

## SUMMARY

*This summary aims to give you an overview of the information contained in this document and should be read in conjunction with the full text of this document. As this is only a summary, it does not contain all the information that may be important to you. You should read this document in its entirety before you decide to [REDACTED] in the [REDACTED].*

*There are risks associated with any [REDACTED]. Some of the particular risks in [REDACTED] in the [REDACTED] are set out in “Risk Factors.” You should read that section carefully before you decide to [REDACTED] in the [REDACTED]. Various expressions used in this section are defined or explained in “Definitions” and “Glossary of Technical Terms” in this document.*

## 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 congenital heart diseases (“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 patent foramen ovale (“PFO”) occluder products and left atrial appendage (“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 Latest Practicable Date, our business focused on occluder products and our heart valve product

\* 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.

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candidates were in various pre-launch stages without marketed heart valve products. 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 collaboratively 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. 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.


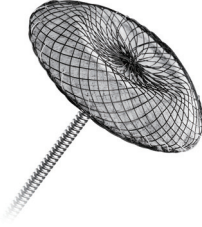
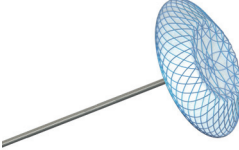
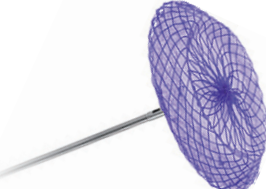
### **Our Product Portfolio**

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. As of the Latest Practicable Date, we were the only provider in China with a product portfolio covering all of these 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 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.

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CHD. We have developed a wealth of occluder products targeting common types of CHD, including primarily atrial septal defect (“ASD”), ventricular septal defect (“VSD”), and patent ductus arteriosus (“PDA”). 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, including our fully biodegradable VSD occluder product. As of the same date, our biodegradable ASD occluder product candidate was in the clinical trial stage, which is expected to receive NMPA approval in the second quarter of 2024.

CHD occluders are medical devices intended for the closure of the remnant opening, or a defect, in the heart resulting from congenital abnormal development. ASD, VSD and PDA occluders target for the closure of the defects for different positions in the heart. The following graphs illustrate the product structure of our ASD occluder products and product candidate.

<u>Product Name</u>	<u>Product Structure</u>
MemoPart <sup>®</sup> ASD Occluder I (Double-rivet)	
MemoPart <sup>®</sup> ASD Occluder II (Single-rivet)	
MemoCarna <sup>®</sup> ASD Occluder III (Oxide Coating)	
MemoSorb <sup>®</sup> ASD Occluder IV (Biodegradable) (product candidate)	

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The following graphs illustrate the product structure of our VSD occluder products.

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**Product Name**

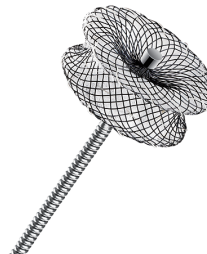
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**Product Structure**

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MemoPart<sup>®</sup> VSD Occluder I  
(Double-rivet)



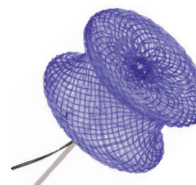
MemoPart<sup>®</sup> VSD Occluder II  
(Single-rivet)



MemoCarna<sup>®</sup> VSD Occluder III (Oxide  
Coating)



MemoSorb<sup>®</sup> VSD Occluder IV  
(Biodegradable)

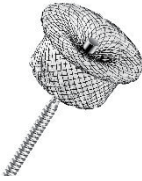







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The following graphs illustrate the product structure of our PDA occluder products.

<b>Product Name</b>	<b>Product Structure</b>	
MemoPart <sup>®</sup> PDA Occluder I (Double-rivet)	 Cylinder-shaped	 Cone-shaped
MemoPart <sup>®</sup> PDA Occluder II (Single-rivet)	 Cylinder-shaped	 Cone-shaped
MemoCarna <sup>®</sup> PDA Occluder III (Oxide Coating)	 Cylinder-shaped	 Cone-shaped

Cardioembolic stroke. We have commercially launched our first generation LAA occluder product in June 2020 and first generation PFO occluder product in August 2012. 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 valid 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. 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.

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PFO occluder is a medical device intended for the closure of the small hole between the right and the left atrium in the heart. The following graphs illustrate the product structure of our PFO occluder product and product candidate.

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**Product Name**

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**Product Structure**

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MemoPart<sup>®</sup> PFO Occluder I



MemoSorb<sup>®</sup> PFO Occluder II (Biodegradable)  
(product candidate)



LAA occluder is a medical device intended for the closure of the small and ear-shaped sac in the muscle wall of the left atrium in the heart. The following graph illustrates the product structure of our MemoLefort<sup>®</sup> LAA Occluder I together with the delivery system.



