our PDA occluder products.

Product Name	Key Features and Benefits	Product Structure
MemoPart® PDA Occluder I (Double-rivet)	• Nitinol material with biocompatibility and elastic deformation capability for secure clamping • Unique cylinder or cone shape to ensure a close and stable fit to the wall of ductus arteriosus • Double-rivet design	 Cylinder-shaped  Cone-shaped
MemoPart® PDA Occluder II (Single-rivet)	• Nitinol material • Unique cylinder or cone shape • Single-rivet design to reduce metal implants and load to the heart	 Cylinder-shaped  Cone-shaped
MemoCarna® PDA Occluder III (Oxide Coating)	• Nitinol material • Unique cylinder or cone shape • Single-rivet design: Datura-shaped braided mesh allowing more flattened discs to facilitate endothelialization and lighter weight to relieve load to the heart • Oxide coating produced under plasma treatment process to minimize the precipitation of nickel ions	 Cylinder-shaped  Cone-shaped

We generated revenue of RMB11.3 million, RMB14.9 million, RMB12.9 million, RMB6.4 million and RMB9.1 million from the sales of our PDA occluder products in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 9.7%, 10.0%, 5.8%, 5.7% and 7.3% of our total revenue in the same periods, respectively.

Occluder Products for Prevention of Cardioembolic Stroke

We take pride in our early-mover advantages in the interventional medical device market targeting cardioembolic stroke. Our product offering for prevention of cardioembolic stroke and related symptoms primarily includes PFO occluders and LAA occluders.

According to the F&S Report, the market size of the global cardioembolic stroke occluder products market is expected to increase from US$1.1 billion in 2021 to US$2.0 billion in 2025 at a CAGR of 16.7%, and further to US$5.4 billion in 2030 at a CAGR of 21.9% from 2025 to 2030. The market size of China's cardioembolic stroke occluder products market is expected to increase from RMB0.6 billion in 2021 to RMB2.4 billion in 2025 at a CAGR of 38.5%, and further to RMB7.8 billion in 2030 at a CAGR of 26.7% from 2025 to 2030, according to the same source.

We generated revenue of RMB0.5 million, RMB9.5 million, RMB48.5 million, RMB28.4 million and RMB7.0 million from the sales of our PFO and LAA occluder products in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 0.4%, 6.4%, 21.8%, 25.6% and 5.6% of our total revenue in the same periods, respectively.

PFO Occluder Products

PFO is a small hole between the right and left atria that exists in everyone before birth, and functionally and anatomically closes in two to three weeks after birth. When a PFO fails to close, a right-to-left abnormal cardiac shunt may develop when the right atrial pressure exceeds the left atrial pressure as a result of activities such as cough and strenuous exercise. The diseases associated with PFO mainly include cardioembolic stroke, migraine, peripheral arterial embolism, and decompression sickness.

A PFO occluder is a device for percutaneous transcatheter closure of a PFO for patients predominantly between the ages of 18 and 65, with prominent effects in reducing the incidence of cardioembolic stroke and migraine. The market size of China's PFO occluder products market is expected to increase from RMB187.1 million in 2021 to RMB370.0 million in 2025 at a CAGR of 18.6%, and further to RMB761.9 million in 2030 at a CAGR of 15.5% from 2025 to 2030, according to the F&S Report. The market size of the global PFO occluder products market is expected to increase from US$189.2 million in 2021 to US$432.2 million in 2025 at a CAGR of 22.9%, and further to US$786.5 million in 2030 at a CAGR of 12.7% from 2025 to 2030, according to the same source.

As of the Latest Practicable Date, we had launched one generation of PFO occluder product, MemoPart® PFO Occluder I, which was granted the initial CE Mark in August 2012. MemoPart® PFO Occluder I is a self-expandable occlusion device made of nitinol wire. The PFO occluder consists of two discs and a connecting waist. The two discs can each be fixed on one side of the PFO. We utilize our physical kneading technique to ensure reliable wire connections without solder. Further, PET flow-occluding fabric is sutured on each disc to aid occlusion. Our PFO occluder products come in various disc diameters and waist sizes, which allows physicians to select the most suitable one depending on the defect that the occluder is intended to close.

As of the Latest Practicable Date, we were developing our second generation PFO occluder product, MemoSorb® PFO Occluder II, which is biodegradable. Similar to biodegradable ASD occluders, biodegradable PFO occluders are designed to degrade over time into carbon dioxide and water upon completion of endothelial repair, compared with traditional metal occluders. Biodegradable PFO occluders also make future atrial septal puncture possible for patients. As of the Latest Practicable Date, our MemoSorb® PFO Occluder II was in the registration preparation process with the NMPA, which is expected to submit the application in the third quarter of 2022 and receive the approval in the third quarter of 2023. We plan to commence clinical trial for MemoSorb® PFO Occluder II in the European Union and the United States in the fourth quarter of 2024.

The following table illustrates the details of our PFO occluder products and product candidates.

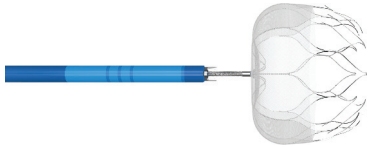
Product Name	Key Features and Benefits	Product Structure
MemoPart® PFO Occluder I	• Nitinol material with biocompatibility and elastic deformation capability for secure and firm clamping • Single-rivet design to reduce metal implants and load to the heart, or double-rivet design	
MemoSorb® PFO Occluder II (Biodegradable) (product candidate)	• Biodegradable material • Single-rivet design • Patented mold locking structure to ensure secure and firm clamping • Platinum marker bands outside the biodegradable wire to enable precise positioning during the procedure	

LAA Occluder Products

The LAA is a long, narrow, curved and blind-ended structure extending forward and downward the anterior wall of the left atrium, which forms during the fourth week of embryonic development. Blood tends to stagnate in the LAA as a result of its shape and the pectinate muscles within it, and in patients with cardioembolic stroke, a vast majority of the clots are formed in the LAA. Our transcatheter LAA occluder products offer a safe and effective method to prevent clots by occluding the LAA. Unlike traditional procedures, LAA occluders can be used as a preventative treatment for patients with the tendency to form cardiogenic embolism and is also suitable for patients with high risks for surgeries. LAA occluders generally have a better result than traditional procedures because it is less likely to cause clots after implementation.

The market size of China's LAA occluder products market is expected to increase from RMB0.5 billion in 2021 to RMB2.1 billion in 2025 at a CAGR of 43.2%, and further to RMB7.1 billion in 2030 at a CAGR of 27.6% from 2025 to 2030, according to the F&S Report. The market size of the global LAA occluder products market is expected to increase from US$0.9 billion in 2021 to US$1.9 billion in 2025 at a CAGR of 20.3%, and further to US$3.4 billion in 2030 at a CAGR of 12.7% from 2025 to 2030, according to the same source.

As of the Latest Practicable Date, we had launched one generation of LAA occluder product, MemoLefort® LAA Closure Occluder I, which was registered with the NMPA in June 2020, serving to prevent cardioembolic stroke caused by atrial fibrillation. We plan to commence the clinical trial for MemoLefort® LAA Occluder I in the European Union in the fourth quarter of 2022. MemoLefort® LAA Closure Occluder I adopts a bud-shaped inner plug frame made of nitinol shape memory alloy. It has outstanding compliance and is adaptive to the ostium of most LAA. The inner plug design allows the occluder to be embedded into the LAA ostium to minimize the area of endothelialization and avoid compression and wear on surrounding tissues, making it deployable either before or after ablation in a one-stop atrial fibrillation ablation and LAA occlusion procedure. Outside the frame, barb-like attachment parts formed by our one-piece cutting technique serve to ensure firm implantation, minimizing the risk of detachment. The concave design of MemoLefort® LAA Closure Occluder I also contributes to its radial support to reinforce its stability. PET flow-occluding fabric is sutured outside the frame to aid occlusion. Our newly launched LAA occluder product has demonstrated therapeutic effects in clinical trials with a 100% operation success rate and reached an LAA closure rate of 97.6% after 12 months following the operation with no probability of post-operative ischemic stroke. Specifically, operation success rate refers to the probability of successful implantation of the LAA occluder without death, which indicates safety, and LAA closure rate refers to the probability of successful implantation of the LAA occluder without dislodging, which indicates efficacy, according to the F&S Report. Our LAA occluders also come in various dimensions, which allows physicians to select the most suitable one depending on the ostium of LAA that the occluder is intended to close. Our LAA occluder product is deployed with a pre-packed specialized delivery system, MemoLefort® LAA Occluder Delivery System. The following graph product illustrates the product structure of our MemoLefort® LAA Occluder I together with the delivery system.



As of the Latest Practicable Date, we were developing our second generation LAA occluder product, LAA Closure Occluder II, which is biodegradable. Similar to the biodegradable ASD and PFO occluders, biodegradable LAA occluders are designed to degrade over time into carbon dioxide and water upon completion of endothelial repair, compared with traditional metal occluders. The biodegradable LAA occluder is particularly suitable for LAA occlusion in patients with severe symptoms, patients with non-valvular atrial fibrillation who are not suitable for anticoagulant treatment, and patients who have severe consequences after such treatment, such as bleeding, and are not able to endure prolonged drug treatment. As of the Latest Practicable Date, our LAA Closure Occluder II was at the stage of type inspection. We plan to commence the clinical trial for LAA Closure Occluder II in China in the fourth quarter of 2022 and in the European Union and the United States thereafter.

We believe our transcatheter LAA occluder products have significant market potential driven by the unmet demand. Since the LAA is the main site of cardiogenic emboli, for patients who are not suitable for long-term oral anticoagulation therapy with high embolism and high bleeding risks, percutaneous LAA closure with LAA occluder products is an effective option to reduce the risk of stroke. The left auricular occlusion technique requires only a single procedure without life-long medication, making it more acceptable to patients than traditional anticoagulation regimens that require life-long medication. In addition, along with the constantly improving medical insurance and reimbursement policies, more patients with atrial fibrillation are expected to choose LAA occluders to prevent stroke and systemic embolism, according to the F&S Report. We expect the demand for our LAA occluder products to increase significantly in the near future.

Other Products

IASD Product Candidates

Our IASD product candidates are designed for the creation of a left-to-right interatrial shunt to effectively relieve left atrium overload. Our IASD product candidates can also help alleviate the right heart pressure for patients with pulmonary arterial hypertension.

As of the Latest Practicable Date, we were developing three generations of IASD product candidates, with IASD I in the clinical trial stage, IASD II in the design stage and IASD III in the type inspection stage. Our IASD I features a nitinol wire frame with an opening in the center to allow left-to-right shunt. Its nitinol material allows effective radial support to maintain the shunt opening. In addition, our IASD I employs a double-disc design for secure and firm clamping. We plan to submit registration application to the NMPA for IASD I in the fourth quarter of 2023. IASD II is designed to be biodegradable, which imposes no interference on future treatment. Its excellent molding also serves to reduce the incidence of clots. We plan to initiate the clinical trial for IASD II in China in the third quarter of 2023, and in the European Union and the United States thereafter. IASD III, or radiofrequency ablation shunt

catheter, is an interventional device designed to ablate the atrial septal with radiofrequency energy. Our IASD III consists of a radiofrequency ablation unit, a catheter and a handle. IASD III can provide continuous and dynamic decompression of the left atrium, which can ease the symptoms and improve the life quality for patients. Our IASD III is designed to be used together with our radiofrequency ablation device. We plan to initiate the clinical trial for IASD III in China in the fourth quarter of 2023. The following diagrams illustrate the structures of our IASD product candidates.

IASD I

IASD II

IASD III

Our radiofrequency ablation device is designed to supply radiofrequency energy to targeted heart tissues for safe and effective ablation treatment. It is reusable in conjunction with our IASD III product candidate. As of the Latest Practicable Date, our radiofrequency ablation device was in the stage of type inspection. We plan to initiate the clinical trial for our radiofrequency ablation device in China in the fourth quarter of 2023.

Vascular Plug Products

We offer vascular plug products which are designed for rapid vessel occlusion. Our vascular plug is a self-expandable device made of finely braided nitinol wire mesh which can be compressed into a delivery sheath and deployed precisely at targets. Its configuration optimizes the occluding effect and endothelialization process.

Our MemoPart® Plug I and MemoPart® Plug II both were granted the initial CE Marks in August 2012, with the first generation having a double-rivet design and the second generation having a single-rivet design. The CE Marks for our MemoPart® Plug I and MemoPart® Plug II expired in April 2021 and we had terminated related sales upon the expiration. We voluntarily chose not to renew such CE Marks considering the insignificant revenue contribution of vascular plug products during the Track Record Period, the time and expenses involved in renewing the CE Marks, and most importantly, the promising research and development progress of our MemoFlex® Plug III, which we expect to have greater market potential based on a review of market conditions. Our MemoFlex® Plug III adopts a high-density mesh configuration where no PET flow-occluding fabric is required. Its double-waist, three-lobe structure serves to achieve effective vessel occlusion. In addition, this structure enables excellent passability and therefore extended reach to distal vasculature. As of the Latest Practicable Date, we had initiated the clinical trial for MemoFlex® Plug III in China, and expect to submit the registration application with the NMPA in the fourth quarter of 2023 and receive approval in the fourth quarter of 2024.

Procedural Accessories

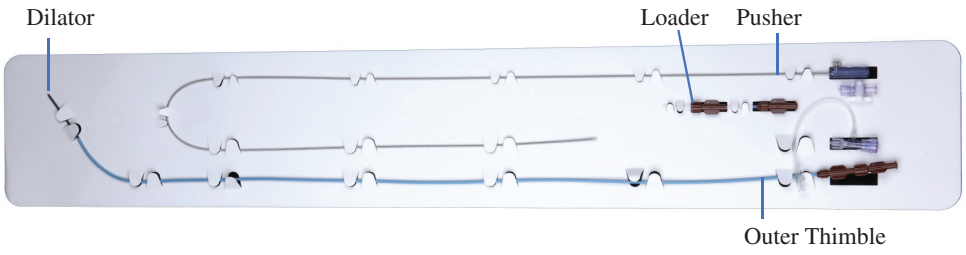
Our procedural accessories for occluders primarily include delivery systems and snares mainly related to CHD occluder products. We generated revenue of RMB28.9 million, RMB32.0 million, RMB41.6 million, RMB18.4 million and RMB27.1 million from the sales of our procedural accessories for occluders in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 24.8%, 21.6%, 18.7%, 16.6% and 21.7% of our total revenue in the same periods, respectively.

Delivery Systems

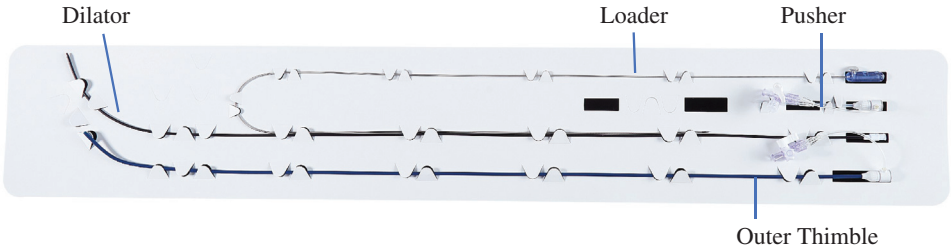
As part of the total solutions offered by our occluder products, we also offer delivery systems specifically design to attach, load, deliver and deploy our occluders and vascular plugs into targets.

Our first-generation delivery system, MemoPart® interventional delivery system I, was approved by the NMPA in December 2007 and was granted the initial CE Mark in August 2012. The catheter of our first generate delivery system is formed of PTFE, while the catheter of the second generation is formed of PTFE in the inside and Pebax® for the outside with stainless steel braided mesh as the middle layer, which demonstrates great bendability. The low-friction PTFE wall allows compatibility with occluders having a broad range of diameters. The threaded coupling locker between joints ensures tight connection, therefore minimizing the risks of accidental joint decoupling and occluder detachment. Furthermore, the catheter tip of the delivery system features a platinum marker band, which enables physicians to visually identify and follow the catheter during the procedure under the guidance of angiography. Our second generation interventional delivery system II was approved by the NMPA in July 2018. We had submitted CE Mark application for our interventional delivery system II in the second quarter of 2022 and expect to receive CE Mark in the second quarter of 2024. We upgraded the first generation by adopting a fully-integrated configuration where the couplings between components are implemented by a plug-in connection with a built-in hemostatic valve. The integrated design greatly streamlines the operational procedure and enables automated hemostasis. Our first and second generation interventional delivery systems are fully compatible with our occluders and vascular plugs that were launched as of the Latest Practicable Date.

The following image illustrates the structures of our MemoPart® interventional delivery system I and integrated intervention delivery system II.



MemoPart® Interventional Delivery System I



Interventional delivery System II (Integrated)

Moreover, we offer a delivery system with a short sheath of 170 mm or 197 mm in length, which received its NMPA approval in November 2021, providing physicians with additional clinical choice in delivering occluders. We also offer an integrated interventional delivery system for Plug III, which received its NMPA approval in October 2021, specialized in delivering the third generation vascular plug with a thin sheath of 3 Fr. to 5 Fr. (approximately 1.0 mm to 1.6 mm) in diameter. Further, in view of the novel design of our biodegradable occluders, we specifically developed an interventional delivery system for them, which was approved by the NMPA in May 2022.

Snares

Snare is an endovascular device that is used to establish arteriovenous channels during occluder implantation procedures as well as retrieve and manipulate atraumatic foreign bodies. The snare is composed of nitinol wire, gold-plated tungsten wire and a PTFE catheter. The loop of nitinol wire features elasticity and kink resistance to allow ease of operation. The gold-plated tungsten wire provides visibility during procedures to increase accuracy and success rate.

As of the Latest Practicable Date, we had successfully commercialized one generation of snare, MemoPart® Snare I, which received CE Mark in November 2016 and NMPA registration certificate in June 2007. As of the Latest Practicable Date, we were designing our second generation snare, Snare II, which features a multiple-loop structure. The Snare II is exempted from clinical trial requirements in accordance with the Catalogues of Medical Devices Exempted from Clinical Trials. We plan to submit our registration application with the NMPA in the third quarter of 2022 and receive its approval in the third quarter of 2023.

Heart Valve Product Candidates

Entrusted Products

As of the Latest Practicable Date, we also conducted research and development for heart valve products targeting valvular diseases. All of our initial heart valve product candidates were acquired from Lepu Medical during the business injection as further elaborated in "History, Reorganization and Corporate Structure — Our Corporate Development — Business Injection", which include, but not limited to, the Entrusted Products, while we have also independently initiated R&D for six heart valve product candidates in the product pipeline by

ourselves since then. Set forth below is a summary of the regulatory restrictions under the prevailing PRC laws and regulations pertaining to the Entrusted Products (the "Entrusted Products Regulatory Restrictions"), which are applicable to the medical devices industry, and relevant implications:

Entrusted Products Regulatory Restrictions *(Note)*	Relevance to Lepu Medical and us	Corresponding Implications
Stage one: R&D		
i. In circumstances where type inspections of medical devices have been conducted under an applicant's name, there is no viable pathway for another enterprise to have the title of the type inspection report transferred to it or otherwise use such type inspection report for application of a registration certificate under its name.	As the type inspections for each of the Entrusted Products had been completed by Lepu Medical under its name, we cannot have the title of the type inspection reports transferred to us or use such type inspection reports for the application of registration of the Entrusted Products under our name.	As a result of items i, ii and iii of the Entrusted Products Regulatory Restrictions set out in this table, at the pre-registration stage, it was not feasible for us to directly take over the subsequent R&D procedures of the Entrusted Products to conduct the procurement of raw materials and production of samples used in the clinical trials and communication with the governmental authorities as necessary. Meanwhile, our Group will undertake the substantial R&D work relating to the Entrusted Products by way of (i) devising the overall R&D plan, (ii) overseeing the implementation and progress of the R&D work, and (iii) deciding on the key external parties to be engaged in the R&D process. As such, we will continue to undertake the substantial R&D work for these Entrusted Products notwithstanding our entrustment arrangement with Lepu Medical for it to undertake a limited scope of R&D work aforementioned due to regulatory restrictions applicable to the Entrusted Products. In addition, relying on the intellectual properties relating to the Entrusted Products that we have acquired under the business injection by Lepu Medical, we are entitled to independently conduct R&D work for new product and existing product upgrades, if any, based on the rights and interests we possess relating to the Entrusted Products without involving the Retained Lepu Medical Group. Please refer to the table headed "Entrustment Arrangements" below and the framework agreement with Lepu Medical as detailed in "Connected Transactions — Non-exempt Continuing Connected Transactions — 2. Entrusted Products Related Framework Agreement" for arrangements relating to Relevant Activities.

Note: The Entrusted Products Regulatory Restrictions are summarized mainly pursuant to (i) the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) (revised in 2017) which were applicable when the asset transfer agreement was executed, and the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) (revised in 2021) which were effective as at the Latest Practicable Date, (ii) the Administrative Measures for Registration of Medical Devices (《醫療器械註冊管理辦法》) (revised in 2014) which were applicable when the asset transfer agreement was executed, and the Administrative Measures for Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》) which replaced the Administrative Measures for Registration of Medical Devices since October 1, 2021 and were effective as at the Latest Practicable Date, (iii) the Administrative Measures for Supervision of the Production of Medical Devices (《醫療器械生產監督管理辦法》) (revised in 2017) which were applicable when the asset transfer agreement was executed, and the Administrative Measures for Supervision of the Production of Medical Devices (《醫療器械生產監督管理辦法》) (revised in 2022) which were effective as at the Latest Practicable Date.