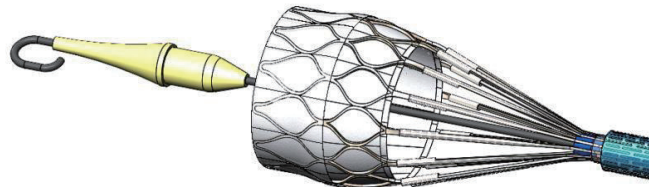
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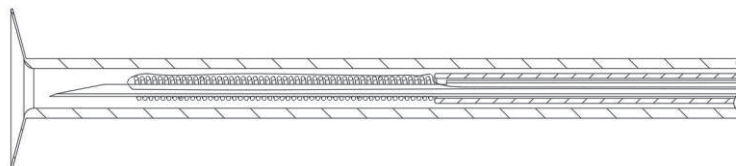
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Valvular diseases. We have cultivated a comprehensive pipeline of interventional heart valve product candidates covering all the major valvular diseases, including primarily aortic valve diseases, mitral valve diseases and tricuspid valve diseases. 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 primarily include transapical mitral valve repair system (chordal) (“TMVCRS”), TMVr-A system and TMVr-F system, which were in the clinical trial stage, the clinical trialstage and the type inspection stage as of the Latest Practicable Date, respectively. 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.

Valvular disease is caused by valvular stenosis or valvular insufficiency in one of the four heart valves (i.e., aortic valve, pulmonary valve, mitral valve, and tricuspid valve) that leads to heart disease. TAVR system is a medical device intended to treat aortic valve diseases to make the aortic valve function properly. The following graph illustrates the product structure of our TAVR system, which is a product candidate.



TMVCRS, TMVr-A system, and TMVr-F system are medical devices intended to treat mitral valve diseases to make the mitral valve function properly. The following graphs illustrate the product structure of our TMVCRS, TMVr-A system, and TMVr-F system, which are product candidates.

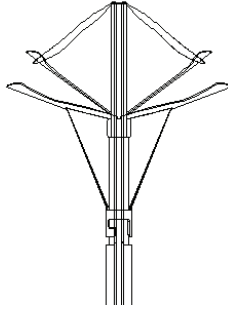


TMVCRS

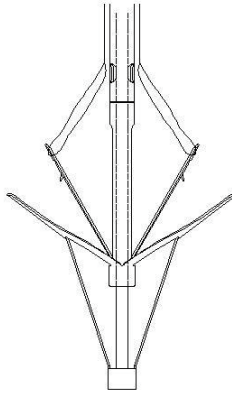
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TMVr-A system



TMVr-F system

For details of our occluder products and product candidates and heart valve product candidates, see “Business — Our Products.”



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

Product <sup>(1)</sup>	Pre-clinical	Clinical Trial <sup>(2)</sup>	Registration <sup>(3)</sup>	Next Milestone/ Actual Launch Time <sup>(4)</sup>
Atrial septal defect occluder			Launched	NMPA Approval in 2003 CE Mark in 2012
			Launched	CE Mark in 2012
			Launched	NMPA Approval in 2020Q2 CE Application in 2022Q4E
		Clinical trial		NMPA Application in 2023Q2E
Ventricular septal defect occluder			Launched	NMPA Approval in 2003 CE Mark in 2012
			Launched	CE Mark in 2012
			Launched	NMPA Approval in 2021Q3 CE Application in 2023Q1E
			Launched	NMPA Approval in 2022Q1
Patent ductus arteriosus occluder			Launched	NMPA Approval in 2003 CE Mark in 2012
			Launched	CE Mark in 2012
			Launched	NMPA Approval in 2021Q2 CE Application in 2023Q2E
			Launched	CE Mark in 2012
Patent foramen ovale occluder			Launched	CE Mark in 2012
		Registration preparation		NMPA Application in 2022Q3E

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	Product <sup>(1)</sup>	Pre-clinical	Clinical Trial <sup>(2)</sup>	Registration <sup>(3)</sup>	Next Milestone/ Actual Launch Time <sup>(4)</sup>
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 <sup>(6)</sup>
	MemoPart® Plug II (Single-rivet)			Launched	CE Mark in 2012 <sup>(6)</sup>
	MemoFlex® Plug III (Double-waist)		Clinical trial		NMPA Application in 2023Q4E
Occluder Products <sup>(5)</sup>	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		
Procedural accessories					