Entrusted Products Regulatory Restrictions *(Note)*	Relevance to Lepu Medical and us	Corresponding Implications
ii. In terms of sample production prior to the registration of medical devices, an applicant for registration of medical devices is generally prohibited from engaging any other enterprise to produce the product samples for registration purpose, unless such medical devices enjoy certain exemptions for falling within a specifically designated category (a category which none of the Entrusted Products falls within).	Lepu Medical is prohibited from engaging us to produce any samples of the Entrusted Products for registration purpose.	Same as above.
Stage two: Upon registration		
iii. The registration certificates or the related registration application rights and interests for medical devices are generally not allowed to be directly transferred.	Lepu Medical is not allowed to directly transfer the registration certificates or the related registration application rights for any of the Entrusted Products to us.	Same as above.
Stage three: Upon commercialization		
iv. In terms of commercial manufacturing, a registrant of medical devices is only allowed to engage a third-party enterprise to manufacture the registered medical devices provided that the registrant remains capable of manufacturing the medical device and the third-party enterprise obtains the manufacture permit for such medical device, except that registrants of medical devices falling within the Prohibited Catalogue are prohibited from engaging any third-party enterprise to manufacture the medical devices listed therein.	Two of the Entrusted Products, *i.e.*, TAVR system and TMVCRS, fall within the Prohibited Catalogue. The other Entrusted Product, *i.e.*, balloon dilatation catheter for aortic valve, does not fall within the Prohibited Catalogue.	As a result of this item iv of the Entrusted Products Regulatory Restrictions, at the post-registration stage: • Lepu Medical is prohibited from engaging us for commercial manufacturing of the TAVR system and TMVCRS unless there are regulatory changes lifting such restriction; and • as for balloon dilatation catheter for aortic valve, Lepu Medical is allowed to engage us for commercial manufacturing, provided that Lepu Medical remains capable of manufacturing the product and we obtain the manufacture permit for such product. As such, we will take initiative to apply for the relevant manufacturing permits as and when the balloon dilatation catheter approaches registration stage. Please refer to the table headed "Entrustment Arrangements" below for the arrangements relating to commercial manufacturing for each of the Entrusted Products.

Taking into account such Entrusted Products Regulatory Restrictions which we became aware of in the process of the Reorganization and considering that it is only reasonable for Lepu Medical to continue with the subsequent registration and manufacturing activities (to the extent that the then applicable PRC laws prohibit us from carrying out such activities) for the Entrusted Products (as applicable) according to our directions and for our benefit, we have built in a series of entrustment arrangements in the asset transfer agreement (including an intellectual property transfer agreement as attached thereto) in January 2021. In particular, among the R&D work for the Entrusted Products, Lepu Medical will be responsible for the procurement of raw materials and producing the sample products used in the subsequent clinical trials, and communicating with the governmental authorities involved therein as necessary. Meanwhile, our Group will undertake the substantial R&D work by way of (i) devising the overall R&D plan, (ii) overseeing the implementation and progress of the R&D work, and (iii) deciding on the key external parties to be engaged in the R&D process. As such, we will continue to undertake the substantial R&D work for it to undertake these Entrusted Products notwithstanding our entrustment arrangement with Lepu Medical for a limited scope of R&D work aforementioned due to regulatory restrictions applicable to the Entrusted Products. In addition, relying on the intellectual properties relating to the Entrusted Products that we have acquired under the business injection, we are entitled to independently conduct R&D work for new product and existing product upgrades, if any, based on the rights and interests we possess relating to the Entrusted Products without involving the Retained Lepu Medical Group. Entrustment Arrangements will last unless and until Lepu Medical is permitted to transfer the registration certificates and the rights thereunder pertaining to the Entrusted Products to us pursuant to the then applicable PRC laws and regulations. Set forth below is a summary of the Entrustment Arrangements and the relevant business rationale:

Entrustment Arrangements

Business Rationale:	Considering the Entrusted Products Regulatory Restrictions and for the purpose of maintaining a clear business delineation between our Group and the Retained Lepu Medical Group in the interventional heart valve business subsequent to the business injection, the Entrustment Arrangements were devised for our Group to gain control of the Entrusted Products to the greatest extent possible under the prevailing regulatory framework and restrictions, with Lepu Medical carrying out the remaining necessary activities for the Entrusted Products according to our instructions and for our benefit.
Specific Arrangements:	(i) ***Control over properties and personnel.*** In line with the business rationale as stated above, we have acquired all intellectual properties and key equipment and assets, materials and personnel pertaining to the interventional heart valve business (including the Entrusted Products) from Lepu Medical, except that: (a) Lepu Medical maintains the minimum level of personnel for the Entrusted Products led by Ms. Zhang Yuxin, our executive Director, deputy general manager and chief technology officer, who will continue to oversee the clinical-related R&D work for the Entrusted Products undertaken by Lepu Medical in accordance with our instructions and with technical support and training from us; and

(b) Lepu Medical maintains necessary production capabilities relating to the Entrusted Products to support the need of product samples for clinical trial purposes.

The intellectual properties that we acquired from Lepu Medical were primarily registered patents and patents under application pertaining to the interventional heart valve business (including the Entrusted Products), as further detailed in Note (1) to the section headed "Appendix VII — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights of Our Group — (b) Patents" and relevant patents or patent applications superscripted with Note (1) thereunder.

(ii) ***Control over activities pertaining to the Entrusted Products and relevant costs***.

(a) *Control over Relevant Activities*. As part of the Entrustment Arrangements, Lepu Medical shall only carry out the research and development, registration and manufacturing activities for the Entrusted Products (to the extent that the then applicable PRC laws and regulations prohibit us from carrying out such activities) (the "Relevant Activities") legally in accordance with our instructions and for our benefit, with the actual costs of the Relevant Activities incurred by Lepu Medical to be reimbursed by us. Our consent is required for any material matters pertaining to the R&D, registration and manufacturing process of the Entrusted Products, including but not limited to key milestones, funding budgets, selection of clinical trial research institutions, investigators, suppliers and other business partners, amending, terminating or entering into any material agreements and business relationships, and any changes in internal protocols, policies or strategies in connection with the Relevant Activities. In particular, with respect to commercial manufacturing,

- Lepu Medical has exclusively and irrevocably authorized us to manufacture the Entrusted Product which does not fall within the Prohibited Catalog (*i.e.*, balloon dilatation catheter for aortic valve) after its registration; and

- Lepu Medical will be responsible for the manufacturing activities (as part of the Relevant Activities) for the TAVR system and TMVCRS after their registration due to restrictions in item iv of the Entrusted Products Regulatory Restrictions as illustrated above. Lepu Medical is in the process of constructing a dedicated facility with commercialization-ready manufacturing capabilities for the TAVR system and TMVCRS, which will be put into operation as and when the TAVR system and TMVCRS approach large-scale manufacturing stage.

(b) *Control over commercialization and sales activities*. Lepu Medical has irrevocably and exclusively authorized us to carry out commercialization and sales activities for each of the Entrusted Products, and our Group has the rights to determine and adjust the prices for each of the Entrusted Products.

(c) *Cost Control*. Lepu Medical and we have formed a joint committee (the "Entrusted Products Committee") pursuant to the terms of the asset transfer agreement in January 2021. The Entrusted Products Committee is responsible for, among others, overseeing the implementation of the Relevant Activities, evaluation and confirmation of milestones achieved, formulating funding budgets, and approving costs incurred pertaining to the Entrusted Products. We have the final confirmatory and decisive power for matters handled by the Entrusted Products Committee according to the asset transfer agreement. As such, the costs relating to Relevant Activities incurred by Lepu Medical had been and will continue to be properly reviewed and approved by us and reflected in our books of account. See "Relationship with Our Controlling Shareholders — Independence from Controlling Shareholders — Financial Independence" for the responsibilities of our financial department which is independent of Lepu Medical. Please also see paragraph (iii)(a) below in this table for Lepu Medical's further covenants with respect to, among others, maintaining/increasing the value of the Entrusted Products, obtaining/maintaining all regulatory documents pursuant to financially and commercially sound standards, and refraining from charging us any additional fees other than the actual costs incurred by it in carrying out the Relevant Activities.

(iii) ***Further covenants by Lepu Medical***.

(a) *Covenants by Lepu Medical under the current regulatory framework.* Lepu Medical irrevocably covenanted that it shall, among others, (1) carry out the Relevant Activities in line with its usual business practices, use its best endeavours to maintain and increase the value of the Entrusted Products and refrain from any action or inaction that may negatively impact the status or value of the Entrusted Products; (2) obtain and maintain all licenses, permits, registration certificates and filings that are necessary for the Entrusted Products in accordance with financially and commercially sound standards and management principles; (3) refrain from charging us any additional fees other than the actual costs incurred by it in carrying out the Relevant Activities; and (4) refrain from entering into any material contracts relating to the Entrusted Products or amending any material internal policies or strategies without our prior written consent.

(b) *Covenants by Lepu Medical in case of favorable regulatory changes.* Lepu Medical further irrevocably covenanted that, if and when, and to the extent permissible under the then applicable PRC laws and regulations, it shall (1) unconditionally transfer all remaining rights (namely, all rights excluding the intellectual property rights which have already been transfered to the Group) relating to the application or registration of the Entrusted Products to us, which include rights relating to R&D, manufacturing and marketing; and (2) cease to carry out any activities (including research and development, manufacturing and commercialization) in connection with the Entrusted Products subsequent to such transfer and/or authorization.

(iv) ***Responsibilities for potential product liabilities***

Should any product liabilities associated with the Entrusted Products arise, Lepu Medical shall be liable for such liabilities by operation of law due to the fact that it is the registrant of the Entrusted Products and will be entitled to claim compensations from our Group pursuant to our contractual arrangement under the Entrusted Products Related Framework Agreement. See "Connected Transactions — Non-exempt Continuing Connected Transactions — 2. Entrusted Products Related Framework Agreement."

As advised by our PRC Legal Advisors, the execution of the asset transfer agreement between Lepu Medical and us where the Entrustment Arrangements (including the entrusted arrangement of the R&D work) have been built in does not violate or constitute a circumvention of the relevant PRC laws and regulations in effect as at the Latest Practicable Date, on the basis that: (1) the purpose of the asset transfer agreement is to have the interventional heart valve business injected into Shanghai Shape Memory Alloy from Lepu Medical and solidify the Group's position as the sole platform under Lepu Medical Group focusing on interventional medical devices primarily targeting structural heart diseases, instead of concealing an illegal intention to circumvent relevant laws and regulations; and (2) the arrangements of the injection of the interventional heart valve business and the Entrustment Arrangements (including the entrusted arrangement of the R&D work) under the asset transfer agreement have been made according to the relevant PRC laws and regulations.

Furthermore, we have entered into a framework agreement with Lepu Medical as detailed in "Connected Transactions — Non-exempt Continuing Connected Transactions — 2. Entrusted Products Related Framework Agreement" to restate the Entrustment Arrangements as a continuing connected transaction under the Listing Rules. We have also designated Ms. Zhang Yuxin, our executive Director, deputy general manager and chief technology officer, as a representative of our Group to oversee the overall R&D of such products. See "— Our Products — Heart Valve Product Candidates," "Relationship with Our Controlling Shareholders — Independence from Controlling Shareholders — Management Independence" and "Connected Transactions — Non-exempt Continuing Connected Transactions — 2. Entrusted Products Related Framework Agreement." We will continuously monitor regulatory updates pertaining to the Entrustment Arrangements to maximize the interest of our Group and our Shareholders as a whole under these arrangements.

Considering (1) the intellectual properties, key equipment and assets, materials and personnel that we have acquired relating to the Entrusted Products, (2) our existing clinical resources and network with numerous hospitals, physicians and KOLs, (3) our planned facilities and space which satisfy the need for the research, development and manufacturing of the Entrusted Products, and (4) our planned use of the [**REDACTED**] from the [**REDACTED**] (as further elaborated in "Future Plans and [**REDACTED**] — [**REDACTED**]") for the development of and activities upon commercialization of our heart valve product candidates (which include the Entrusted Products) that we will, with respect to the Entrusted Products, either apply through our collaborations with Lepu (for activities that we cannot conduct on our own) or incur as our internal cost (for activities that we will then be able to conduct), our Directors are of the view that our Group would be capable to undertake the research and development for the Entrusted Products should the Entrusted Products Regulatory Restrictions be lifted. After due consideration of above and having discussed with the Directors to understand the key bases of their view and discussed with the PRC Legal Advisors in relation to the Entrusted Products Regulatory Restrictions, the Sole Sponsor confirms that nothing material has come to its attention that would contradict the view of the Directors.

In view of the Entrusted Products Regulatory Restrictions pertaining to the Entrusted Products, i.e., the TAVR system, TMVCRS, and balloon dilatation catheter for aortic valve, we entered into the Entrustment Arrangements whereby we have entrusted Lepu Medical to carry out Relevant Activities of the Entrusted Products legally according to our instructions and for our benefit. Lepu Medical has irrevocably covenanted that it shall, among other things, exclusively authorize us to manufacture the Entrusted Products and unconditionally transfer all rights relating to the application or registration of the Entrusted Products to us, as and when such authorization and/or transfer become permissible under applicable PRC laws.

Future Plan for the Entrusted Products and the Entire Heart Valve Product Candidates

For the R&D, we have assembled a research and development team for heart valve product candidates of more than 50 members, whose expertise spans a broad range of related fields, such as biomaterials, biomedical science, material science, and mechanical engineering. With this solid team, we have achieved meaningful advances in the R&D activities for the heart valve product candidates that were acquired from Lepu Medical during the business injection, and have also independently initiated R&D for six heart valve product candidates in the product pipeline. As such, we believe we will be able to efficiently execute our research and development strategies for heart valve product candidates. To retain the R&D members, in addition to offering competitive compensation packages, we provide them with well-structured training resources and learning opportunities to improve their technical skills and business mindset. In addition, we provide them with prospects of career advancement within our Group. For example, we may offer them opportunities to participate in the daily management activities of the research and development for specific product candidates, to align their interests with that of our Company, which we believe would also enhance their loyalty to us. We have also entered into standard confidentiality agreements with members of our heart valve research and development team, which also contain non-compete provisions, in order to retain them and safeguard our intellectual property rights. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Operations — Our future success depends on our ability to retain key executives and to attract, retain and motivate other qualified and highly skilled personnel, and we may experience labor shortages or increases in labor costs."

For the sales and marketing, we will continue to utilize our established sales force and sales network for occluder business to promote our heart valve business. We established our sales force and expanded our sales network targeting hospitals for demands in interventional medical devices primarily targeting structural heart diseases. Both our occluder products and heart valve product candidates belong to such interventional medical devices primarily targeting structural heart diseases. Accordingly, we believe we can leverage our established sales network to market our heart valve product candidates, as we have established our reputation among cardiologists, distributors, and most importantly, patients over the years.

For the manufacturing, utilizing the new production lines to be built for the heart valve product candidates, we plan to manufacture all of our heart valve product candidates, including our Entrusted Products, with (1) balloon dilatation catheter for aortic valve that we are not restricted for manufacturing, and (2) TAVR system and TMVCRS upon the regulatory changes lifting the restriction on commercial manufacturing for us. Specifically, we intend to purchase relevant machinery and equipment, and recruit and train production workers.

Set forth below is a summary of the work allocation between Lepu Medical and us at various stages pertaining to the Entrusted Products under the current regulatory framework and in the event that all Entrusted Products Regulatory Restrictions are uplifted:

Name of Entrusted Product	**Stage**	**Work allocation between Lepu Medical and us under the current regulatory framework** *N.B. Notwithstanding the work allocation below, our consent is required for any material matters in each stage pertaining to the Entrusted Products in connection with the Relevant Activities.*	**Work allocation between Lepu Medical and us in the event that all Entrusted Products Regulatory Restrictions become uplifted**
TAVR system	Pre-registration	*Lepu Medical:* Procurement of raw materials and producing sample products used in subsequent clinical trials, and communicating with the governmental authorities involved therein as necessary. *Our Group:* Devising the overall R&D plan, overseeing the implementation and progress of the R&D work, and deciding on the key external parties to be engaged in the R&D process.	Our Group would be responsible for the entire R&D process.
	Manufacturing	Lepu Medical	Our Group
	Sales and marketing	Our Group	Our Group

Name of Entrusted Product	Stage	**Work allocation between Lepu Medical and us under the current regulatory framework** *N.B. Notwithstanding the work allocation below, our consent is required for any material matters in each stage pertaining to the Entrusted Products in connection with the Relevant Activities.*	**Work allocation between Lepu Medical and us in the event that all Entrusted Products Regulatory Restrictions become uplifted**
TMVCRS	Pre-registration	*Lepu Medical:* Procurement of raw materials and producing sample products used in subsequent clinical trials, and communicating with the governmental authorities involved therein as necessary. *Our Group:* Devising the overall R&D plan, overseeing the implementation and progress of the R&D work, and deciding on the key external parties to be engaged in the R&D process.	Our Group would be responsible for the entire R&D process.
	Manufacturing	Lepu Medical	Our Group
	Sales and marketing	Our Group	Our Group
Balloon dilatation catheter for aortic valve	Pre-registration	*Lepu Medical:* Procurement of raw materials and producing sample products used in subsequent clinical trials, and communicating with the governmental authorities involved therein as necessary. *Our Group:* Devising the overall R&D plan, overseeing the implementation and progress of the R&D work, and deciding on the key external parties to be engaged in the R&D process.	Our Group would be responsible for the entire R&D process.
	Manufacturing	Our Group	Our Group
	Sales and marketing	Our Group	Our Group

Valvular Disease and Our Heart Valve Product Candidates

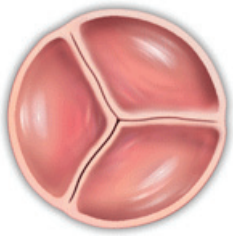
According to the F&S Report, valvular disease is characterized by damage to or a defect in one of the four heart valves: aortic, pulmonary, mitral or tricuspid. The aortic valve governs blood flow between the heart and the aorta, and thereby the blood vessels to the rest of the body. The pulmonary valve controls the flow of blood from the heart to the lungs. The mitral and tricuspid valves control the flow of blood between the atria and the ventricles (the upper and lower chambers of the heart). The aortic and mitral valves are the ones most frequently affected by valvular disease. Among all valvular diseases, aortic stenosis and mitral regurgitation are the most common types by prevalence, and degenerative changes are the main cause in the United States and Europe. In China, rheumatic diseases are the main cause, but along with the improving living standards, the aging of the population and extending life-expectancy, degenerative changes have become the main cause of valvular disease in the population over 65 years of age.

Our transcatheter heart valve product candidates are delivered into patient's diseased heart through a minimally invasive heart procedure using a catheter-based delivery system. Our transcatheter heart valve product candidates provide a beneficial alternative treatment for patients who are inoperable or at intermediate or high risk of complications from traditional open-chest surgery. The nonsurgical procedure of transcatheter heart valve products are proved superior to traditional surgical procedure with respect to preventing death, stroke or re-hospitalization. Transcatheter heart valve products are also associated with shorter hospital stays and less disturbance to patients' daily activities.

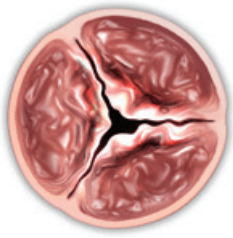
Our transcatheter heart valve product candidates also have advantages over mechanical heart valve products. Compared to transcatheter heart valve products which use tissue valves, mechanical valves increase a patient's risk of blood clot formation and severe bleeding from the mandatory anti-clotting medication. As a result, transcatheter heart valves are more suitable than mechanical valves for elderly patients, patients who cannot be anticoagulated in the presence of bleeding factors, and women during pregnancy.

Aortic Valve Product Candidates

According to the F&S Report, aortic valve disease is a condition in which the valve between the main pumping chamber of one's heart, the left ventricle, and the main artery to the body, the aorta, does not work properly. Aortic valve disease may be a condition present at birth, or may result from other causes, including age-related changes to the heart, infections, high blood pressure or injury to the heart. Major types of aortic valve disease include aortic stenosis and aortic regurgitation. Aortic stenosis is the narrowing of the aortic valve, obstructing blood flow from the left ventricle to the ascending aorta during systole. Causes include congenital aortic valve structure abnormalities, rheumatic fever, and senile aortic valve calcification. The following images demonstrate a normal aortic valve, on the left, and an aortic stenosis, on the right.



Normal aortic valve



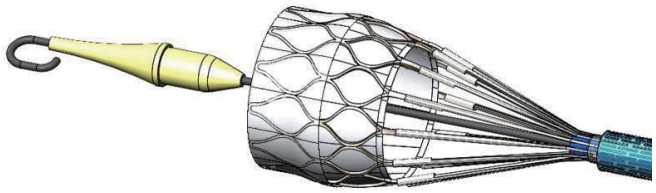
Aortic stenosis

Our aortic valve product candidates are designed to treat aortic stenosis, and mainly include TAVR system and various non-implantation therapeutic auxiliary devices. According to the F&S Report, due to the insufficient number of qualified hospitals with experienced physicians, the TAVR market in China is significantly under-penetrated with only 0.8% of eligible patients treated by TAVR procedures in 2021, as compared to 4.3% globally. The number of TAVR operations to be performed in China is expected to grow from 6,600 in 2021 to 43,000 in 2025, with a CAGR of 59.6%, according to the same source. Accordingly, the market size of China's TAVR market is expected to increase from RMB0.9 billion in 2021 to RMB4.9 billion in 2025 at a CAGR of 52.0%, and further to RMB11.4 billion in 2030 at a CAGR of 18.5% from 2025 to 2030, according to the same source. The market size of the global TAVR market is expected to increase from US$6.1 billion in 2021 to US$10.0 billion in 2025 at a CAGR of 13.1%, and further to US$15.9 billion in 2030 at a CAGR of 9.8% from 2025 to 2030, according to the same source.

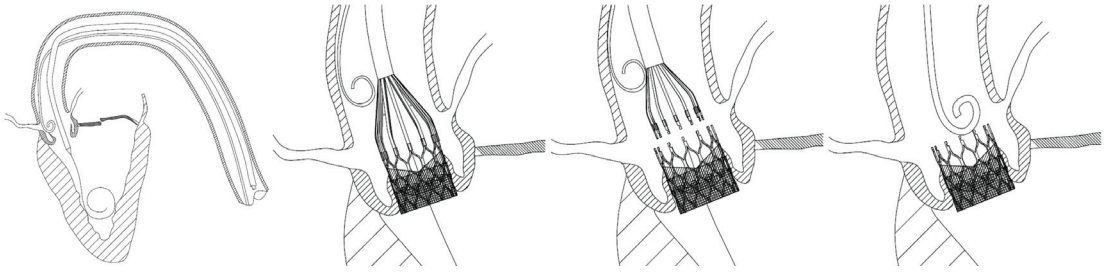
TAVR System

Our TAVR system is a bio-prosthesis aortic valve that primarily consists of a self-expanding nitinol stent sutured with bovine pericardial valve leaflets and PET skirt. Our TAVR system adopts bovine pericardium as the valve leaflet material to provide excellent durability and hemodynamic performance. In addition, bovine pericardium exhibits greater fatigue resistance compared to porcine pericardium, another frequently-used pericardium material, which in turn reduces the damage to the valve caused by the blood flow. The short stent design in our TAVR system enables reduced volume of metal implants and reduced risk of blocking the coronary ostium. With our unique release and unlocking design, the valve is fully deployed after being released from the delivery system, enabling a real-time evaluation of the valve working status prior to unlocking. Our TAVR system is expected to be 100% deployable, retrievable and repositionable before decoupling from the delivery system, and such features are not present in any commercialized TAVR systems in China as of the Latest Practicable Date, according to the F&S Report. Specifically, "100% deployable" means that the TAVR system can be circularly unfolded at all levels after being released from the delivery component, free of any constraint on radial direction. These features allow physicians multiple attempts to adjust the position of the valve during the procedure and greatly improves the overall procedure success rate. These features may also lower the risk of post-operative complications resulted from malpositioning, and therefore reduce the time for post-operative management. Our TAVR system is compatible with both transfemoral and transapical delivery, so that a physician will be able to choose the best delivery route according to the patient's particular physical condition. In addition, our TAVR system is designed to include a delivery component and a loading component to optimize precision and stability during the procedure.

The following graph illustrates the product structure of our TAVR system, which is a product candidate.



The following diagrams from left to right illustrate the delivery procedure of our TAVR system, including the valve prior to releasing, the valve released from the delivery system but yet to be unlocked, the unlocking process, and the implanted valve, respectively.



We began to develop our TAVR system in 2016, aiming to provide innovative medical solutions for patients with aortic valve diseases. As of the Latest Practicable Date, our TAVR system was in the clinical trial stage. The results from pre-clinical animal studies have demonstrated ideal loading, positioning, releasing and retrieving of our TAVR system in animals. We also completed the type inspection at the NMPA in December 2020. As of the Latest Practicable Date, we had initiated the clinical trial and expect to submit registration application with the NMPA in the fourth quarter of 2023.

We are also evaluating the opportunities to market our TAVR system overseas, especially in emerging markets that recognize the CE Mark. We plan to initiate the clinical trial for TAVR system in the European Union in the fourth quarter of 2024.

Transcatheter Aortic Valve Stenosis Therapy System

As alternatives to valve replacement, non-implantation aortic stenosis treatment methods are becoming attractive especially to the patients aging from 50 to 65 years old. Non-implantation aortic stenosis treatments can restore the physiological function of the valve without implanting a valve into the heart, therefore avoiding the risk of valve failure and secondary surgery.

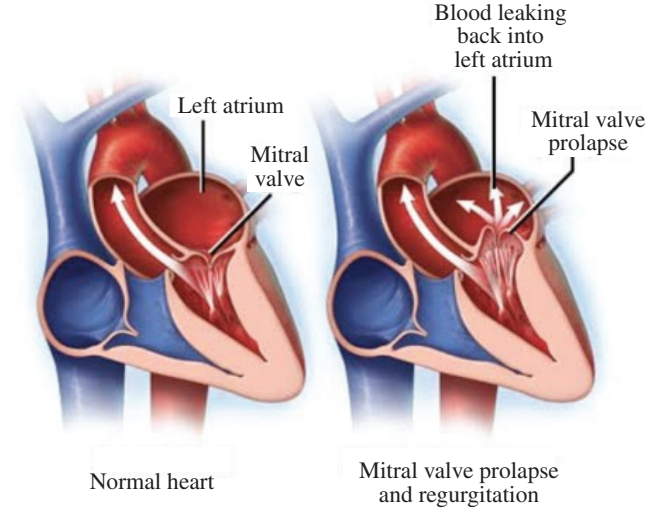
We conducted research in non-implantation treatment of aortic stenosis and are developing our transcatheter aortic valve stenosis therapy system and accompanying pulsed acoustical generator. The pulsed acoustical generator is used in conjunction with the transcatheter aortic valve stenosis therapy system in treating calcified aortic stenosis. The transcatheter aortic valve stenosis therapy system anchors the calcified valve, and the pulsed acoustical generator transmits high-voltage and high-energy pulses to the calcified parts of the valve through catheter, therefore reducing the transvalvular pressure difference and increasing the opening area of native aortic valve. As of the Latest Practicable Date, our transcatheter aortic valve stenosis therapy system and pulsed acoustical generator were in the type inspection stage. We plan to commence the relevant clinical trial in China in the fourth quarter of 2023.

As of the Latest Practicable Date, our transcatheter aortic valve system (balloon dilation) designed for patients with aortic stenosis was in the type inspection stage, and artificial heart valve with polymer leaflets for transcatheter implantation and aortic valve perfusion system were in the design stage. See "— Product Candidates in Design Stage."

Mitral Valve Product Candidates

The mitral valve is a one-way valve located between the heart's two left chambers and allows blood to flow from the atrium to the ventricle. It has two movable leaflets, the anterior leaflet and the posterior leaflet, to ensure blood flows in only one direction. When the mitral valve does not close properly, blood is allowed to leak backwards in the heart, which is called mitral regurgitation. According to the F&S Report, mitral regurgitation is the incompetency of the mitral valve causing flow from the left ventricle into the left atrium during ventricular systole. The prevalence of mitral regurgitation increases with age, which accounts for approximately 65% of mitral valve diseases. Acute mitral regurgitation may cause acute pulmonary edema and cardiogenic shock or sudden cardiac death. Chronic mitral regurgitation may cause gradual enlargement of the left atrium.

The following images illustrate the anatomy of mitral valve, on the left, and mitral regurgitation, on the right.

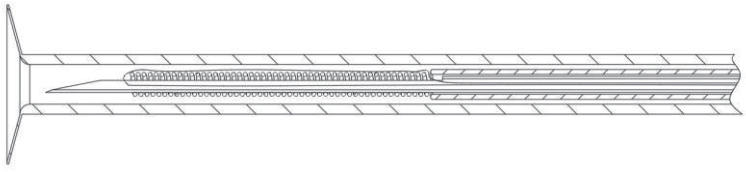


Our mitral valve product candidates mainly include TMVCRS, TMVr systems, and TMVR system.

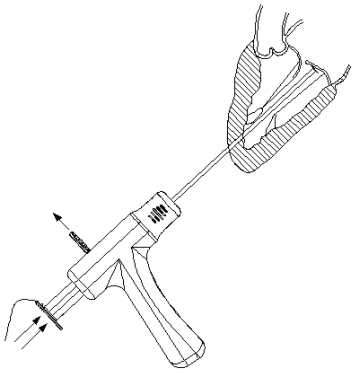
TMVCRS

Our TMVCRS is a transapical artificial chordal repair system targeting mitral regurgitation. Our TMVCRS consists of two configurations, one enabling implantation of artificial chordae and the other enabling edge-to-edge chordae repair. The implantation of artificial chordae is suitable for treating degenerative mitral regurgitation caused by chordal prolapse, while the edge-to-edge chordae repair can treat both degenerative mitral regurgitation and functional mitral regurgitation.

Our TMVCRS is designed to be deployed transapically to allow better manipulation and handling of the device. The delivery tube and ePTFE artificial chords in our TMVCRS are visible under ultrasound, making it possible to deploy the TMVCRS under the guidance of ultrasound, without the need for radiation. Our TMVCRS is also advantageous in the ability of adjusting the length of the chordae in real time under ultrasound without cardiac arrest during the procedure. As compared with traditional surgical artificial chordae repair procedures, where the left atrium is opened under cardiac arrest and no length adjustment is possible once the procedure is completed, our TMVCRS adopts a transapical approach, where after the artificial chordae is implanted on the valve leaflet, the artificial chordae is pulled at the apex cordis, and the mitral valve closure effect is observed by physicians in real time under ultrasound. Once the best effect is determined, the apex cordis is sutured and the procedure is completed. The following graph illustrates the product structure of our TMVCRS.



The following graph illustrates the operation of our TMVCRS.



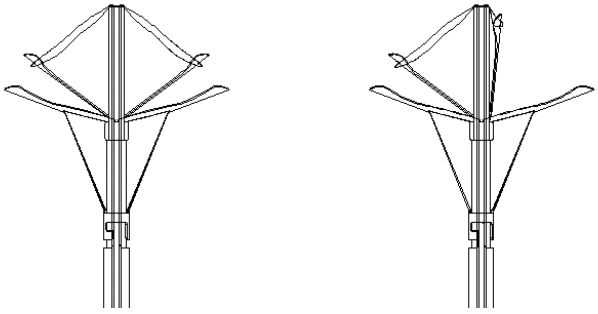
TMVCRS

TMVr-A and TMVr-F systems

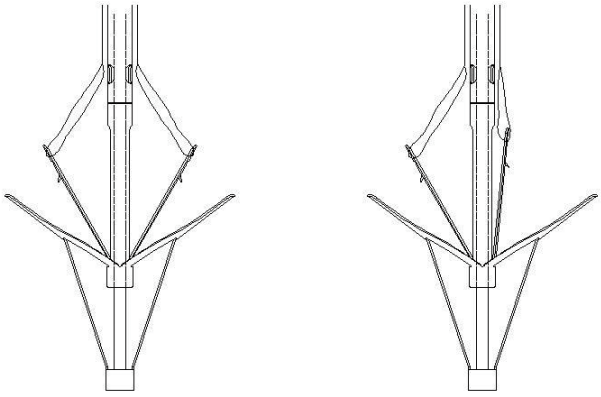
According to the F&S Report, the market size of the global TMVr market is expected to increase from US$0.9 billion in 2021 to US$2.5 billion in 2025 at a CAGR of 29.3%, and further to US$5.5 billion in 2030 at a CAGR of 17.1% from 2025 to 2030. The market size of China's TMVr market is expected to increase from RMB39.9 million in 2021 to RMB1.6 billion in 2025 at a CAGR of 152.0%, and further to RMB4.8 billion in 2030 at a CAGR of 24.4% from 2025 to 2030, according to the same source.

Our TMVr systems, or TMVr-A and TMVr-F systems, are interventional medical devices designed for the edge-to-edge repair of mitral valve to treat patients with mitral regurgitation, including both functional mitral regurgitation and degenerative mitral regurgitation. The TMVr-A system can be delivered through a transapical delivery and the TMVr-F system can be delivered through a transfemoral delivery, in which the straightforward transapical delivery allows better manipulation and handling of the system and reduced the operative duration, while the transfemoral delivery is less invasive. Our TMVr-A system is designed to be paired with one of the thinnest delivery sheaths to minimize potential damage to the heart. Our TMVr-A and TMVr-F systems consist of a pair of upper clamping arms and a pair of lower clamping arms, all made of nitinol and coated with PET skirt, both of which are biocompatible. In addition, our TMVr-A and TMVr-F systems are both designed to include a delivery component with a puncture sheath component to optimize precision and stability during the procedure.

Furthermore, our TMVr-A and TMVr-F systems are designed to allow better manipulation and handling of the systems. The higher level of control and operability, as compared to other existing competing products, serves to reduce the duration and difficulty of TMVr procedures, which we believe will be a key competitive edge of our TMVr systems. The upper clamping arms in our TMVr-A and TMVr-F systems are independently controllable by manipulating a pulling wire, with each of the clamping arms holding one of the mitral valve leaflets. Once both the anterior and posterior leaflets of the mitral valve are successfully captured, the TMVr-A and TMVr-F systems are closed by pulling the wire, which in turn pulls the mitral valve leaflets together. The following images illustrate the operating principles of our TMVr-A and TMVr-F systems. The left images present a state in which clamping arms on both sides are simultaneously operated, each of which being ready to capture a mitral leaflet. The right images present a state in which the clamping arm on one side is independently operated to capture a mitral leaflet.



TMVr-A system



TMVr-F system

The central spacer in between the two upper clamping arms of our TMVr-A and TMVr-F systems is coated with PET skirt to fill the internal space and further reduce the regurgitation. The central spacer is elastic to reduce the risk of harm to leaflets. We have developed various specifications for our TMVr-A and TMVr-F systems to accommodate different anatomical structures. In addition, our TMVr-A system is also deployable under the guidance of ultrasound, without the need for radiation during the procedure.

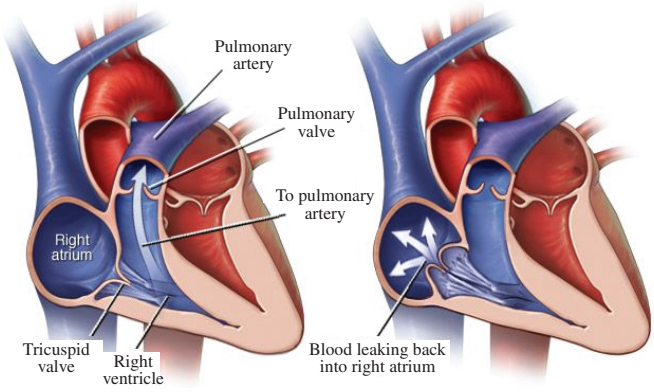
As of the Latest Practicable Date, our transcatheter mitral valve replacement ("TMVR") system was in the design stage. See "— Product Candidates in Design Stage."

We began to develop our TMVCRS, TMVr-A system, and TMVr-F system in 2018, aiming to provide innovative medical solutions for mitral valve patients. As of the Latest Practicable Date, we had successfully commenced the clinical trial for TMVCRS enabling implantation of artificial chordae in China. We plan to submit the registration application with the NMPA in the third quarter of 2024. As of the Latest Practicable Date, our TMVr-A system was at the clinical trial stage. We plan to submit the registration application with the NMPA in the fourth quarter of 2023. As of the Latest Practicable Date, our TMVr-F system was in the type inspection stage and our all other mitral valve product candidates were in the design stage. We plan to commence the clinical trial for TMVr-F in China in the fourth quarter of 2022 and submit registration application with the NMPA in the fourth quarter of 2024. See "— Product Candidates in Design Stage."

We are also evaluating opportunities to market our TMVr-A system and TMVr-F system overseas, especially in emerging markets that recognize the CE Mark. We plan to initiate clinical trials for TMVr-A system and TMVr-F system in the European Union and the United States in the fourth quarter of 2025.

Tricuspid Valve Product Candidates

Tricuspid valve regurgitation is a condition in which the valve between the right ventricle and right atrium cannot close properly, which further leads to regurgitation. The malfunctioning valve allows blood to flow back into the right atrium. The following images illustrate the normal tricuspid valve, on the left, and occurrence of tricuspid valve regurgitation, on the right.



As of the Latest Practicable Date, we were developing our transcatheter tricuspid valve repair system ("TTVRS") to treat tricuspid valve regurgitation. Our TTVRS can effect an edge-to-edge repair of diseased tricuspid valve. As of the Latest Practicable Date, TTVRS was in the design stage. We plan to commence the clinical trial for TTVRS in China in the fourth quarter of 2023. We were also in the process of developing our transcatheter tricuspid valve replacement system, which was in the design stage as of the Latest Practicable Date. We plan to commence the related clinical trial in China in the third quarter of 2024. See "— Product Candidates in Design Stage."

Pulmonary Valve Product Candidate

Pulmonic regurgitation is a condition where the pulmonary valve, which controls blood flow from the right ventricle to the lungs, fails to close properly, allowing blood to leak back to the right ventricle. As of the Latest Practicable Date, we were developing our transcatheter pulmonary valve replacement system to treat pulmonic regurgitation. Our transcatheter pulmonary valve replacement system was in the design stage as of the Latest Practicable Date, and we plan to commence the related clinical trial in China in the fourth quarter of 2024. See "— Product Candidates in Design Stage."

Procedural Accessories for Heart Valve Product Candidates

Our procedural accessories are specialized procedural tools for implanting our heart valve product candidates. As of the Latest Practicable Date, we were developing a series of accessories in various pre-launch stages.

Balloon Dilatation Catheter for Aortic Valve

Our balloon dilatation catheter for aortic valve is used during implanting aortic valve products. It consists of a balloon, a coaxial tube, a tip, a tube base and an visualization ring. The balloon is a high pressure resistant non-compliant balloon. The balloon size ranges from 8mm to 28mm and thus is suitable for various types of aortic valve stenosis. It is designed to effectively expand the aortic valve stenosis without causing vascular complications due to excessive expansion. The coaxial tube provides a large filling channel, reduces the time of balloon filling and discharging, and thus reduces the operative duration. The tip of the catheter is made of flexible Pebax® material and is shaped as a cone, making it possible to smoothly pass through the blood vessel and reduce blood vessel damage. The visualization ring is made of tantalum, which has excellent corrosion resistance and visualization effect. The visualization ring can assist the physician in determining the position of the balloon during the procedure. As of the Latest Practicable Date, our balloon dilatation catheter for aortic valve was in the clinical trial stage in China. We plan to submit the registration application with the NMPA in the fourth quarter of 2022. We also plan to apply for the CE Mark for our balloon dilatation catheter for aortic valve.

Thrombus Protection Device

TAVR-related stroke may be caused by the shedding of aortic atherosclerotic plaque when the delivery system passes through the aorta, or it may be caused by the shedding of calcification from the aortic valve due to balloon expansion. The Neurological Complications of Contemporary Unprotected TAVR (Yale Neuro TAVR) study showed that, 94% of patients had new brain lesions after TAVR, 25% of patients had new nerve damage after TAVR, and 40% of patients had symptoms of cognitive decline within 30 days after surgery. Therefore, reducing the occurrence of new brain damage after TAVR surgery caused by thrombus is an urgent problem to be solved.

Our thrombus protection device is used in the TAVR procedure to prevent thrombus from entering the brain and reduce the occurrence of stroke. Our thrombus protection device mainly includes two filter screens made of elastic materials. The filter screens are fixed to the push wire of the delivery system by welding. As of the Latest Practicable Date, our thrombus protection device was in type inspection stage.

Vascular Closure Device System

Our vascular closure device system is designed for targeted transcatheter delivery of degradable hemostatic substance to arterial puncture site to facilitate closure and minimize complications. As of the Latest Practicable Date, our vascular closure device system was in design stage.

Disposable Introducing Sheath

Our disposable introducing sheath is composed of a catheter sheath and a dilator. The handle of the catheter sheath adopts a three-layer sealing structure, which fully stops bleeding and significantly reduces the friction when the introducing sheath passes through blood vessels. The catheter sheath and the dilator are both coated with a hydrophilic coating to reduce damage to blood vessels. The design of our disposable introducing sheath enables easy blood sample collection and liquid infusion during procedures. We had submitted the registration application to the NMPA for disposable introducing sheath in July 2022 and expect to receive the approval in the second quarter of 2023.

Disposable Delivery Sheath

Our disposable delivery sheath is a dedicated medical instrument delivery device for target sites such as atrial septum, ventricular septum and arterial catheter. As of the Latest Practicable Date, we had completed the type inspection for our disposable delivery sheath and expect to submit the registration application with the NMPA in the fourth quarter of 2022.

Disposable Atrial Septal Puncture System

Our disposable atrial septal puncture system is used for atrial septal puncture in cardiac transcatheter procedures to obtain left heart access. It consists of an atrial septal puncture needle and an atrial septal puncture sheath. As of the Latest Practicable Date, our disposable atrial septal puncture system was in the stage of type inspection.

Product Candidates in Design Stage

As of the Latest Practicable Date, we had 11 major product candidates in the design stage covering different product categories of interventional medical devices for structural heart diseases. The following table summarizes information on our product candidates in the design stage.

Category and Name	Classification of Medical Devices in terms of NMPA	Design Features and Applications
Heart Valve Product Candidates		
Artificial heart valve with polymer leaflets for transcatheter implantation	Class III	Novel polymer material as the valve leaflet material with improved durability; larger orifice area and smaller profile; suitable for transcatheter heart valve products

Category and Name	Classification of Medical Devices in terms of NMPA	Design Features and Applications
Aortic valve perfusion system	Class III	Targeted drug delivery for aortic valve calcification
Transcatheter annulus repair system	Class III	Anchored and sized on the mitral valve annulus under real-time ultrasound guidance to reduce regurgitation; pre-formed shape with barbs, providing stable positioning
TMVR system	Class III	Suitable for treating patients with severe mitral regurgitation or unsuitable for open-chest surgery or TMVr; D-shaped stent design to avoid left ventricular outflow tract obstruction
Transcatheter papillary muscle repair system	Class III	Real-time adjustment of papillary muscle under ultrasound guidance
Transcatheter tricuspid valve repair system	Class III	Each clip arm being independently adjustable to capture one leaflet
Transcatheter tricuspid valve replacement system	Class III	Suitable for treating tricuspid valve regurgitation
Transcatheter pulmonary valve replacement system	Class III	Suitable for treating pulmonic regurgitation
Vascular closure device system	Class III	Procedural accessories
Occluder Product Candidates		
IASD II (Biodegradable)	Class III	Relieving left atrium overload; biodegradable
Snare II (Multiple-loop Snare)	Class III (exempted from clinical trial requirements)	Capturing and retrieving inferior cardiovascular equipment; multi-loop design which reinforces both accuracy and reliability

Our Global Distribution Footprint

We generated revenue from the Retained Lepu Medical Group for products sold overseas of RMB7.8 million, RMB28.0 million, RMB10.2 million, RMB8.5 million and RMB0.6 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, accounting for 6.7%, 18.9%, 4.6%, 7.7% and 0.5% of our total revenue in the same periods, respectively. Through gradual termination of our cooperation with the Retained Lepu Medical Group for the distribution of our products overseas, as of September 30, 2021, we had entered into distribution agreements with overseas distributors directly, except for India. See "Connected Transactions — Non-Exempt Continuing Connected Transactions" and "— Sales, Distribution and Marketing — Sales Arrangements." We believe direct distribution

arrangement with such distributors allows for more control over our overseas distributor networks and better understanding of overseas market demands. Prior to the change in the distribution model for overseas markets in 2021, the Retained Lepu Medical Group was our sole distributor for overseas markets. As of the Latest Practicable Date, we had accumulated considerable experience in product registration and launch in the European Union and attained valid CE Marks for nine of our products. Depending on the market demand and conditions, we plan to commence necessary overseas clinical trial process for select product candidates and gradually complete overseas registration for our product candidates in key target markets. We plan to purchase materials and equipment, conduct animal studies, clinical trials, inspections and registration, and engage local agencies and consultants for clinical trials and registration matters. We also intend to accelerate the commercialization of our future biodegradable occluder product candidates and heart valve product candidates in overseas markets such as the European Union, Southeast Asia and the United States.

OUR PLATFORM

Since our inception, we have developed a comprehensive and synergistic medical device platform focusing on interventional medical devices targeting structural heart diseases, which lays the foundation for our research and development, manufacture and commercialization activities. On our platform, employees of different functional teams collaborate together to guide the pathway for our products and product candidates. Our established industry connections and distributor network further contribute to the commercial viability of our product portfolio.

Research and Development

Our Research and Development Team

We have built our research and development team with technological expertise in various areas, primarily including nitinol shape memory material cutting and braiding techniques, animal source material processing techniques, biodegradable material controlled release techniques, suturing techniques, and structure design and processing techniques. We have developed a comprehensive portfolio of 50 marketed products and major product candidates, and maintained an expansive collection of intellectual property rights including 229 registered patents and 55 pending patent applications in China as of the Latest Practicable Date. As of the same date, we also had 14 patents under application in the United States and the European Union.

As of the Latest Practicable Date, our research and development team had 78 members based in Beijing and Shanghai, approximately 39.7% of whom possess a master's or higher degree in relevant fields. Our research and development team is led by Ms. ZHANG Yuxin, our executive Director and chief technology officer, who has over 10 years of experience in medical device research and development and is the co-inventor of more than 30 patents. Our research and development team is further divided into the occluder team and the heart valve team, each with specialized tasks, to facilitate the product development process. We have

entered into legally-binding confidentiality and non-compete agreements with our key employees and employees involved in our research and development activities. We have also entered into service invention agreements with such employees, pursuant to which any intellectual property conceived and developed during their employment belongs to us and they waive all relevant rights or claims to such intellectual property.

In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we incurred research and development expenses of RMB25.8 million, RMB39.0 million, RMB41.4 million, RMB16.4 million and RMB19.6 million, respectively, representing 22.2%, 26.3%, 18.6%, 14.8% and 15.7%, respectively, of our total revenue for the same periods. See "Financial Information — Description of Certain Consolidated Statements of Profit or Loss — Research and Development Expenses."

Collaboration with Research Institutions, Hospitals, KOLs and Physicians

Our research and development teams collaborate closely with research institutions and hospitals, who provide invaluable insights, guidance and recommendations. We lead the research and development process of our products. We collect market information from physicians and hospitals as well as professional advice from KOLs at the project proposal stage to optimize product design. After we have a preliminary design, we seek suggestions from partnered research institutions and KOLs to evaluate feasibility and further refine product features. Specifically, we collaborate with the National Engineering Research Center for Biomaterials (國家生物醫學材料工程技術研究中心) to study the properties of biodegradable polymer materials in order to facilitate our research and development of biodegradable occluder products. Specifically, Dr. Yunbing Wang, who serves as the director of the National Engineering Research Center for Biomaterials, the academic dean of the College of Biomedical Engineering of Sichuan University (四川大學生物醫學工程學院), and the vice chairman of the Chinese Society for Biomaterials (中國生物材料學會), has agreed to serve as our external consultant. We have also collaborated with Fuwai Yunnan Cardiovascular Hospital (雲南省阜外心血管病醫院) in completing the world's first fully biodegradable VSD Occluder implantation in February 2018 during its clinical trial, which marks a breakthrough in the field of fully biodegradable occluders globally, according to the F&S Report. We have also collaborated with a prominent medical institution in China in the research and development of our TAVR system which is expected to be 100% deployable, retrievable and repositionable before being detached from the delivery system. We are generally responsible for the research and development activities at our own cost, and the collaborating institutions are responsible for providing premises, equipment, research advice and technical instructions to us. We are entitled to the ownership of substantially all of the technologies developed from such collaborations, including patented and unpatented technologies. We also maintain continuous communications with research institutions, KOLs, physicians and hospitals, who are informed of our latest research and development progress. In addition, we actively participate in medical conferences and industry exhibitions and host meetings and seminars to foster collaborative relationship with industry participants.

Product Design and Pre-clinical Development

Product Design

Our product design typically involves three phases, including project proposal, project approval, and design and development.

- *Project proposal.* Our sales and marketing staff collect market information and coordinate with KOLs and physicians to keep our research and development team well informed of market demands of physicians and patients. Our research and development staff conduct economic and feasibility analysis, with costs, product functions, market potential, existing products and regulatory requirements taken into consideration. After the analysis, our research and development staff formulate a preliminary product protocol.

- *Project approval*. After a project has passed all internal assessments, representatives from our research and development, clinical management, supply chain and manufacturing and quality control and management teams collectively review the project proposal and determine whether the project should proceed and also set a detailed project timetable. The research and development team shares their studies on project feasibility. The supply chain team assists with determining raw material requirements. The quality control and clinical management team helps ensure that the product design complies with all applicable laws and regulations. The manufacturing team then produces and modifies product samples. Based on feedback from functional teams, the senior management will then determine whether a project should proceed.

- *Design and development.* Our new medical device product design and development is guided by our internal control protocol. See "— Quality Control" for more details.

Pre-clinical Animal Studies

To evaluate the function, safety and efficacy of our product and product candidates in a cost-effective manner with controllable risk exposures, we typically perform a pre-clinical animal study before our products reaching clinical trial stage. We collaborate with qualified third parties to conduct animal studies. Under the agreements with such third parties, we formulate detailed animal study protocols which specify the goals and requirements for animal studies, and send the protocols to the testing institutions to evaluate feasibility and relevant cost. 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. Pursuant to the agreements, the third parties must maintain strict confidentiality. We own all the data, results and intellectual property rights developed from the animal tests. We can terminate the agreements with prior written notice to the third parties. Based on the animal study results, we will then confirm our product design or make improvements to its safety and efficacy. We believe we are well-positioned to identify potential risks and improve our products through animal studies.

Clinical Trials

Within our research and development team, we have a clinical management team, which is responsible to conduct clinical trials for our products. We have established a specialized clinical management team with extensive experience in conducting clinical trials as well as communicating with hospitals, CROs and other parties involved in the clinical trials.

We conduct clinical trials of our new products in order to obtain the requisite regulatory approvals and collect post-procedure data that can improve and enhance the design and features of our products. In addition, robust clinical data are an important marketing tool for increasing the credibility of our brand and products. The goal of a clinical trial is to verify the clinical efficacy and safety of a device. Within our research and development team, we have assembled a regulatory affairs team, which is independent from our clinical management team, in charge of regulatory approval to submit our clinical report together with other materials to the relevant government agencies. As of the Latest Practicable Date, we were in the process of seven clinical trials in China, and our current clinical data and practices are designed to meet the standards of the Norms on the Quality Management for the Clinical Trials of Medical Devices (《醫療器械臨床試驗質量管理規範》) as promulgated by the China Food and Drug Administration (currently known as the NMPA) and National Health and Family Planning Commission of the PRC. Our occluder products, such as ASD, VSD, PDA and PFO occluder products, typically go through non-inferiority clinical trials designed to evaluate efficacy and safety by comparing the safety and efficacy endpoints among patients undergoing procedures using our occluder product candidate to be launched and our marketed occluder product of older generations or marketed occluder product of other reputable medical device providers. According to the F&S Report, it is an industry norm in China for medical device providers to adopt single-arm clinical trials for product candidates in emerging markets with very limited marketed products. In line with industry standard, our heart valve product candidates typically go through single-arm clinical trials, where a sample of individuals with the targeted medical condition is given the experimental therapy and then followed up over time to observe their response and prognosis to collect efficacy and safety data. We also plan to commence overseas clinical process for MemoSorb® VSD Occluder IV, and as soon as practicable when suitable market conditions arise after we obtain the NMPA approval for certain product candidates, such as MemoSorb® ASD Occluder IV, MemoSorb® PFO Occluder II, MemoLefort® LAA Occluder I, LAA Occluder II, TAVR system, TMVr-A, and TMVr-F.

In line with industry practice, during the Track Record Period, we engaged industry-leading CROs to provide certain supporting services in the clinical trials for our products. Such CROs, including Beijing Tailian BioPharma Co., Ltd. (北京太鏈生物醫藥有限公司) and Beijing Excellence Angel Medicinal Technological Progress Co., Ltd. (北京卓越天使醫藥科技發展有限公司), are private companies in China primarily engaged in providing clinical support to the pharmaceutical, biotechnology and medical device industries on a contract basis. We select our CROs based on various factors, including service quality, capability, reputation, cost-effectiveness and research experience in treating heart disease. We typically enter into master service agreements with our CROs 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 monitor the CROs 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. Since 2018, all the

clinical trial results, none of which contains any personally identifiable information, are stored in and managed through an online electronic data capture system, which is only accessed by our responsible employees, the employees of the CRO that are in charge of the clinical trial and personnel of other professional parties that we cooperate with during the clinical trial process. We recorded service fees paid to the same CRO of RMB0.2 million in 2019, representing the last installment for our LAA occluder product. We recorded service fees paid to our CROs of RMB2.8 million in 2020 in connection with the clinical trials for our fully biodegradable VSD occluder product, biodegradable ASD occluder product candidate and biodegradable PFO occluder product candidate. We recorded service fees paid to our CROs of RMB12.3 million in 2021 in connection with the clinical trials for our fully biodegradable VSD occluder product, biodegradable PFO occluder product candidate, biodegradable ASD occluder product candidate and TMVr-A system. We recorded service fees paid to our CROs of RMB2.1 million in the six months ended June 30, 2022 in connection with the clinical trials for our IASD I and biodegradable ASD occluder product candidate. We did not record any service fee payable to our CROs as of December 31, 2019 and 2020. We recorded service fee payable to our CROs of RMB1.3 million as of December 31, 2021. We did not record any service fee payable to our CROs as of June 30, 2022. Such service fees were typically determined by the nature of the services provided, manpower involved, amount of time and resources devoted, as well as other operational costs of the CROs. We became acquainted with one of our CROs through referral by Lepu Medical, to whom the CRO had provided clinical trial management services. We became acquainted with another one of our CROs through its parent company, which had provided site management services for us. We became acquainted with the remainder of our CROs during the Track Record Period through public tender processes. To the best of our Directors' knowledge, save as disclosed above, none of our CROs (including their respective shareholders, directors or senior management, or any of their respective associates) had any past or present relationships (including, without limitation, business, employment, family, trust, financing, shareholding or otherwise) with our Group, our shareholders, Directors, senior management or any of their respective associates.

Collaboration with Clinical Trial Institutions

The NMPA maintains a catalog of hospitals approved as clinical trial institutions, from which we select a number of leading hospitals to conduct our clinical trials. The factors we consider when selecting such institutions include their credentials, expertise, technology, facilities and patient demographics. We typically enter into an agreement with each selected hospital for each clinical trial, under which we and the participating hospitals prepare a clinical trial protocol following Good Clinical Practice standards that describes in detail the goal of the clinical trial, the methods and the procedures of the trial, and the risks involved. The clinical trial protocol is also subject to the review of ethics committee. Pursuant to the agreements, the institutions are required to conduct clinical trials strictly in accordance with the protocol, collect data, and develop clinical conclusions at the end of each clinical trial. The lead institution will prepare formal reports based on the clinical data submitted by all participating institutions. In return for the services from the institutions, we make scheduled payments as agreed in the agreements. Under the agreements, we generally own all the intellectual property and trial results while the participating institutions may use the clinical trial results for academic activities with our prior approval.

We generally select approximately 10 hospitals located in major cities as our clinical trial institutions for each clinical trial. As of the Latest Practicable Date, we had collaborated with over 40 hospitals in China for our various clinical trials.

Manufacturing

Production Facilities

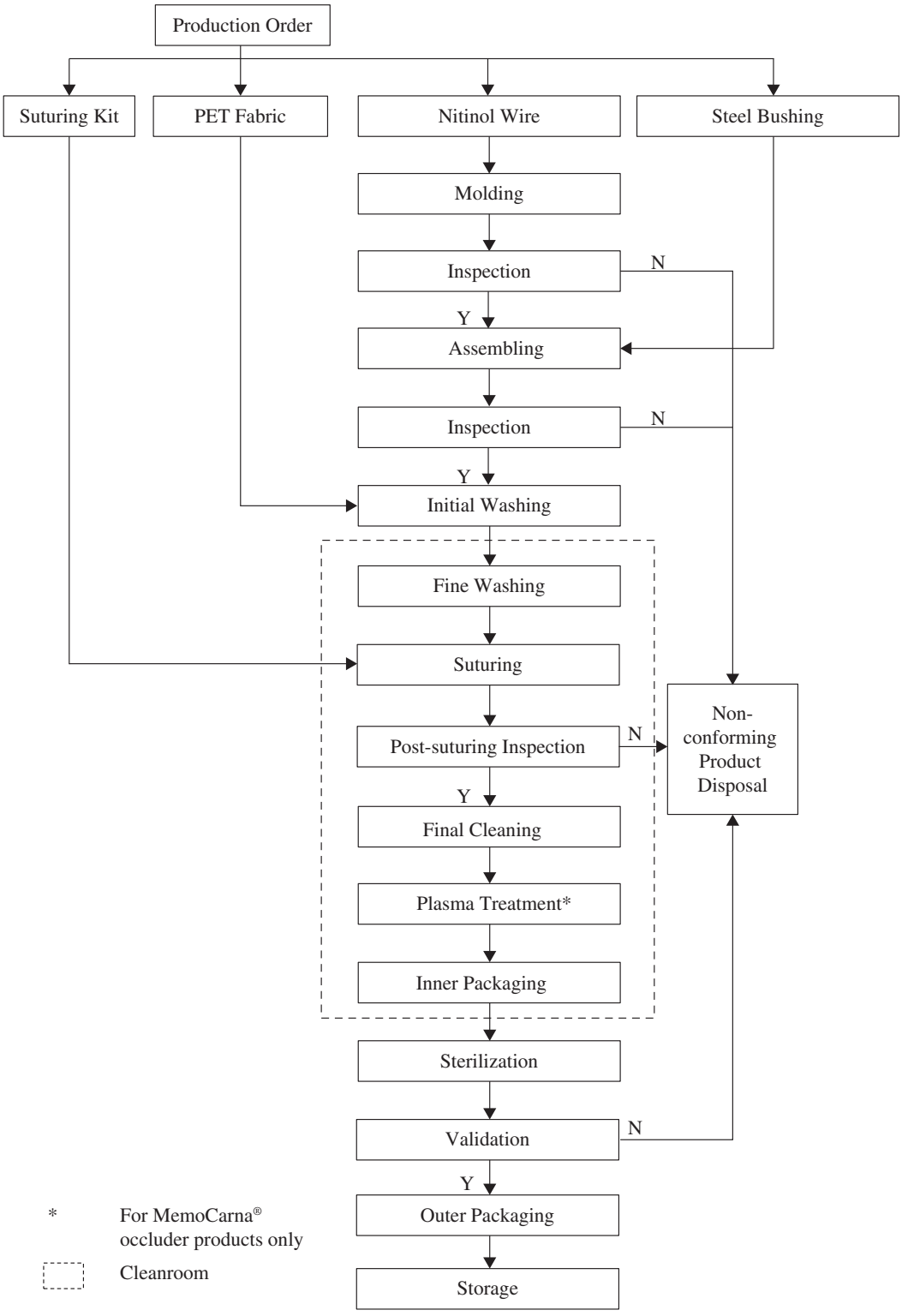
We manufacture, assemble and test our products at our production facilities located on our self-owned properties in Shanghai. As of the Latest Practicable Date, we had obtained the medical device production permit to manufacture our products in our Shanghai production facilities. During the Track Record Period, we conducted research, development and manufacturing activities of our occluder products and product candidates targeting CHD and cardioembolic stroke as well as our heart valve product candidates primarily in our self-owned manufacturing facilities in Shanghai, including cleanrooms in accordance with the Good Manufacturing Practice for Bacteria-free Medical Devices. See "— Properties."

We typically require our employees to undergo health checks before they start producing medical devices, and we require new employees to undergo training before they commence work on our production lines. The on-board training typically covers equipment operation protocols, cleanroom hygiene, product manufacturing and inspection protocols, product introduction, quality control requirements, manufacturing security requirements, as well as administrative affairs. We also provide continuous on-the-job training with respect to specific steps in the production process. We believe that this comprehensive training enables us to increase our capacity utilization rate and product yield rate, and to enhance our production quality. In addition, we believe standard operating protocols can help us ensure workplace safety and regulatory compliance.

The machines we own and use for manufacturing and testing mainly include laser engraving machines, tissue incubating machines, laser cutting machines, laser welding machines, electropolish machines, catheter welding machines, balloon molding machines, folding winders, hydrophilic coating machines, heart valve fatigue testing equipment, heart valve stent fatigue testing equipment, pulsating flow equipment, and super deep scene 3D microscopes. As of the Latest Practicable Date, the useful lives of these machines ranged from 60 and 120 months. For details of the depreciation method of our machines, refer to Note 2.7 to the Accountant's Report in Appendix I to this document. We have multiple machinery suppliers so we are not dependent on any one supplier. Since we maintain our machines on a regular basis, we had not experienced any material or prolonged interruptions due to equipment or machinery failure during the Track Record Period and up to the Latest Practicable Date.

Production Process

Generally, it usually takes on average 0.6 hours per production personnel to produce one unit of our occluder products. The diagram below sets out an illustrative flowchart for the production process for our occluder products (excluding our biodegradable occluders under development).



Our production process typically involves the following steps for our occluder products.

- *Raw material quality inspection.* We examine the quality of the raw materials purchased in accordance with the internally-established technical requirements and procurement specifications.

- *Molding.* We shape raw materials into semi-finished components and parts through specifically designed procedures such as laser cutting, physical kneading and heat processing. We inspect the dimensions of the semi-finished products and assess the molding results to ensure that they conform to our production specifics and quality control requirements.

- *Washing.* We carry out the initial washing on the semi-finished products before moving them into the cleanroom. Within the cleanroom, we wash the semi-finished products for a second time with ultrasonic cleaner and then dry them.

- *Suturing and assembling.* Suturing must be done through our specifically designed process by experienced technicians as it requires significant technical know-how in assessing the appearance and tightness. We then conduct a comprehensive quality inspection on the products.

- *Cleaning.* We clean the products to remove any potential particles from the manufacturing process. For our MemoCarna® occluder products, we also have the products go through a plasma treatment process to produce a uniform and dense oxide coating on the surfaces.

- *Packaging.* We pre-package the finished products.

- *Sterilization.* We transport the packaged products to a third-party sterilization service provider for professional sterilization.

- *Finished product validation.* We proceed with the outer packaging process and conduct a comprehensive quality inspection on sterilized products. We then deliver the finished products to our warehouse for proper storage.

All the steps in our production process are conducted in compliance with the Good Manufacturing Practice for Medical Devices (《醫療器械生產質量管理規範》) as promulgated by China Food and Drug Administration (currently known as NMPA). The procedures within the dotted line above are conducted within a controlled cleanroom environment in accordance with the Good Manufacturing Practice for Bacteria-free Medical Devices, and the procedures outside the dotted line are conducted in regular environments. To maintain the controlled environment in our cleanrooms, in addition to regular internal inspections, we also engage qualified third parties to perform thorough inspections on an annual basis, with inspection reports issued. We have implemented quality management systems as part of our manufacturing processes. Our major quality control inspection including

(1) raw material inspection in accordance with technical requirements and procurement specifications on appearance, dimension, physical properties, chemical properties and microbial properties; (2) in-process inspection in accordance with manufacturing process inspection procedures on the appearance, dimension and physical properties of semi -finished products; (3) finished product validation in accordance with technical requirements and inspection procedures on appearance, dimension, physical properties, chemical properties, microbial properties and sterilization results. We conduct substantially all the key manufacturing procedures in-house except for sterilization. In line with industry practice, we collaborate with contract sterilization facilities to utilize their industry-conformed equipment, well-trained personnel and thorough understanding of recognized sterilization standards, in addition to saving cost. Moreover, the ethylene oxide sterilization involved in our manufacturing process is required to be conducted by qualified sterilization facilities in accordance with local environmental impact assessment planning. To ensure a consistent standard of sterilization, we generally delegate the work to one primary entity. We are able to monitor and control the standard and quality of the delegated sterilization work through our agreements with the third party. The delegated party is obligated to perform sterilization in accordance with confirmed parameters and validate sterilization results under the Requirements for the Development, Validation and Routine Control of the Sterilization Process of Medical Devices, Part I of the Sterilization of Healthcare Products with Ethylene Oxide (《醫療保健產品滅菌環氧乙烷第1部分：醫療器械滅菌過程的開發、確認和常規控制的要求》). We retain the right to inspect the delegated party's facility and equipment, evaluate whether it adheres to the required standards and request the delegated party to improve accordingly. Also, the delegated party's work product is subject to our examination. To further ensure that the sterilization process can be effectively conducted, we have established cooperative relationships with two qualified sterilization partners to safeguard against any contingencies of one of them.

Production Capacity, Actual Production Volume and Utilization Rates

The following table sets forth the production capacity, actual production volume and utilization rate for the production of occluder products and occluder related procedural accessories for the periods indicated.

	Year ended December 31,			Six months ended June 30,
	2019	2020	2021	2022
Occluder products				
Production capacity (units)[(1)]	42,000	42,000	51,600	25,800
Actual production volume (units)	38,962	32,881	42,908	21,649
Utilization rate (%)[(2)]	92.8%	78.3%	83.2%	83.9%
Occluder related procedural accessories				
Production capacity (units)[(1)]	46,000	46,000	57,500	28,750
Actual production volume (units)	41,702	43,379	56,274	27,612
Utilization rate (%)[(2)]	90.7%	94.3%	97.9%	96.0%

(1) Our production capacity is based on the assumption that (i) it takes on average 0.6 hours per person to produce one unit of occluder products, and each person worked eight hours per day in 2019 and 2020 and produced approximately 3,500 units of occluder products per year, and each person worked 10 hours per day in 2021 and the six months ended June 30, 2022 and produced approximately 4,300 units of occluder products per year (or approximately 2,150 units per half year), which reflected the extended operation hours of our manufacturing facilities to align with the growing demand for occluder products; (ii) it takes on average 0.18 hours per person to produce one unit of occluder related procedural accessories, and each person worked eight hours per day in 2019 and 2020 and produced approximately 11,500 units of occluder related procedural accessories per year, and each person worked 10 hours per day in 2021 and the six months ended June 30, 2022 and produced approximately 14,375 units of occluder related procedural accessories per year (or approximately 7,187 units per half year), which reflected the extended operation hours of our manufacturing facilities to align with the growing demand for our occluder related procedural accessories, and (iii) the number of employees working on producing occluder products remains stable at 12 and the number of employees working on producing occluder related procedural accessories remains stable at four.

(2) Utilization rate equals actual production volume divided by production capacity. The utilization rate for occluder products decreased in 2020 as compared to 2019, primarily due to the reduced demand among hospitals for medical devices driven by the decrease in the number of operations unrelated to COVID-19 that were conducted, as most of the hospitals devoted their resources primarily to dealing with COVID-19 in the first half of 2020. The utilization rate for occluder products increased in 2021, primarily due to the increased demand driven by the effective containment of the COVID-19 outbreak in China and the newly launched occluder products. The utilization rate for occluder related procedural accessories generally increased during the Track Record Period, primarily due to increased sales of our snares.

SALES, DISTRIBUTION AND MARKETING

Sales and Marketing Team

As of the Latest Practicable Date, our sales and marketing team had 60 members. Our sales and marketing team was led by Ms. ZHANG Xiani, our deputy general manager, who had over 10 years of extensive sales and marketing experience in the medical device industry. See "Directors, Supervisors and Senior Management." We primarily recruit sales and marketing staff with education background and work experience in the medical device industry. We offer regular training sessions to our newly recruited sales and marketing staff to develop their knowledge of our products, industry knowledge and sales skills. We have also built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution.

In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we incurred distribution expenses of RMB21.8 million, RMB23.1 million, RMB43.1 million, RMB17.4 million and RMB16.6 million, respectively, representing 18.7%, 15.6%, 19.4%, 15.7% and 13.3%, respectively, of our total revenue for the same periods. See "Financial Information — Description of Certain Consolidated Statements of Profit or Loss — Distribution Expenses."

Sales and Marketing Strategy

The interventional medical device market targeting structural heart diseases consists primarily of three major fields of application, i.e., CHD, cardioembolic stroke, and valvular diseases, according to the F&S Report. We have a product portfolio covering all of these fields, with our major products and product candidates including CHD occluder products and product candidates with related procedural accessories, PFO and LAA occluder products and product candidates with related procedural accessories for prevention of cardioembolic stroke and related symptoms, including migraine, peripheral arterial embolism, and decompression sickness, heart valve product candidates with related procedural accessories and other products and product candidates. All of our commercialized CHD, PFO and LAA occluder products with related procedural accessories, our heart valve product candidates with related procedural accessories upon commercialization and other products and product candidates are interventional medical devices targeting structural heart diseases, which are mostly deployed by the cardiology departments in hospitals. According to the F&S Report, the sales channels of medical devices are generally department-specific as different hospital departments are generally covered by distinct distributors. Accordingly, we have established our sales force and expanded our sales network targeting hospitals for demands in interventional medical devices primarily targeting structural heart diseases. We have designed consistent sales and marketing strategy targeting to sell all kinds of our products to the cardiology departments in hospitals, with slightly different focuses primarily due to the different level of the minimally invasive implantation technique and skill of the physicians for different major product types, as set forth below.

CHD occluder products. The implantation technique of CHD occluder products with related procedural accessories is relatively mature among physicians, thanks to the prevalent adoption of relevant occluder products and the related implantation trainings in hospitals in the past 20 years, according to the F&S Report. Accordingly, we did not provide relevant implantation trainings and guidance for our CHD occluder products to physicians at the cardiology departments in hospitals where our products are sold. Instead, as part of our sales and marketing strategy, we focus on educate physicians about the differences of the key features and benefits of the different generations of our CHD occluder products to assist them in making better and more appropriate choices for patients.

LAA occluder products. The LAA occlusion technique to implant LAA occluder products with related procedural accessories is still in the early stage with limited practice and implantation trainings among physicians, according to the F&S Report. Accordingly, we provide relevant implantation trainings and guidance for our LAA occluder products, as part of our sales and marketing strategy targeting physicians at the cardiology departments in hospitals where our products are sold.

Heart valve product candidates. The minimally invasive implantation procedure for heart valve products with related procedural accessories is relatively sophisticated, demanding necessary assistance of multi-disciplinary teams of physicians, according to the F&S Report. There is insufficient number of qualified hospitals with experienced physicians to conduct the implantation procedure for heart valve products in China, according to the same source. Accordingly, we plan to provide relevant implantation trainings and guidance for our heart valve product candidates upon commercialization, as part of our sales and marketing strategy targeting physicians at the cardiology departments in hospitals where our products are expected to be sold. In addition, we will continue to utilize our established sales force and sales network for occluder business to promote our heart valve business. We believe we can leverage our established sales network to market our heart valve product candidates, as we have established our reputation among cardiologists, distributors, and most importantly, patients over the years.

Marketing Model

We sell our products to hospitals through academic promotion and marketing, including product introduction, technical training, surgical assistance and live surgery broadcast, by establishing research and clinical collaboration and training relationships with hospitals and physicians. We regularly meet with physicians and KOLs to discuss our products, conduct product demonstrations and provide related training. We believe that through such frequent communications, demonstrations and training, we are able to maintain good working relationships with these KOLs and physicians, and help them gain familiarity with our products, which we believe will contribute to the market acceptance of our products. We actively participate in medical conferences and industry exhibitions and host meetings and seminars to introduce our products to physicians. We believe that such meetings and conferences are key opportunities for us to present our products and product candidates and can increase our market recognition. We also leverage our distributors to market our products.

We also from time to time engage third-party consultants to carry out market research and analysis on different topics across the interventional medical device industry targeting structural heart diseases, aiming to enable more targeted marketing efforts. When selecting such consultants, we consider the experience and ability of the service providers in conducting market research and providing consultation services in the interventional medical device industry and the pricing of their services. See "Financial Information — Description of Certain Consolidated Statements of Profit or Loss Items — Distribution Expenses." The agreements with such consultants during the Track Record Period typically include the following major terms.

- *Duration.* The agreements with our consultants generally provide a fixed term of less than one year.

- *Rights and obligations.* Our consultants shall provide services in accordance with our specific requirements under the agreements in a designated geographic area, which generally include, among others, (1) carrying out market research and analysis including field studies on the market conditions and competitive landscape for our designated products, (2) delivering comprehensive research results supported by solid market data, and (3) tracking the sales performance of the designated products and making targeted marketing suggestions. We shall have the right to understand and monitor the research progress.

- *Pricing.* The agreements generally stipulate a fixed price covering all expenses incurred.

- *Payment method.* We generally make one-time payments to our consultants.

- *Exclusivity.* We generally engage the consultants to carry out market research and analysis in a designated geographic area. Under certain agreements, the consultants shall not directly or indirectly provide market research services for our competitors within the designated geographic area. We will retain all legal means to defend our rights and interests if the consultants were found to violate the exclusivity clause.

- *Confidentiality.* The consultants shall not disclose to any third party our confidential information or the data and information covered by the research results they provided to us, which clause shall survive the term of the agreements.

- *Termination.* The agreements can generally be terminated upon mutual consents or a party's failure to perform its principal obligations under the agreements.

To the best of our Directors' knowledge, save for acting as our consultants, there are no past or present relationships (including business, family, employment, financing or otherwise) between the consultants (other than Shanghai Motang Medical Technology Company Limited (上海魔糖醫學科技有限公司) ("Motang")) and our Company, our subsidiaries, shareholders, directors or senior management, or any of their respective associates. Shanghai Shape Memory Alloy engaged Motang for an one-off promotion service for our occluder products in 2018 at a consideration of approximately RMB200,000. We held 10% of the equity interest in Motang from October 31, 2016 until December 29, 2020, at which time we transferred such interest to Lepu Medical at a consideration of approximately RMB1.0 million. The consideration was determined based on the unaudited owners' equity of Motang as stated in its management accounts. To the best of our Directors' knowledge, the remaining 90% of Motang's shareholding interest has been held by a third party independent of both of us and Lepu Medical. We made such 10% investment in Motang in anticipation of the business synergy such investment might bring about, considering Motang principally focused on academic promotion of medical technologies. To the best of our Directors' knowledge, there is no other past or present relationship between Motang and us and we do not expect to engage Motang again in the foreseeable future.

Sales Arrangements

We sell products both through distributors and directly to hospitals. In line with market practice, we sell a significant portion of our products to distributors who on-sell our products to hospitals. As of June 30, 2022, we had established a nationwide network of 288 distributors and directly sold our products to nine hospitals.

For our domestic markets in China, we sell products through our domestic distributors, including the Retained Lepu Medical Group, and we require our distributors not to sell our products to sub-distributors. Our sales and marketing team works together with our distributors to identify market opportunities and design distribution strategies. By working closely with our distributors, we gain valuable insights into the operations of each local distributor and the demands of physicians, which allows us to ensure the effectiveness of our marketing activities.

For direct sales, our sales and marketing staff carry out product introduction and business discussions with potential customers for new engagements. We set annual sales targets for our products at the beginning of each year. We regularly assess information that our sales and marketing staff and our distributors gather from hospitals on the number of implantations of our products. We also refer to the historical numbers of implantations of our devices for our sales projections. We believe that the information provided by our sales and marketing team allows us to estimate market demand for our products, and therefore to adjust production and inventory level dynamics.

We historically sold our products overseas through the Retained Lepu Medical Group in addition to cooperation with it in domestic distribution, to leverage its mature overseas sales network. The Retained Lepu Medical Group further distributed our products to sub-distributors overseas. According to the F&S Report, it is an industry norm to engage sub-distributors for overseas markets in the medical device industry. The Retained Lepu Medical Group had the right to directly manage the sub-distributors and we had limited control over them. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Commercialization and Distribution — We depend on distributors for a substantial portion of our revenue and our revenue growth. We may fail to maintain or renew relationships with distributors, or further expand our network of distributors." As of September 30, 2021, we had terminated our cooperation with the Retained Lepu Medical Group for the distribution of our products overseas and entered into distribution agreements with overseas distributors directly, except for India. See "Connected Transactions — Non-Exempt Continuing Connected Transactions." We have built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas going forward. We have implemented regional management strategy and assigned regional sales personnel to attend to the specific needs and customs in the target markets and to communicate with distributors in that region on a regular basis in order to monitor their sales performance and inventory levels. The regional sales personnel are also responsible for establishing and maintaining collaborative connections with local KOLs. We also plan to host various branding and marketing events in overseas markets to build up brand recognition and therefore promote product sales.

The following table sets forth a breakdown of our revenue generated from distributors (including the Retained Lepu Medical Group) and direct sales for the periods indicated.

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total
	(RMB in thousands, except for percentages)									
							(Unaudited)			
Sales to distributors	106,848	91.8	137,259	92.6	209,008	93.9	105,235	94.8	121,020	97.0
– Sales to the Retained Lepu Medical Group	10,212	8.8	31,039	20.9	15,952	7.2	11,471	10.3	2,560	2.1
– Sales to other distributors	96,636	83.0	106,220	71.7	193,055	86.7	93,764	84.5	118,460	94.9
– For domestic market	96,636	83.0	106,220	71.7	181,000	81.3	92,683	83.5	99,816	80.0
– For overseas markets	–	–	–	–	12,055	5.4	1,081	1.0	18,644	14.9
Direct sales to hospitals[(1)]	9,603	8.2	10,988	7.4	13,576	6.1	5,733	5.2	3,785	3.0
Total	116,451	100.0	148,247	100.0	222,583	100.0	110,968	100.0	124,804	100.0

(1) Most of the revenue generated from direct sales to hospitals were generated from Class III Grade A hospitals.

Sales to Distributors

We have established an extensive and growing distributor network. As of June 30, 2022, for our domestic markets in China, we had 288 distributors covering all provinces, municipalities and autonomous regions in China; for our products sold overseas, we sold our products to 44 countries and regions.

Selection and Management of Distributors

Our sales and marketing department selects our domestic distributors based on their experience in the medical device industry, their sales channels and hospital coverage. Our distributors must hold a business license for medical device operations (《醫療器械經營許可證》) and other necessary business licenses and permits to sell medical devices in the region where they conduct activities. We review their qualification documents to ensure that they have the appropriate license and background before entering into agreements with them. 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.

Our relationship with our distributors is of a seller and buyer, instead of a principal and an agent. During the Track Record Period, to the best of our Directors' knowledge, save for acting as our distributors or sub-distributors, none of our distributors or sub-distributors (including their respective shareholders, directors, senior management or any of their respective associates), except for the Retained Lepu Medical Group, had any past or present relationship (including, without limitation, business, family, trust, employment, shareholding, financing or otherwise) with our Group, our Shareholders, Directors and senior management or any of their respective associates. See "Connected Transactions — Non-Exempt Continuing Connected Transactions." Therefore, our Directors are of the view that we did not rely on the Retained Lepu Medical Group for the sales and distribution of our products. Our Directors have confirmed that during the Track Record Period and up to the Latest Practicable Date, none of our distributors had materially breached our contract terms, and we did not have any material dispute with our distributors. To the best of our Directors' knowledge, none of our distributors or sub-distributors were the subject of any material non-compliance incidents, claims, litigation or legal proceedings (whether actual or threatened) in relation to sales of our products during the Track Record Period and up to the Latest Practicable Date.

We manage our distributors by providing technical training and conduct regular evaluation to assess their performance. Our training mainly covers product information and medical knowledge. We regularly review our distributors' sales performance, including the comparison of their actual sales amount with target sales amount, and the feedback from their authorized hospitals. Depending on our evaluation of their performance, we may grant rebates to our distributors, or terminate our cooperation with them. Specifically, we may offer volume rebates to a distributor who outperforms the pre-determined sales goal by awarding additional gratuitous units of our products. See "Financial Information — Discussion of Major Balance Sheet Items — Contract Liabilities" for details of our rebate policy.

We believe that our sales to distributors during the Track Record Period reflected genuine market demand, and there was effective management and control over the inventory levels of our distributors. We recognize revenue from distributor sales when the products are transferred to distributors and generally do not accept product returns. See "Financial Information — Significant Accounting Policies, Judgments and Estimates — Revenue Recognition" and Note 2.24 to the Accountant's Report in Appendix I to this document for more details.

We monitor the usage of our products sold by our distributors by (1) only allowing distributors to distribute to designated hospitals, (2) communicating with distributors regularly to gather relevant sales and inventory data, including information on hospital names, sales quantity, product type and product quality complaints, and (3) visiting hospitals to investigate their usage of our products on a regular basis. During the Track Record Period, we communicated with the Retained Lepu Medical Group from time to time to gather relevant data in connection with sales potential and other information to monitor the distribution of our products in overseas markets. We believe the above communication with our distributors as well as the relevant data and information we gather from them help us to set reasonable sales targets for distributors and adopt appropriate sales and pricing strategies.

Prevention of Cannibalization

In order to avoid cannibalization of sales among our domestic distributors, we have adopted the following measures:

- *Geographic restrictions*. We generally only authorize one distributor to sell our products to each hospital.

- *Product type restrictions*. We specify the types of products that distributors are authorized to sell in the written authorization letters. Our distributors can only sell certain types of our products to their designated hospitals as provided under the authorization.

- *End customer monitoring*. Our sales and marketing staff visit hospitals where our products are sold to confirm details of the distributors they work with and any potential instances of non-compliance with our distribution agreements or policies. Furthermore, hospitals generally have internal policies which require them to only conduct business with distributors who have appropriate authorization from medical device manufacturers. We also communicate with physicians and hospitals that use our products through our academic activities, medical conferences and industry exhibitions that we attend in order to monitor the actual usage of our products and to collect feedback on our products.

- *Mutual supervision policy*. We encourage our distributors to supervise each other and report to us unauthorized sales by other distributors. In the event of any report or identification of such potential non-compliance, we conduct independent verification of such reported behavior, and may penalize the relevant distributors according to the distribution agreements and our internal policies, for example, by imposing monetary penalties or termination of business relationships.

- *Accountability*. Any sales outside of the designated hospitals will be deemed as cannibalization. If we discover any cannibalization activity by our distributors, we are entitled to pursue liabilities against such distributors and to terminate our authorization and/or business relationships.

Distribution Agreements

We enter into standard distribution and other auxiliary agreements with each of our distributors for the domestic market, which sets out the rights and obligations of both parties. We also grant our distributors an authorization letter, which specifies designated hospitals and products which they are authorized to sell. In addition, we enter into a separate agreement with our distributors to set out specific purchase volume requirements and unit prices. The agreements we enter into with the Retained Lepu Medical Group are on substantially the same terms as those with other domestic distributors that are independent third parties. To the best knowledge of our Directors, there was no material breach of distribution agreements that caused the termination of any distribution agreement during the Track Record Period. The following is a summary of key arrangements with our domestic distributors during the Track Record Period.

- *Duration*. Our standard distribution agreement has a term of one year and will be automatically renewed for three months.

- *Exclusivity and prevention of cannibalization.* The distributors are authorized to sell our products only within the designated hospitals and are prohibited from selling outside the designated hospitals. Any sales outside of the designated hospitals will typically be deemed as cannibalization. If we discover any cannibalization activity by our distributors, we are entitled to request such distributors to return all the products that were sold outside of the designated hospitals, and reimburse us an agreed-upon percentage of its annual sales amount. Our distributors, including their affiliates, are also prohibited from selling competing products without our prior written confirmation.

- *Sub-distributors.* We operated a single-layer of distributors during the Track Record Period and do not intend to allow any distributor to procure sub-distributors in the domestic market. According to the F&S Report, hospitals in China require medical device distributors to obtain authorization letters granted by manufacturers as a prerequisite for selling the relevant products to hospitals. We grant such authorization letters only to distributors selected by our sales and marketing department. During the Track Record Period, we did not grant such letters to more

than one layer of distributors in the domestic market. As advised by our PRC Legal Advisors, as of the Latest Practicable Date, a few provinces and municipal cities in China, including Anhui province, Shaanxi province, Fujian province, Liaoning province, Qinghai province, Tibet and Taiyuan city of Shanxi province, had implemented the two-invoice system to regulate the distribution of medical consumables. We did not engage more than one layer of distributors nor cooperate with the Retained Lepu Medical Group for further distribution in such provinces or municipal cities during the Track Record Period. Our PRC Legal Advisors are of the view that our distribution model does not violate the two-invoice system implemented in such provinces and municipal cities, based on the following: (1) according to the relevant local rules, the two-invoice system means that in the distribution chains of medical consumables, only two invoices can be issued when medical consumables are ultimately sold to public medical institutions, i.e., one issued by a manufacturer to its distributor and the other issued by such distributor to a public medical institution. The local rules generally require public medical institutions to examine the two invoices when they conduct the inspection of medical consumables. As a result, under the two-invoice system, a manufacturer or a distributor, if in violation of the two-invoice system, will not be accepted by public medical institutions as their supplier of medical consumables; (2) our domestic distribution agreements in such provinces and municipal cities have specifically required our domestic distributors not to procure or engage any sub-distributors to sell our products, except for several distribution agreements in which we have been in the process of negotiating with relevant distributors to include such terms; and (3) as confirmed by our Directors, in the process of our business operation, we have strictly complied with the relevant local rules in relation to the two-invoice system and have not collaborated with distributors to engage more than one layer of distributors in such provinces or municipal cities, nor have we received any penalty as a result of violating the two-invoice system. If we engage more than one layer of distributors in the provinces or municipal cities that have implemented the two-invoice system, we could risk violating the relevant local regulations and may be subject to regulatory measures imposed by the relevant local government authorities. See "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Two-Invoice System."

- *Obligations.* Our distributors are obligated to, among other things, (1) comply with relevant laws and regulations; (2) keep inventory and usage records of all products; (3) store the product appropriately in accordance with the instructions set out in the product manual; and (4) work together with our sales and marketing team to identify market opportunities, design distribution strategies, participate in medical meetings and seminars, and provide training to physicians.

- *Pricing*. We contractually fix the selling prices to our distributors.

- *Credit term.* We generally do not grant credit period to our distributors. Under limited circumstances, we may grant distributors who have a good track record with us a temporary credit period.

- *Delivery.* We are responsible for transporting our products to the distributor and bearing the costs of transportation.

- *Product return and customers' rights to claim additional units.* We generally are not responsible for product sale, return or exchange once our products are sold to the distributors. We may allow for an exchange only if the product is proved to be defective, and the exchanged product will be subject to inspections by our quality control team. According to the F&S Report, in line with industry practice, distributors generally have the right to claim additional units when the original units are discarded during the process of implantation upon our confirmation based on evidence provided by them, such as product serial number.

- *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 three years after its termination.

- *Termination.* Each party has the right to terminate the agreement if the other party breaches the terms and conditions therein.

During the Track Record Period, we entered into framework distribution agreement with the Retained Lepu Medical Group, which had a term of four years from 2018 to 2022, for our products sold to overseas market. We generated revenue from the Retained Lepu Medical Group for products sold overseas of RMB7.8 million, RMB28.0 million, RMB10.2 million, RMB8.5 million and RMB0.6 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, accounting for 6.7%, 18.9%, 4.6%, 7.7% and 0.5% of our total revenue in the same periods, respectively.

As of September 30, 2021, we had terminated our cooperation with the Retained Lepu Medical Group for the distribution of our products overseas and entered into distribution agreements with overseas distributors directly, except for India. See "Connected Transactions — Non-Exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement" and "— Sales Arrangements." The new distribution agreements we enter into directly with the overseas distributors are in substantially identical terms with that with the Retained Lepu Medical Group. As a result of the change in the distribution model for overseas markets, we have taken over the roles and responsibilities of the Retained Lepu Medical Group, such as distributor communications and management as well as other overseas sales and marketing activities. We believe direct distribution arrangement with such distributors allows for more control over our overseas distributor networks and better understanding of overseas market demands. We have also hired the key sales and marketing personnel from Lepu Medical who used to be responsible for our overseas distribution and built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas. See "— Sales Arrangements." We will continue to expand our sales and marketing team and recruit approximately 30 to 50 sales and marketing personnel for overseas distribution in the European Union, Southeast Asia and the United States. In addition, we plan to establish overseas sales offices and recruit sales and marketing personnel located in key overseas markets in the future to facilitate our overseas distribution. Also, we plan to conduct market conferences and academic promotion activities in overseas markets. See "Future Plans and [**REDACTED**] — [**REDACTED**]."

As a result of the change in the distribution model for overseas markets, we expect our costs and expenses related to overseas distribution, such as distribution expenses for overseas sales and marketing activities and general and administrative expenses in relation to management of overseas distributors, to increase following the change in the distribution model for overseas markets. We nevertheless expect no significant change for our profitability and liquidity following such change. There were no material changes in the prices our overseas distributors paid for our products in 2021 before and after the change in the distribution model for overseas markets. In the same period, the average selling prices we received from the Retained Lepu Medical Group for our major products, including CHD occluder products and occluder related procedural accessories, were approximately RMB3,020 per unit and RMB739 per unit for overseas markets, respectively; and the average selling prices we received directly from our overseas distributors after the change in the distribution model for our CHD occluder products and occluder related procedural accessories were approximately RMB3,066 per unit and RMB815 per unit, respectively, which were similar to those the Retained Lepu Medical Group received from the overseas distributors before the distribution model change. We had not sold LAA occluder product to overseas markets during the Track Record Period. The gross profit margin for our sales to the Retained Lepu Medical Group for overseas markets was 87.5% for 2021, and that for our sales directly to overseas distributors was 88.8% for the same period. For overseas markets, we generally require distributors, including the Retained Lepu Medical Group, to make full payment within seven calendar days after the order acceptance is confirmed by us. Our standard distribution agreements with overseas distributors typically include the following major terms. According to the F&S Report, the key terms and conditions of our distribution agreements with overseas distributors are consistent and comparable with industry practice.

- *Duration*. Our standard overseas distribution agreement generally has an initial term of one year. Upon the expiration of the initial term, the agreement may be renewed for six months if the distributors meet certain minimum purchase and sales requirements during the initial term.

- *Exclusivity.* Our overseas distributors are authorized to sell our products only within designated geographic area. In addition, the distributors may not directly or indirectly resell to buyers residing outside the designated area.

- *Sub-distributors.* Our overseas distributors generally have the right to recruit on their own behalf sub-distributors in the designated area and grant authorization for the sub-distribution of our products in the designated area upon our prior written consent. The distributors shall be liable for the actions of the sub-distributors in the designated area. There is no specific requirement on single-layer distributors in overseas markets.

- *Minimum purchase volume.* We typically set a minimum purchase volume with our overseas distributors depending upon various conditions at the target market such as patient number as well as the brand awareness and market acceptance of our products. We will review the minimum purchase volume at the end of the contract term and adjust if necessary. The minimum purchase volume serves as an annual

sales goal instead of strict purchase requirements. If a distributor fails to meet its sales goal, we generally will consider factors such as the distributor's distribution capability and general market conditions to adjust the sales goal for the next contract term or determine whether to terminate our agreement with it. During the Track Record Period, our overseas distributors and sub-distributors have generally been able to achieve the sales goals, except for having been negatively affected during the COVID-19 outbreak.

- *Obligations.* Our overseas distributors are obligated to, among other things, (1) act as an independent contractor, purchasing our products, seeking sales and customers as well reselling our products on their own; (2) undertake that it has not used our brand or name or has not received any material advance or financial assistance from us; (3) comply with relevant laws and regulations; (4) provide a report on marketing and sales information for the designated area on a monthly basis; and (5) devote their best efforts to the adequate promotion, exploitation and development of sales of our products within the designated area.

- *Pricing and payment*. We generally set out the current prices in the overseas distribution agreement, which may be amended by us from time to time at our sole discretion provided that we so advise the distributor at least three months in advance in writing specifying the changes and the effective date of the changes.

- *Credit term*. The overseas distributors generally shall make full payment within seven calendar days after the order acceptance is confirmed by us.

- *Delivery.* Our oversea distributors bear costs for importing, storing and selling our products in the designated area.

- *Product return and exchange.* In line with the industry practice, we generally do not allow our overseas distributors to exchange or return products, unless under limited circumstances such as product quality issues and incorrect products manufactured or shipped because of our mistakes.

- *Confidentiality.* Each party agrees not to divulge to any third party and not to use, except for the purpose of the distribution agreement, any information of the other party, which is of confidential nature to the other party. In addition, upon expiration or termination of the agreement, each party shall return to the other party all confidential material which they have received during the term of this agreement from the other party.

- *Termination.* Each party has the right to terminate the agreement if the other party breaches or violates an essential obligation and fails to remedy the breach or violation within 30 calendar days after it is requested by the other party in writing to do so. In the event of termination, our overseas distributors shall refrain from further usage of our trademarks, secure that any sub-distributor shall immediately refrain from using our trademarks, and transfer any permissions and licenses required for selling our products in the designated area to us.

Number of Distributors and Sub-distributors

The table below sets forth the changes in the number of our distributors during the Track Record Period.

	Year ended December 31,			Six months ended June 30,
	2019	2020	2021	2022
As of the beginning of the period	155	177	248	316
Additions of new distributors	51	93	140	109
Termination of existing distributors	(29)	(22)	(72)	(137)
Net increase/(decrease) in distributors	22	71	68	(28)
As of the end of period	177	248	316	288

The number of our distributors increased from 2019 to 2021, primarily due to (1) our enhanced business recognition, (2) our enhanced promotional efforts, and (3) the overall growth of the relevant market and industry. The number of our distributors decreased during the six months ended June 30, 2022, primarily because we terminated our cooperation with certain distributors that we considered did not have competitive business scale, hospital coverage and/or promotional strategies, especially in light of our launch of new CHD occluder products and LAA occluder product. Instead, we have established cooperation with new distributors who present competitive edge in distributing our newly launched products. As a result, revenue generated from sales to distributors increased from RMB105.2 million in the six months ended June 30, 2021 to RMB121.0 million in the six months ended June 30, 2022, despite the impact of COVID-19 resurgence in Shanghai in the first half of 2022. The termination of existing distributors, which includes both non-renewal upon expiration of the term of the distribution agreements and termination prior to such expiration, was primarily due to (1) commercial considerations, such as optimization of our distributor network and adjustment of business scope by former distributors, and (2) failure by former distributors to fulfill the prescribed sales goals such as certain sales volume depending on the number and the region of the hospitals covered. We are committed to continuing to refine our distributor network and select the distributors that are suitable for us.

The following table sets out the breakdown as to the number of distributors terminated during the Track Record Period and their respective revenue contribution for the periods indicated.

		Year ended December 31,						Six months ended June 30, 2022	
		2019		2020		2021			
	Number of distributors terminated	Revenue	% of Total	Revenue	% of Total	Revenue	% of Total	Revenue	% of Total
		(RMB in thousands, except for percentages)							
During 2019	29	13	0.0	–	–	–	–	–	–
During 2020	22	2,763	2.4	–	–	–	–	–	–
During 2021	72	6,604	5.7	6,698	4.5	337	0.2	–	–
During the six months ended June 30, 2022	137	17,082	14.7	23,613	15.9	57,661	25.9	–	–

The table below sets forth the changes in the number of our distributors and sub-distributors for overseas markets through the Retained Lepu Medical Group during the Track Record Period.

	Year ended December 31,			Six months ended June 30,
	2019[1]	2020[1]	2021[2]	2022
As of the beginning of the period	36	45	39	54
Additions of new sub-distributors/ distributors	20	9	16	4
Termination of existing sub-distributors/ distributors	(11)	(15)	(1)	(4)
Net increase/(decrease) in sub-distributors/distributors	9	(6)	15	0
As of the end of period	45	39	54	54

(1) Represent number of sub-distributors.

(2) By June 2021, we had established direct business relationships with all 39 sub-distributors for overseas markets as of the beginning of 2021. Among such 39 distributors, Lepu India, a member of the Retained Lepu Medical Group, used to act as our sub-distributor where Lepu Medical on-sold our products prior to the distribution model change. See "Connected Transactions — Non-Exempt Continuing Connected Transactions."

The number of our sub-distributors decreased from 45 as of December 31, 2019 to 39 as of December 31, 2020, primarily as a result of the COVID-19 outbreak. During the Track Record Period, we have learned from the Retained Lepu Medical Group that the termination of existing sub-distributors, which includes both non-renewal upon expiration of the term of the distribution agreements and termination prior to such expiration, was primarily due to commercial considerations, such as optimization of the overseas distribution network and adjustment of business scope by former sub-distributors. For example, certain former sub-distributors terminated their agreements with the Retained Lepu Medical Group in 2020, as they faced reduced market demand amidst the COVID-19 outbreak and discontinued their distribution business.

Domestic Direct Sales to Hospitals

In addition to the sales through our distributors, we sell our products directly to public hospitals. In 2019, 2020, 2021 and the six months ended June 30, 2022, we sold our products directly to 10, 12, nine and five hospitals, respectively, and recognized revenue of RMB9.6 million, RMB11.0 million, RMB13.6 million and RMB3.8 million, respectively, accounting for approximately 8.2%, 7.4%, 6.1% and 3.0% of our total revenue in the same periods, respectively. The decrease of our direct sales scale in the six months ended June 30, 2022 was primarily due to certain hospitals' preference to purchase our products through local distributors, who are more familiar with their specific demands. We recognize revenue from the direct sales to hospitals after the products are implemented into the patients' bodies. See "Financial Information — Significant Accounting Policies, Judgments and Estimates — Revenue Recognition" for more details.

During the Track Record Period, we did not have any disputes with the hospitals relating to the settlement of trade receivables.

Pricing

According to the F&S Report, in China, the government maintains a high level of involvement in the determination of retail prices of medical devices, as the prices are affected by the bidding and tender processes regulated by government agencies and hospitals. In addition, China has adopted a centralized procurement regime in an effort to regulate prices of certain types of medical devices with huge consumption through group procurement at the provincial level, which may exert downward pressure on the pricing of medical devices that are included under such regime. During the Track Record Period and up to the Latest Practicable Date, none of our medical devices was included under the said centralized procurement regime in China. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Commercialization and Distribution — Downward changes in the pricing of our products may have a material adverse effect on our business, results of operations and financial condition."

According to the F&S Report, medical device manufacturers shall participate in the public tender processes organized by the procurement platforms managed by the government agencies at provincial or municipal level, in order to be qualified to sell their products to hospitals in such provinces or municipalities. Accordingly, we participate in public tender processes organized by such procurement platforms to secure the right to sell our products to the hospitals in the provinces or municipalities. Our distributors do not participate in such public tender processes at the provincial or municipal level. We determine the bidding prices by considering our costs and expenses and the prices of similar products in the past. If our products win the bids, such products would be qualified for future procurement by the hospitals in the provinces or municipalities, and our winning bid prices would become the public prices of our products, which generally determine the maximum retail prices that we may offer to the hospitals in direct sales, or that our distributors may bid in the public tender processes organized by the hospitals.

For our direct sales to hospitals, we sell our products at prices equal to or lower than the public prices. We generally sell our products at uniform ex-factory prices to our distributors in China, including both the Retained Lepu Medical Group and other distributors that are independent third parties. When determining the price of our products sold to distributors, we consider factors such as our costs and expenses, availability and prices of competing products, novelties and differences in features between our products and competing products as well as purchasing power and general acceptance of the market. We maintained relatively stable pricing for our first generation products over the years, and we generally do not expect to downward adjust the prices of our products of older generations solely as a result of the commercialization of our new products. Our distributors participate in the public tender processes organized by hospitals with the bidding prices generally equal to or lower than the public prices. We do not provide volume discounts to distributors and, for our recently launched products, we generally do not adjust our ex-factory prices. The pricing of our products may be adjusted from time to time as a result of regulatory changes, such as changes in medical reimbursement coverage. In addition, in April 2016, the PRC government announced a pilot program in certain provinces in China to implement the two-invoice system, which generally limits the network of distributors to a single layer of distributors for sale of medical devices from manufacturers to hospitals to control medical device prices. See "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Two-Invoice System." The two-invoice system has little impact on the public prices of our products, which are determined through the public tender processes organized by the procurement platforms.

For our products sold overseas through the Retained Lepu Medical Group during the Track Record Period, the Retained Lepu Medical Group determined prices through commercial negotiations with sub-distributors based on a number of factors, primarily including the specific market conditions of each overseas market, product specifications, the scale and potential of overseas customers, their purchase amounts and the pricing of multinational competitors in the same market. With its long-standing experience and reputation in the overseas market and established sales network, the Retained Lepu Medical Group had been actively assisting us in the overseas sales since 2012. As a result, prior to 2020, for our products for onsale to overseas markets, we sold such products to the Retained Lepu Medical Group at prices calculated by adding a prevailing margin to our cost of production. As we had gradually built up our own brand recognition and sales capabilities, by the beginning of 2020, the contribution from the Retained Lepu Medical Group to the overseas distribution of our

products had been reduced to such an extent that its involvement and functions became similar to our distributors in China. We and the Retained Lepu Medical Group have agreed to adjust the pricing model for our sales to the Retained Lepu Medical Group accordingly so that the consideration paid by the Retained Lepu Medical Group since the beginning of 2020 has been calculated based on an agreed discount, at prevailing market rates, to the price paid by the overseas sub-distributors, which has resulted in a substantial increase in our selling prices to the Retained Lepu Medical Group. The gross profit margin that we generated from our sales to the Retained Lepu Medical Group in 2020 was at the comparable rate with that generated from the sales to our other distributors that are independent third parties. Furthermore, we have gradually established direct business relationships with overseas distributors since in 2021 and now sell our products to such distributors directly at prevailing market rates. See "Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement."

For our oxide-coated occluder products with a single-rivet design which we expect to launch in the European Union, we intend to determine the pricing with reference to the price of comparable products from major players in local markets.

We believe that we have implemented an effective pricing strategy. According to the F&S Report, the ex-factory prices for our CHD occluders are competitive in comparison with both major domestic and international players. In addition, we believe that our strong brand reputation and effective marketing activities give us strong bargaining power with our distributors. As a result, during the Track Record Period, we generally were able to maintain stable ex-factory prices for all of our major products. Going forward, we plan to focus more on the research and development and commercialization of new products with advanced features, in order to compete effectively and maintain our profit margin.

Medical insurance reimbursement coverage for medical devices in China is determined at the provincial level. See "Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — National Medical Insurance Program" for more details. As the national medical insurance reimbursement system in China covers the treatment of CHD, all the occluder products and the related procedural accessories for the treatment of CHD are eligible for the medical insurance reimbursement. Accordingly, as of the Latest Practicable Date, our MemoPart®ASD Occluder I, MemoPart® VSD Occluder I, MemoPart® PDA Occluder I, MemoPart® interventional delivery system I, MemoPart® Snare I and interventional delivery system II were eligible for medical insurance reimbursement in all the provinces, autonomous regions and municipal cities in China. As of the same date, our MemoCarna® ASD Occluder III, MemoCarna® PDA Occluder III, MemoLefort® LAA Closure Occluder I, MemoCarna® VSD Occluder III, integrated interventional delivery system for Plug III, delivery system and interventional delivery system (biodegradable) were eligible for medical insurance reimbursement in certain provinces in China, such as Shanghai, Tianjin, Jiangsu province, Anhui province, Guangdong province, Guangxi Zhuang autonomous region, Fujian province, Yunnan province, Guizhou province, Liaoning province, Henan province, Shandong province, Gansu province, Shaanxi province, Xinjiang Uygur autonomous region, Inner Mongolia autonomous region, Zhejiang province, Tibet autonomous region, Shanxi province, Beijing, Hebei province, Heilongjiang province, Sichuan province, Chongqing, Qinghai province, Jiangxi province, Hainan province, Hunan province, Hubei province and Ningxia Hui autonomous region. We strategically develop and position our products taking into consideration these insurance reimbursement schemes. Whether a product is included in the

medical insurance reimbursement coverage may impact the prices our end customer pay for our products. However, medical insurance reimbursement coverage has no direct impact on the pricing of our products to our customers, including primarily distributors and hospitals. Such pricing is generally determined by the public prices, which are determined through the public tender processes organized by the procurement platforms.

Anti-bribery Measures

We have implemented anti-corruption policies for all of our employees, including our direct sales personnel involved in our sales and marketing activities. In addition, our distributors are subject to anti-bribery obligations pursuant to the distribution agreements, under which distributors (1) are required to comply with and require their employees and affiliates to comply with applicable anti-bribery and anti-unfair competition laws and regulations, and (2) are prohibited from offering or promising money or anything of value to our employees, regulatory authorities and any other individuals or entities as required by laws and regulations. See "— Risk Management and Internal Control — Internal Control."

The Audit Committee is the main responsible body to supervise the anti-fraud and anti-corruption work conducted by our internal audit department, including organizing the annual fraud risk assessment of all departments and subsidiaries of our Company, carrying out anti-fraud and anti-corruption training sessions and activities, handling anti-fraud and anti-corruption reports, organizing the relevant case investigation, offering rectification suggestion and reporting to our management and the Board of Directors on such matters.

We have set up telephone reporting hotline and email address for our employees and business partners to report violation of professional ethics by our employees, including suspected fraud, corruption or bribery misconducts. Our internal audit department conducts investigation for such reports and allegations, keeps written records, and reports the investigation results to our management and the Board of Directors. Specifically, our internal audit department will establish special investigation teams comprised of employees from our internal audit department and other relevant departments to conduct joint investigations. Our internal audit department may also engage external experts to participate in the investigation as necessary. The special investigation teams shall assess the relevant internal controls and produce written reports to make recommendations for improvement. In the meantime, employees who are confirmed to commit fraud, corruption, bribery or other misconducts shall receive internal economic and administrative disciplinary punishments in accordance with the relevant internal policies. If the misconducts violate relevant laws, such employees may also face civil or criminal penalties in accordance with relevant laws. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Extensive Government Regulations — If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, results of operations and financial condition. We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees or other third parties."

CUSTOMERS

Our customers are distributors who on-sell our products to hospitals and, to a lesser extent, hospitals to which we sell our products directly. During the Track Record Period, we derived substantially all of our revenue from the sale of CHD occluder products and related procedural accessories. In 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate revenue generated from our five largest customers, who are primarily distributors of medical devices, related technical services, chemicals and other goods and public hospitals, was RMB32.2 million, RMB56.0 million, RMB47.2 million and RMB18.9 million, respectively, accounting for 27.6%, 37.8%, 21.2% and 15.1% of our total revenue for the same periods, respectively. Sales to our largest customer in 2019, 2020, 2021 and the six months ended June 30, 2022 were RMB10.2 million, RMB31.0 million, RMB16.0 million and RMB4.4 million, respectively, representing 8.8%, 20.9%, 7.2% and 3.5% of our total revenue for the same periods, respectively. The following table sets forth certain information of our five largest customers during the Track Record Period.

Customer	Transaction amount	Percentage of total revenue	Credit/settlement terms*	Length of relationship as of the Latest Practicable Date	Principal business
	(RMB in million)	*(%)*			
For the year ended December 31, 2019					
Retained Lepu Medical Group	10.2	8.8	Dispatch within one week upon full prepayment by cash, wire transfer etc.	September 2010 – present	Manufacturing and sales of medical devices
Customer A	7.9	6.8	Dispatch upon full prepayment by cash, wire transfer etc.	May 2017 – present	Sales of medical devices and related technical services
Customer B	5.1	4.4	Dispatch upon full prepayment by cash, wire transfer etc.	January 2017 – present	Sales and importing and exporting of medical devices
Customer C	4.9	4.2	Dispatch upon full prepayment by cash, wire transfer etc.	August 2012 – present	Sales of medical devices and other goods
Customer D	4.1	3.4	Dispatch upon full prepayment by cash, wire transfer etc.	May 2018 – present	Sales of medical devices and chemical raw materials
Total	32.2	27.6			

Customer	Transaction amount	Percentage of total revenue	Credit/settlement terms*	Length of relationship as of the Latest Practicable Date	Principal business
	(RMB in million)	*(%)*			
For the year ended December 31, 2020					
Retained Lepu Medical Group	31.0	20.9	Dispatch within one week upon full prepayment by cash, wire transfer etc.	September 2010 – present	Manufacturing and sales of medical devices
Customer A	10.8	7.3	Dispatch upon full prepayment by cash, wire transfer etc.	May 2017 – present	Sales of medical devices and related technical services
Customer C	6.8	4.6	Dispatch upon full prepayment by cash, wire transfer etc.	August 2012 – present	Sales of medical devices and other goods
Customer E	3.8	2.5	60-day credit period upon receipt of certain forms of acceptance for products delivered	February 2019 – present	Hospital
Customer D	3.6	2.5	Dispatch upon full prepayment by cash, wire transfer etc.	May 2018 – present	Sales of medical devices and chemical raw materials
Total	56.0	37.8			

Customer	Transaction amount	Percentage of total revenue	Credit/settlement terms*	Length of relationship as of the Latest Practicable Date	Principal Business
	(RMB in million)	*(%)*			
For the year ended December 31, 2021					
Retained Lepu Medical Group	16.0	7.2	Dispatch within one week upon full prepayment by cash, wire transfer etc.	September 2010 – present	Manufacturing and sales of medical devices
Customer A	11.4	5.1	Dispatch upon full prepayment by cash, wire transfer etc.	May 2017 – present	Sales of medical devices and related technical services
Customer F	9.6	4.3	Dispatch upon full prepayment by cash, wire transfer etc.	July 2021 – present	Sales of medical devices and other goods
Customer G	5.3	2.4	Dispatch upon full prepayment by cash, wire transfer etc.	December 2015 – present	Sales of medical devices and related development and technical services
Customer D	5.0	2.2	Dispatch upon full prepayment by cash, wire transfer etc.	May 2018 – present	Sales of medical devices and chemical raw materials
Total	47.2	21.2			

Customer	Transaction amount	Percentage of total revenue	Credit/settlement terms*	Length of relationship as of the Latest Practicable Date	Principal business
	(RMB in million)	*(%)*			
For the six months ended June 30, 2022					
Customer H	4.4	3.5	Dispatch upon full prepayment by cash, wire transfer etc.	January 2021 – present	Sales of medical devices and chemicals
Customer C	3.7	3.0	Dispatch upon full prepayment by cash, wire transfer etc.	August 2012 – present	Sales of medical devices
Customer I	3.7	3.0	Dispatch upon full prepayment by cash, wire transfer etc.	January 2022 – present	Sales of medical devices and experiment equipment
Customer J	3.7	2.9	Dispatch upon full prepayment by cash, wire transfer etc.	December 2020 – present	Sales of medical devices and pharmaceutical R&D
Customer K	3.4	2.7	Payments made in US Dollars by money transfer due within seven calendars days after the order was confirmed	June 2021 – present	Distribution of medical devices
Total	18.9	15.1			

* Based on our agreements with such customers. In practice, we may grant credit periods for certain distributors with whom we have had a long-term business relationship and significant transaction volume, according to our internal trade receivables management policy.

During the Track Record Period, we collaborated with the Retained Lepu Medical Group to distribute our products overseas and in China, and generated revenue from sales to the Retained Lepu Medical Group of RMB10.2 million, RMB31.0 million, RMB16.0 million and RMB2.6 million in 2019, 2020, 2021 and the six months ended June 30, 2022, respectively. Such transactions were conducted in the ordinary course of business at arm's length with reference to normal commercial terms. See "Connected Transactions — Non-Exempt Continuing Connected Transactions" and "— Sales, Distribution and Marketing — Sales Arrangements" for details. Save as disclosed above, during the Track Record Period and up to the Latest Practicable Date, none of our Directors, their close associates or, to the knowledge of our Directors, any Shareholder with 5% or more of the issued Shares of our Company, had any interest in our five largest customers.

In 2016, we became acquainted with the founder of Customer A, an independent third party, through referrals by another independent third party business partner in the medical device industry. We began to cooperate with Customer A since its founding, considering its founder's extensive experience in selling interventional medical devices targeting CHD among hospitals, and accordingly Customer A's established access to and distribution network among public hospitals, especially Class III Hospitals. During the Track Record Period, our transaction amount with Customer A was RMB7.9 million, RMB10.8 million and RMB11.4 million in 2019, 2020 and 2021, respectively. Such transaction amounts were commensurate with the growth of Customer A's scale of operations over the corresponding periods. According to publicly available information, Customer A's registered capital was RMB1.0 million, which typically does not represent the scale of revenue or profits of a company in China. As advised by our PRC Legal Advisors, there is no requirement for the scale of the registered capital for Customer A under PRC law. To the best of our Directors' knowledge, save for acting as our customer, there are no past or present relationships (including, without limitation, business, employment, family, trust, financing, shareholding or otherwise) between Customer A or any of its associates on one hand, and each of our Company and our subsidiaries, their controlling shareholders, directors and senior management, and any of their respective associates on the other hand. The independent third party business partner that referred Customer A to us was a director of one of our distributors. To the best of our Directors' knowledge, save for acting as our distributor and referring Customer A to us, there are no past or present relationships (including, without limitation, business, employment, family, trust, financing, shareholding or otherwise) between our Company and such independent third party business partner, or any of their respective associates.

After-sales Services

We have a dedicated after-sales services team responsible for collecting feedback, addressing complaints and inquiries, compiling customer profiles and collaborating with our research and development personnel on product design and improvements.

We also provide channels for complaints regarding our products, including actively collecting customer feedback through written, oral, email and telecom communications, among others. We also collaborate closely with physicians and hospitals to gather their and their patients' product feedback and improvement suggestions in order to develop new features that cater to the evolving market demands. Customers are able to submit their complaints via distributors or communicate with us directly through our marketing center. We handle complaints pursuant to our internal complaints handling guidelines. Upon receiving a complaint, we typically initiate targeted investigations to determine whether a replacement or refund is needed, under which circumstances we will take remedial measures as required by our corrective and preventive action policies to deter future similar incidents. In addition, if we determine that an incident involving our product constitutes an adverse event under NMPA regulations, we will communicate closely with the relevant hospitals and report the incident to the NMPA in a timely manner. We will also continue to communicate with the NMPA and the hospitals and further assess and confirm the cause for the adverse events and whether the events are related to our products. During the Track Record Period and up to the Latest Practicable Date, we had received several customer complaints through the NMPA adverse event detection system. After careful analysis and evaluation, such complaints were determined to be unrelated to our products, and the determinations were subsequently approved by Shanghai Municipal Center for Monitoring the Adverse Effect of Drugs and Medical Devices (上海市藥品和醫療器械不良反應監測中心), which is administered by Shanghai Medical Products Administration and as advised by our PRC Legal Advisors, is the competent entity to investigate, evaluate and give feedback on the adverse events of medical devices registered or filed for record within its administrative region, according to the Administrative Measures for Surveillance and Re-evaluation of Medical Device-related Adverse Events (《醫療器械不良事件監測和再評價管理辦法》).

RAW MATERIALS AND SUPPLIERS

Suppliers

During the Track Record Period, our suppliers mainly included suppliers of raw materials and machinery and equipment, and institutions that provided testing or clinical trial related services. In 2019, 2020, 2021 and the six months ended June 30, 2022, purchases from our five largest suppliers, who are primarily manufacturers of hardware products, providers of raw materials, catheters and other products for minimally invasive procedures, providers of printing services, office suppliers and plastic products, amounted to RMB7.4 million, RMB8.6 million, RMB18.8 million and RMB9.0 million, respectively, accounting for 70.6%, 69.1%, 56.3% and 49.2% of our total purchases for the same periods, respectively. Purchases from the largest supplier in 2019, 2020, 2021 and the six months ended June 30, 2022 were RMB2.8 million, RMB2.3 million, RMB7.0 million and RMB2.9 million, respectively, representing 26.3%, 18.7%, 21.1% and 15.9% of our total purchases for the same periods, respectively. The following table sets forth certain information of our five largest suppliers during the Track Record Period.

Supplier	Transaction amount	Percentage of total purchase	Credit/settlement terms[1]	Length of relationship as of the Latest Practicable Date	Principal business	Financial standing and scale of business operation[2]
	(RMB in million)	*(%)*				
For the year ended December 31, 2019						
Supplier A	2.8	26.3	Payment upon product delivery in conformity with agreed specifications	March 2009 – present	Manufacturing, processing and sales of hardware products	Registered capital was RMB0.1 million
Supplier B	1.5	14.4	50% prepayment and prepayment of the remaining prior to dispatch	March 2013 – present	Manufacturing and sales of medical devices	Registered capital was RMB10.0 million
Supplier C	1.4	12.9	Dispatch within six weeks upon full prepayment	February 2012 – present	Sales of catheters and other products for minimally invasive procedures	N/A[3]
Retained Lepu Medical Group	1.1	10.7	Payment within one week in RMB upon product delivery	May 2014 – present	Manufacturing and sales of medical devices	The registered capital of Lepu Medical was RMB1.8 billion, its revenue in 2021 was RMB10.7 billion and total assets as of December 31, 2021 was RMB20.7 billion
Supplier D	0.6	6.3	Payment upon product delivery by wire transfer	November 2015 – present	Printing services and sales of office supplies and plastic products	Registered capital was RMB0.5 million
Total	7.4	70.6				

Supplier	Transaction amount	Percentage of total purchase	Credit/settlement terms[1]	Length of relationship as of the Latest Practicable Date	Principal business	Financial standing and scale of business operation[2]
	(RMB in million)	*(%)*				
For the year ended December 31, 2020						
Supplier B	2.3	18.7	50% prepayment and prepayment of the remaining prior to dispatch	March 2013 – present	Manufacturing and sales of medical devices	Registered capital was RMB10.0 million
Supplier A	2.2	17.7	Payment upon product delivery in conformity with agreed specifications	March 2009 – present	Manufacturing, processing and sales of hardware products	Registered capital was RMB0.1 million
Supplier C	1.9	15.5	Dispatch within six weeks upon full prepayment	February 2012 – present	Sales of catheters and other products for minimally invasive procedures	N/A[3]
Retained Lepu Medical Group	1.1	9.1	Payment in RMB within one week upon product delivery	May 2014 – present	Manufacturing and sales of medical devices	The registered capital of Lepu Medical was RMB1.8 billion, its revenue in 2021 was RMB10.7 billion and total assets as of December 31, 2021 was RMB20.7 billion
Supplier E	1.0	8.1	50% prepayment and prepayment of the remaining prior to dispatch	December 2018 – present	Sales of medical devices	Revenue in 2021 was US$2.8 billion and total assets as of December 31, 2021 was US$6.9 billion
Total	8.6	69.1				

Supplier	Transaction amount	Percentage of total revenue	Credit/settlement terms[1]	Length of relationship as of the Latest Practicable Date	Principal Business	Financial standing and scale of business operation[2]
	(RMB in million)	*(%)*				
For the year ended December 31, 2021						
Supplier E	7.0	21.1	50% prepayment and prepayment of the remaining prior to dispatch	December 2018 – present	Sales of medical devices	Revenue in 2021 was US$2.8 billion and total assets as of December 31, 2021 was US$6.9 billion
Supplier B	5.0	15.1	50% prepayment and prepayment of the remaining prior to dispatch	March 2013 – present	Manufacturing and sales of medical devices	Registered capital was RMB10.0 million
Supplier A	2.8	8.3	Payment upon product delivery in conformity with agreed specifications	March 2009 – present	Manufacturing, processing and sales of hardware products	Registered capital was RMB0.1 million
Supplier F	2.1	6.3	Dispatch upon full prepayment and within 10 weeks upon receipt of the procurement order	July 2011 – present	Sales of composite materials	N/A[3]
Supplier C	1.8	5.4	Dispatch within six weeks upon full prepayment	February 2012 – present	Sales of catheters and other products for minimally invasive procedures	N/A[3]
Total	18.8	56.3				

Supplier	Transaction amount	Percentage of total purchase	Credit/settlement terms[1]	Length of relationship as of the Latest Practicable Date	Principal business	Financial standing and scale of business operation[2]
	(RMB in million)	*(%)*				
For the six months ended June 30, 2022						
Supplier B	2.9	15.9	50% prepayment and prepayment of the remaining prior to dispatch	March 2013 – present	Manufacturing and sales of medical devices	Registered capital was RMB10.0 million
Supplier A	2.5	13.7	Payment upon product delivery in conformity with agreed specifications	March 2009 – present	Manufacturing, processing and sales of hardware products	Registered capital was RMB0.1 million
Supplier E	1.8	9.8	50% prepayment and prepayment of the remaining prior to dispatch	December 2018 – present	Sales of medical devices	Revenue in 2021 was US$2.8 billion and total assets as of December 31, 2021 was US$6.9 billion
Supplier C	0.9	5.1	Dispatch within six weeks upon full prepayment	February 2012 – present	Sales of catheters and other products for minimally invasive procedure	N/A[3]
Supplier G	0.9	4.7	50% prepayment and prepayment of the remaining prior to dispatch based on actual volume	August 2013 – present	Technical promotion services and import and export services	Registered capital was RMB0.3 million
Total	9.0	49.2				

(1) Based on our agreements with such suppliers. In practice, we may receive credit periods from some of our suppliers with whom we have had long-term business relationship.

(2) The financial standing and scale of business operation were derived from annual reports and/or other publicly available information concerning the relevant companies.

(3) Each of Supplier C and Supplier F is a U.S.-based private company, for which there are no public records of its financial standing and scale of business operation.

In 2019, 2020, 2021 and the six months ended June 30, 2022, we procured certain non-core components and parts from the Retained Lepu Medical Group, and our purchases from the Retained Lepu Medical Group were RMB1.1 million, RMB1.1 million, RMB1.7 million and nil, respectively. Such transactions were conducted in the ordinary course of business at arm's length with reference to normal commercial terms. Save as disclosed above, during the Track Record Period and up to the Latest Practicable Date, none of our Directors, their close associates or, to the knowledge of our Directors, any Shareholder with 5% or more of the issued Shares of our Company, had any interest in our five largest suppliers.

Overlapping of Customers and Suppliers

Our Directors confirmed that none of our major customers was also our major suppliers during the Track Record Period, except for the Retained Lepu Medical Group, which was our major distributor as well as our major supplier in 2019 and 2020. See "Financial Information — Related Party Transactions" for details. Negotiations of the terms of our sales to and purchases from the Retained Lepu Medical Group were conducted on an individual basis, and the sales and purchases were neither inter-connected or inter-conditional with each other. Our Directors confirmed that all of our sales to and purchases from the Retained Lepu Medical Group were conducted in the ordinary course of business under normal commercial terms and on arm's length basis.

Raw Materials

Principal raw materials for our products are nitinol materials, animal source materials, polymer materials and sheathes and other metal components. We have formulated detailed quality standards for raw materials, covering both technical specifications and regulatory compliance requirements. We only procure raw materials from selected suppliers that can satisfy our stringent standards to ensure the consistently high quality and performance of our products. We will include suppliers in our list of qualified suppliers only after they have gone through the processes stipulated in our evaluation and control protocol for suppliers, which include documented qualification review, field review and sample inspection. Multiple departments throughout the product lifecycle, such as supply chain, manufacturing, quality control as well as research and development, will all participate in this initial review to evaluate and jointly approve the qualifications of new suppliers. We also require the suppliers to enter into a quality technical agreement with us before including them in our list. All raw materials supplied will be subject to continuous inspections during our cooperation, and will only be admitted into our manufacturing facilities upon passing our strict inspections. In addition, our supply chain team will re-evaluate all qualified suppliers annually in terms of, among others, qualification rate, quality complaint management, supply punctuality, and after-sales service.

The nitinol products used in our products are primarily produced in China, the United States, Germany and Japan, and the sheathes we use are primarily procured from China, the United States, and Ireland. Specifically, the biodegradable wires and nitinol tubes used in our products are solely sourced from overseas, for which we have backup suppliers in place. We generally have over seven years of business relationship with each of our top five suppliers of raw materials during the Track Record Period. We intend to maintain stable business relationships with our major suppliers of raw materials. We have maintained a list of backup suppliers to minimize the risks associated with shortage of raw materials. Furthermore, we are inclined to procure an increasing portion of the raw materials from qualified domestic suppliers, to shield against potential risks caused by international relations. During the Track Record Period and up to the Latest Practicable Date, we did not experience any shortage of raw materials that may have a material adverse effect on our business and operations. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Manufacture and Supply — 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."

As of the Latest Practicable Date, the existing trade tensions or the trade war did not have material adverse effect on our raw materials supply. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Operations — Changes in international trade policies and trade barriers, or the escalation of trade tensions, may have an adverse effect on our business." We have experienced certain negative impact on our business as a result of the impact on the operations of our suppliers by the COVID-19 outbreak, primarily reflected in the delay in logistics for suppliers of raw materials resulting from the temporary restrictions or bans on traveling by local governments to contain the spread of the COVID-19. We strategically purchased surplus inventory of raw materials as part of our provisional strategies amid the COVID-19 outbreak. As of the Latest Practicable Date, we were informed that all of our suppliers had resumed operation and we had not experienced any major supply chain disruption.

Our supply chain team is responsible for communicating with suppliers, keeping procurement records and evaluating potential and existing suppliers. Our supply chain team works closely with other internal teams to ensure proper management of our procurement process. For example, our research and development team is responsible for providing specifics of raw materials to be purchased, which is subject to our quality control team's further review. Our manufacturing team and inventory management team monitor our usage and needs for raw materials on a rolling basis and evaluates the performance of sample and actual raw materials. Our quality control team is also involved in the procurement process to conduct on-going inspections and ensure compliance with internal and regulatory standards.

Procurement Agreements with Suppliers

We generally enter into purchase agreements with suppliers on an order-by-order basis. Pursuant to the purchase agreements, we are obliged to purchase a fixed amount of raw materials at the agreed-upon price set forth therein. The purchase agreements also set out the specifications of raw materials purchased, and stipulate that we are entitled to reject raw materials that do not comply with such specifications or our quality technical requirements. The supplier also guarantees that their raw materials shall satisfy our requirements as specified under the agreements. In addition, we generally enter into quality technical agreements with our suppliers of raw materials prior to the execution of the purchase agreements, which set out our quality standards and inspection procedures.

During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material difficulties in procuring our principal raw materials both in China and overseas, and had not experienced significant fluctuations in the prices offered by our suppliers both in China and overseas, despite the minor impact of the recent COVID-19 outbreak. To the best knowledge of our Directors, there has been no material breach of procurement agreements with our suppliers during the Track Record Period and up to the Latest Practicable Date. Our Directors believe that our inventory of raw materials could meet our production requirements for the next six to 12 months, and that we would not experience any material difficulties in procuring our principal raw materials or passing on increases in the procurement costs to our customers.

INVENTORY

Our inventory mainly includes raw materials, work-in-progress and finished products. We have established an inventory management system to monitor our warehousing process. We generally maintain an inventory level of three-month sales volume for our finished goods and six to 12 months' supply of our raw materials, which may vary according to customer demands and our sales and production plans.

Our specialized warehouse personnel are responsible for the storage and distribution of our inventories. We determine the required inventory level for raw materials based on the average sales volume of the same periods in the past three years and the production volume of the current year, and evaluate and adjust the inventory level frequently with reference to factors such as procurement cycles, market conditions and our research and development plans. We also take into consideration the COVID-19 global status, international relations and the production cycles of our backup suppliers, and strategically enlarge our inventories when necessary. Raw materials are separately stored in different areas of the warehouse according to their respective storage condition requirements, properties, usages and batch numbers. Our products are generally subject to a shelf life of three years. All our products are sold on a first-in-first-out basis. We examine our work-in-progress and finished products frequently to identify any that are damaged, expired or soon-to-be expired pursuant to our protocols, which are disposed of or for which provisions are made. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material shortage in supply or overstock of inventory.

QUALITY CONTROL

Our quality control team is involved in our daily operations. We have established a three-tier quality control system based on (1) domestic medical device laws and regulations, (2) EU medical device laws and regulations as well as (3) the relevant international quality authentication standard to monitor all aspects throughout the product lifecycle, such as product design and development, raw material supply and procurement, product manufacturing and delivery, and after-sales follow-ups, to ensure the quality management of our products. We also participated in the formulation of various industry quality standards, such as the section for cardiac occluders in the PRC Pharmaceutical Industry Standard YY/T 15533-2017, the section for occluders in the Risk List and Inspection Points for the Manufacturing of 25 Kinds of Medical Devices including Disposable Sterile Syringes (《一次性使用無菌注射器等25種醫療器械生產環節風險清單和檢查要點》) issued by China Food and Drug Administration (currently known as the NMPA). We also participated in the research on the subject matter of the Evaluation Method and Standardization of Nitinol Shape Memory Alloy and Implantable Devices (鎳鈦形狀記憶合金及植入器械評價方法和標準化).

We have complied with all of our quality qualification requirements in material respects and have passed all of the inspections up to the Latest Practicable Date. During the Track Record Period and up to the Latest Practicable Date, we had not received any material complaints from our customers and our products had not been subject to any material claim, litigation or investigation. In addition, during the Track Record Period and up to the Latest Practicable Date, we did not experience any material product return or exchange, or any product recall.

INTELLECTUAL PROPERTY

As a medical device provider focusing on innovative interventional solutions for structural heart diseases, intellectual property rights are crucial to our business. We have built a comprehensive intellectual property portfolio in China and overseas to protect our technologies, inventions and know-hows. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any intellectual property disputes or infringement claims which had, or were likely to have, any material adverse impact on our Group.

As of the Latest Practicable Date, we owned 229 patents in China, including 26 invention patents, 200 utility models and three industrial designs. Our invention patents include a non-core basic technology in relation to occluder product which we licensed in from a third party. As of the same date, we also had 55 pending patent applications in China, including 50 invention patents and five utility models. To facilitate our strategy to enter overseas markets, we also had 14 pending patent applications in the United States and the European Union. We are the legitimate holder on record of such patents and patent applications, and the research and development of substantially all of them relied on our internal efforts. See "Appendix VII — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights of Our Group" for a list of our material intellectual properties.

The following table illustrates the patents and patent applications we owned in relation to our key products and key product candidates as of the Latest Practicable Date.

Product	Coverage of Patent Protection	Status (Number of Patents/Patent Applications)	Covered Regions
MemoPart® ASD Occluder I (Double-rivet)	Occluder	Granted 4 Pending 1	PRC
MemoCarna® ASD Occluder III (Oxide Coating)	Occluder	Granted 2 Pending 1	PRC
MemoSorb® ASD Occluder IV (Biodegradable)	Occluder	Granted 8 Pending 11	PRC, PCT
MemoSorb® VSD Occluder IV (Biodegradable)	Occluder	Granted 9 Pending 12	PRC, PCT
MemoSorb® PFO Occluder II (Biodegradable)	Occluder	Granted 10 Pending 13	PRC, PCT
MemoLefort® LAA Closure Occluder I	Occluder + Related delivery system	Granted 2	PRC
LAA Closure Occluder II (Biodegradable)	Occluder + Related delivery system	Granted 7 Pending 16	PRC, PCT

Product	Coverage of Patent Protection	Status (Number of Patents/Patent Applications)	Covered Regions
Transcatheter aortic valve replacement ("TAVR") system	Transcatheter aortic valve + Related delivery system	Pending 7	PRC, United States, European Union
Transapical mitral valve clip repair system ("TMVr-A")	Clip	Granted 3 Pending 3	PRC
Transfemoral mitral valve clip repair system ("TMVr-F")	Clip	Granted 3 Pending 3	PRC

COMPETITION

We operate in a rapidly changing and highly competitive market. While we believe our strong research and development 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 interventional solutions for structural heart diseases. As the interventional medical device market targeting structural heart diseases continues to grow and evolve, we may face increased competition from new market entrants.

We compete primarily based on the clinical performance of our products and product candidates, our ability to commercialize products, research and development capabilities, sales and distribution networks and brand recognition. We believe we are well-positioned to effectively compete on the basis of the factors listed above. However, some of our current or future competitors may have longer operating histories, greater brand recognition or more financial resources than we do. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Commercialization and Distribution — We may face intense competition in the interventional medical device market targeting structural heart diseases, which may result in others discovering, developing or commercializing competing products before or more successfully than we do."

For details of our major competitors, see "Industry Overview."

EMPLOYEES

As of June 30, 2022 and the Latest Practicable Date, we had a total of 230 and 232 full-time employees, respectively. All of our employees are based in China. The following table sets forth a breakdown of our full-time employees by function as of the dates indicated.

	As of June 30, 2022		As of the Latest Practicable Date	
Function	**Number**	**% of Total**	**Number**	**% of Total**
Management	27	11.7	27	11.6
Research and development	76	33.0	78	33.6
Supply chain and manufacturing	45	19.6	49	21.1
Quality control	18	7.8	18	7.8
Sales and marketing	64	27.8	60	25.9
Total	230	100.0	232	100.0

Our success depends on our ability to attract, retain and motivate qualified personnel. We primarily recruit our employees through recruitment agencies, internal referrals and online recruiting channels, including our corporate website, job search websites and social networking platforms. We have adopted training protocols, pursuant to which we provide on-board and regular continuing trainings for our employees. As part of our human resources strategy, we offer employees competitive salaries, performance-based cash bonuses and other incentives. We make contributions to social insurance and housing provident funds as required under PRC laws and regulations. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Operations — Failure to make adequate contributions to social insurance and housing provident fund for our employees as required by PRC regulations may subject us to penalties." In addition, we maintain additional commercial accident insurance for all our employees. We believe that we maintain a good working relationship with our employees, and we had not experienced any material labor dispute or strike, or any difficulty in recruiting staff for our operations during the Track Record Period and up to the Latest Practicable Date. As of the Latest Practicable Date, our employees had not been represented by any labor union.

In compliance with relevant PRC laws and regulations, we enter into employment agreements with our employees to cover matters such as wages, benefits and grounds for termination. We enter into standard confidentiality agreements with all of our full-time employees, which also contain non-compete provisions. Such non-compete provisions 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, require the employee to enter into a non-compete agreement for generally three years after the termination of his or her employment.

PROPERTIES

Owned Properties

As of the Latest Practicable Date, we owned properties in Songjiang District, Shanghai, with an aggregate gross floor area of approximately 10,296.19 square meters. These properties are mainly used as our production facilities, laboratories and offices, which are non-property activities as defined under Rule 5.01(2) of the Listing Rules. We had obtained titles, land use rights and building ownership certificates for all of our owned properties in China. Our PRC Legal Advisors are of the view that we have valid legal titles to these properties and land use rights for the land occupied by these buildings, and that we are entitled to legally occupy, use, benefit from, transfer, lease, pledge or otherwise dispose of these properties. See "Appendix III — Property Valuation Report" to this document for more information.

Two floors we occupied in the same building with a gross floor area of approximately 3,582.17 square meters where our headquarters are located and where we conduct substantially all of our manufacturing activities were renovated without obtaining the construction commencement permit (施工許可證) and going through the construction completion acceptance procedures (竣工驗收). According to PRC laws and regulations, the maximum penalty we may incur for such incidents would be a fine of RMB544,800. Given that the potential highest fines would only account for a small proportion of our total assets or revenue, as advised by our PRC Legal Advisors, our Directors are of the view that such incidents will not have a material adverse effect on our business and financial condition. As of the Latest Practicable Date, we were not aware of any actual or contemplated actions, claims or investigations by any government authorities or third parties against us with respect to the lack of relevant certificates or permits for such renovation. See "Risk Factors — Risks relating to our business and industries — Failure to comply with PRC property laws and relevant regulations may adversely affect our business, results of operations and financial condition."

Leased Properties

As of the Latest Practicable Date, we also leased 14 properties under six lease agreements in Songjiang District, Shanghai, and Changping District, Beijing, with an aggregate gross floor area of approximately 2,241.74 square meters. Such properties primarily serve as the office premises of the Beijing branch of Shanghai Shape Memory Alloy and our employee dormitories. Our lease agreements in respect of the abovementioned 14 leased properties generally have expiration dates ranging from November 2022 to May 2024. All lessors are independent third parties, except for the Retained Lepu Medical Group. See "Connected Transactions" for details of our lease arrangements with the Retained Lepu Medical Group. We plan to renew our leases or negotiate new terms when the existing leases expire. We did not experience material difficulties in negotiating renewal of our leases with our landlords during the Track Record Period and up to the Latest Practicable Date.

Pursuant to the applicable PRC laws and regulations, lease agreements must be registered with the local branch of the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部). The registration of such leases will require the cooperation of our lessors. As of the Latest Practicable Date, we had not obtained lease registration for 14 properties we leased under six lease agreements in China, primarily due to the difficulty of procuring our lessor's cooperation to register such lease. As advised by our PRC Legal Advisors, the lack of registration of the lease agreement will not affect its validity. According to the relevant PRC laws and regulations, we may be ordered by the relevant government authorities to register the relevant lease agreements within a prescribed period, failing which we may be subject to a fine ranging from RMB1,000 to RMB10,000 for each non-registered lease. As of the Latest Practicable Date, we had not received any such request or suffered any such fine from the relevant government authorities. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Operations — Failure to comply with PRC property laws and relevant regulations may adversely affect our business, results of operations and financial condition."

INSURANCE

We maintain certain insurance policies as of the Latest Practicable Date. For example, we maintain insurance policies that cover losses arising from accidents and natural calamities in respect of our machinery, equipment, inventories and other fixed assets in our research and manufacturing facilities. We also maintain insurance policies covering clinical trial liability and are in the process of securing an insurance policy against product liability claims. We consider the coverage from insurance policies maintained by us to be adequate for our current operations. During the Track Record Period, we did not submit any material insurance claims, nor did we experience any business interruptions that had a material adverse effect on our business, results of operations or financial condition. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Operations — Our insurance coverage may not be adequate, which could expose us to significant costs and business disruption."

ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE

The increasing risk from climate change, environmental protection is viewed as an integral corporate responsibility at our Company, and therefore we are dedicated to lowering the environmental impact of all aspects of our business operations. Environmental stewardship and corporate social responsibility are a key part of our core growth philosophy which, along with our focus on sustainability, diversity, and public interests, we expect to generate value for our Shareholders. As such, our Group has followed a comprehensive policy on environmental, social and corporate governance responsibilities (the "ESG Policy") in accordance with the Listing Rules, which sets forth our corporate social responsibility objectives and provides guidance on how we practice corporate social responsibility in our daily operations and productions.

Under our ESG Policy, we strive to operate in a manner that protects the environment and the safety and health of our employees and communities. Our target is to sustainably connect with our employees, customers, and business partners through a combination of initiatives which create long-lasting benefits to our Company as a community, these initiatives include further development and training activities for employees, clear redress procedures for customers, and prioritising local suppliers with sustainable practices when selecting business partners. In addition, under our ESG Policy, we have also been promoting diversity at our Company through continuous implementation of pro-diversity management practices, as well as through equal, fair treatment and career opportunities for all employees. Our Company maintains a policy against sex, family roles, disability, religion and race related discrimination in all our hiring processes. Throughout our hiring process, we do not ask about the interviewee's religious beliefs nor sexual orientation. By implementing these practices, we aim to cultivate health, wellbeing, and work-life balance for all our employees.

Our Board has the collective responsibility to establish, review, and revise the ESG Policy of our Company. Zhang Xiani (張夏妮), our deputy general manager, will be delegated to handle all ESG-related topics, and she shall oversee the evaluation of any ESG-related risks that our company may face. Furthermore, we will establish an ESG working group comprised of employees, which would convene every six months to discuss and determine relevant ESG topics that require addressing by our Company. For example, our ESG working group will work on ESG requirements of our suppliers, including giving priority to suppliers with environmentally friendly products and services; in addition, we will closely monitor environmental and social risks in our supply chain based on input from our ESG working group. Finally, our Board has enlisted the services of independent third parties to evaluate potential ESG risks faced by our Company, as well as provide comment on our ESG Policy, strategies, and set targets. Based on the received comments, we shall revise our ESG Policy accordingly.

We believe we have adequate policies ensuring compliance with all health, safety, social and environmental protection regulations. Specifically, we (1) have various guidelines governing workplace safety and fire control; (2) inspect our office premises and production facilities regularly to identify emergencies and safety hazards and minimize related risks; and (3) keep health records for all employees and conduct health examinations before and during their employment with us, especially for employees directly engaged in production activities. As mentioned above, independent third parties and our ESG working group shall review our policies on a regular basis to ensure all ESG topics have been covered.

Our Company has complied with relevant PRC health, safety, social and environmental law and regulations, which are strictly enforced by local environmental protection authorities through regular inspections. While we do not operate in a highly polluting industry, we make every effort to reduce our generation of hazardous waste, non-hazardous waste, and other emissions. As such, we have implemented company-wide health, safety, social and environmental protection policies and standard operating procedures that include workplace management, process safety management, waste treatment and disposal, and emergency planning and response. For example, we utilize metal equipment rather than single-use plastic for laboratory use, and we promote precision in laboratory experiments to reduce producing unwanted hazardous waste and wastewater. Regarding any emissions and discharges which cannot be avoided, our Company has taken necessary measures to ensure compliance with all

applicable national, industrial, and local standards, laws, regulations and policies. These include our air pollutants emissions, which comply with all corresponding emission limits under the Integrated Emission Standards of Air Pollutants (DB31/933-2015) after filtering and purifying; our wastewater discharges, which are categorised as level three under the Integrated Wastewater Discharge Standard (DB/31/199-2018) and has been deemed to not cause material impact to surrounding water environment; and our noise emission, which was categorized as level three under the Noise Emission Standard for Industrial Enterprises at Boundary (GB12348-2008), which would not cause a material impact on the surroundings.

Regarding hazardous waste generated by our Company, our operations involve the use of hazardous and flammable chemical materials and special equipment, while also producing hazardous waste. To treat these hazardous wastes, we have entered into hazardous waste disposal agreements with third parties for the disposal and reclamation of these materials and wastes. Furthermore, we have adopted internal policies with respect to handling hazardous waste, which include detailed outlines on employee training, delegation of responsibility, emergency plans, and management procedures. In particular, we have implemented work safety guidelines setting out safety practices, accident prevention and accident reporting procedures. Our employees which are responsible for manufacturing and quality control are required to hold relevant qualifications, as well as wear proper safety gear when working. We conduct regular safety inspections and maintenance for our manufacturing facility.

In addition, we shall also be reducing our environmental footprint through further emphasis on energy saving, emissions control, and sustainable development. For example, under the ESG policy, we will adopt measures targeted at attaining an efficient use of natural resources and energy, and establish clear policies on the reduction and handling of dangerous waste.

We believe that climate change brings about both risks and opportunities for our Company. While we do not foresee any short-term risks, we have identified several long-term risks which may affect our Company's business operations. Firstly, as our Company's site of operations is on the coastal area in Shanghai, sea level rise caused by climate change may adversely impact both our employees and production. In addition, climate change may also exacerbate the frequency of extreme weather condition, resulting in potential financial and human capital loss. Furthermore, our Company may be requested by authorities to fully adopt renewable energy as our source of electricity and power, the transition of which may increase the cost of operations. Finally, we also foresee an increase in the frequency of blackouts due to the heavy load on the electricity grid as caused by climate change, which may lead to unpredictable disturbances to our operations. To mitigate these identified risks, our Company shall be implementing practices accordingly. For example, we will purchase property insurance and prepare contingency plans to minimise the cost of damages from extreme weather conditions. Whereas for opportunities, research has shown that increased temperatures due to climate change may lead to an increased risk of heart attacks among the general population. As we are a provider of interventional medical devices that primarily target structural heart diseases, climate change may lead to an increase in demand for our Company's products.

The following table presents the latest key environmental data of our Company for the year ended December 31, 2020:

	Total Amount	Intensity (per RMB1.0 million revenue)
Purchased Electricity	501,656 kWh	3,383.92 kWh
Freshwater Usage	5,315 m^3	35.85 m^3
Hazardous Waste	5,969 kg	40.26 kg
Packaging Material	10,638 kg	71.76 kg
Scope 1 + Scope 2 Emissions	371.69 tonne CO_2e	2.51 tonne CO_2e

Our Company has set our environmental targets based on the above metrics. Within the next five years, we aim to reduce the intensity of our freshwater usage, hazardous waste generation, packaging material usage, and emissions (Scope 1 + Scope 2) by approximately 5%, with the specifics of our targets as listed below:

	Intensity within Five Years (per RMB1.0 million revenue)
Freshwater Usage	34 m^3
Hazardous Waste	38 kg
Packaging Material	68 kg
Scope 1 + Scope 2 Emissions	2.35 tonne CO2e

Based on our progress, we may adjust our five-year target as needed. For example, if our Company has fallen behind on the originally set emissions target, we shall purchase the required amount of carbon certificates.

During the Track Record Period and up to the Latest Practicable Date, we had been in compliance with the relevant PRC laws and regulations in all material aspects, and had not been subject to any material claim or penalty in relation to health, safety, social and environmental protection, or been involved in any significant work place accident or fatality. Our Directors consider that the annual cost of compliance with the applicable health, safety, social and environmental laws and regulations was not material during the Track Record Period and we do not expect the cost of such compliance to be material going forward.

LICENSES, PERMITS AND APPROVALS

We are subject to regular inspections, examinations and audits by local regulators including the Shanghai Medical Products Administration and are required to obtain various permits, licenses, approvals and certifications from government authorities as required under PRC laws and regulations. We are required to obtain registration certificates for our products, which are all Class III medical devices, from relevant regulatory authorities prior to commercialization. According to applicable PRC laws and regulations, the registration certificates for Class III medical devices are valid for five years and subject to renewal. As of the Latest Practicable Date, we had maintained 14 NMPA registration certificates for Class III medical devices, which had an expiration date ranging from November 22, 2022 to May 17, 2027. In addition, we are required to maintain a number of licenses, permits and approvals for our production and operations, such as the Medical Device Production Permit (醫療器械生產許可證), the Medical Device Operation Permit (醫療器械經營許可證), the Medical Device Export Certificate (醫療器械產品出口銷售證明) and the Internet Drug Information Service Qualification Certificate (互聯網藥品信息服務資格證書).

Our PRC Legal Advisors are of the view that, as of the Latest Practicable Date, we had obtained all requisite permits, licenses, approvals and certifications that are material for our business operations in China, and such licenses, permits and certifications all remained in full effect. As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and certificates to sell our products in all of the relevant overseas jurisdictions to which we exported our products. We did not experience any material difficulties in obtaining, making or renewing such licenses, permits, approvals, certificates and filings during the Track Record Period.

LEGAL PROCEEDINGS AND COMPLIANCE

Legal Proceedings

We are subject to legal, arbitral or administrative proceedings arising in the ordinary course of our business from time to time. As of the Latest Practicable Date, we were not involved in any legal, arbitral or administrative proceeding pending or, to our knowledge, threatened against us or any of our Directors that could have a material adverse effect on our business, results of operations or financial condition.

Non-compliance

According to our PRC Legal Advisors, during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operations. Our Directors are of the view that, we had complied, in all material respects, with all relevant laws and regulations in the jurisdictions we operate in during the Track Record Period and up to the Latest Practicable Date.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks during our operations. In addition, we also face numerous market risks, such as foreign exchange risk, credit risk and liquidity risk that arise in our ordinary course of business. For a discussion on these market risks, see "Financial Information — Quantitative and Qualitative Disclosures about Market Risk." We have implemented various policies and procedures to ensure effective risk management at each aspect of our operations, including research and development, manufacturing and supply, quality control, inventory management, sales and distribution, financial reporting and information system.

Our Board oversees and manages the overall risks associated with our operations. We [have] established an Audit Committee to review and supervise the financial reporting process and internal control system of our Group. See "Directors, Supervisors and Senior Management — Board Committees — Audit Committee" for the qualifications and experience of these committee members as well as a detailed description of the responsibility of our Audit Committee. We [have prepared] written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code and Corporate Governance Report as set out in Appendix 14 to the Listing Rules.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have designed and adopted strict internal procedures to ensure the compliance of our business operations with the relevant rules and regulations. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- Our financial and legal departments examine the agreement terms and review all relevant documents for our business operations. Our operational teams, with the assistant our financial and legal departments, will review the qualifications of our business partners and all the other necessary underlying due diligence materials, before we enter into any agreement or business arrangements.

- Our regulatory affairs department oversees the obtaining of requisite governmental pre-approvals, consents, licenses and permits, to ensure the compliance of our research, development, manufacture and commercialization activities.

- We have maintained anti-corruption policies and code of ethics and business conduct among our employees, especially our direct sales personnel involved in our sales and marketing activities. We have also implemented protocols to ensure the integrity of our research and development as well as registration and approval processes. Further, we have also arranged training on the consequences and prevention of corruptive conducts, and monitor related activities on an on-going basis.

- We have adopted various measures and procedures regarding each aspect of our operations, such as protection of intellectual property, environmental protection and safety. We provide periodic training on these measures and procedures to our employees as part of our employee training program and regularly monitor the implementation of those measures and procedures.

- We have designated responsible personnel in our Company to monitor the ongoing compliance by our Company with relevant PRC laws and regulations and other applicable laws and regulations that govern our business operations and oversee the implementation of any necessary measures. In addition, we plan to provide our Directors, Supervisors, senior management and relevant employees with continuing training programs and/or updates regarding relevant laws and regulations on a regular basis with a view to proactively identify any concerns and issues relating to any potential non-compliance.

In addition, as part of our internal control system, we have implemented specific measures to ensure we are compliant with International Sanctions laws.

- We will not conduct any sales, directly or indirectly, to Iran or any other Comprehensively Sanctioned Country;

- To further enhance our existing internal risk management functions, our legal department is responsible for monitoring our exposure to sanctions risks and our implementation of the related internal control procedures. Our legal department will hold at least two meetings each year to monitor our exposure to sanctions risks;

- We will evaluate the sanctions risks prior to determining whether we should embark on any business opportunities in countries subject to International Sanctions and with Sanctioned Persons. According to our internal control procedures, our legal department needs to review and approve all relevant business transaction documentation from customers or potential customers from countries subject to International Sanctions and with Sanctioned Persons. If any potential sanctions risk or suspicious transaction is identified, we may seek advice from reputable external international legal counsel with necessary expertise and experience in International Sanctions matters;

- Our Directors will continuously monitor the [**REDACTED**] from the [**REDACTED**], as well as any other funds raised through the Stock Exchange, to ensure that such funds will not be used to finance or facilitate, directly or indirectly, activities or business with, or for the benefit of, countries subject to International Sanctions or Sanctioned Persons where this would be in breach of International Sanctions;

- Our legal department will periodically review our internal control policies and procedures with respect to sanctions matters. As and when our legal department considers necessary, we will retain external international legal counsel with necessary expertise and experience in sanctions matters for recommendations and advice; and

- If necessary, we will arrange external international legal counsel to provide training programs relating to the sanctions to our Directors, our senior management and other relevant personnel to assist them in evaluating the potential sanctions risks in our daily operations, in particular, to perform screening procedures where appropriate in respect of counterparties to our Group's business to ensure none of them are Sanctioned Persons. Our external international legal counsel will provide a current list of countries subject to International Sanctions and Sanctioned Persons to our Directors, senior management and other relevant personnel, who will in turn disseminate such information internally.

Hogan Lovells, our International Sanctions Legal Advisors have reviewed and evaluated these internal control measures and are of the view that these measures appear adequate and effective for our Company, based on our products and risk assessment, to comply with applicable international sanction laws.