**SUMMARY**

Product <sup>(1)</sup>	Pre-clinical	Clinical Trial <sup>(2)</sup>	Registration <sup>(3)</sup>	Next Milestone/ Actual Launch Time <sup>(4)</sup>
<b>Heart Valve Products</b>  Aortic valve products	○	Clinical trial		NMPA Application in 2023Q4E
		Design stage		Clinical Trial in PRC in 2024Q4E
		Type inspection		Clinical Trial in PRC in 2023Q4E
		Type inspection		Clinical Trial in PRC in 2023Q4E
		Type inspection		Clinical Trial in PRC in 2024Q4E
		Design stage		Clinical Trial in PRC in 2024Q4E
		Clinical trial		NMPA Application in 2024Q3E
	○	Clinical trial		NMPA Application in 2023Q4E
		Design stage		Clinical Trial in PRC in 2023Q4E
	○	Type inspection		Clinical Trial in PRC in 2023Q4E
<b>Mitral valve products</b>  Mitral valve products		Design stage		Clinical Trial in PRC in 2024Q4E
		Design stage		Clinical Trial in PRC in 2024Q4E
		Design stage		Clinical Trial in PRC in 2024Q4E
		Design stage		Clinical Trial in PRC in 2024Q4E

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	Product <sup>(1)</sup>	Pre-clinical	Clinical Trial <sup>(2)</sup>	Registration <sup>(3)</sup>	Next Milestone/ Actual Launch Time <sup>(4)</sup>
Tricuspid valve product	Transcatheter tricuspid valve repair system	Design stage			Clinical Trial in PRC in 2023Q4E
	Transcatheter tricuspid valve replacement system	Design stage			Clinical Trial in PRC in 2024Q3E
	Transcatheter pulmonary valve replacement system	Design stage			Clinical Trial in PRC in 2024Q4E
Pulmonary valve product	Balloon dilatation catheter for aortic valve	Clinical trial			NMPA Application in 2022Q4E
	Disposable introducing sheath	Registration in progress			NMPA Approval in 2023Q2E
Procedural accessories	Thrombus protection device	Type inspection			Clinical Trial in PRC in 2023Q4E
	Disposable delivery sheath	Registration preparation			NMPA Application in 2022Q4E
	Disposable atrial septal puncture system	Type inspection			NMPA Application in 2022Q4E
	Vascular closure device system	Design stage			Clinical Trial in PRC in 2023Q4E

• 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 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 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 2022; MemoLefort® LAA Occluder I in the European Union in the fourth quarter of 2022; interventional delivery system for biodegradable

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- 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 and TMVr-F 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.

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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 229 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 typically lead the research and development process of our products. 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.

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\* 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.

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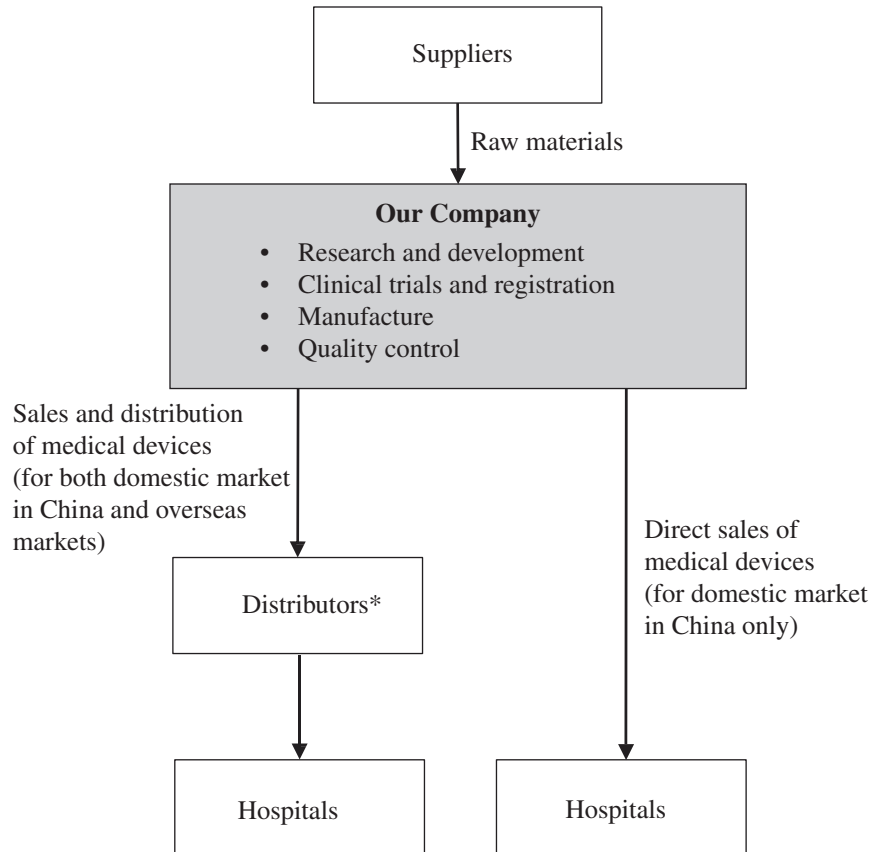
Manufacture. We have accumulated expertise and established practice protocols, which serves to ensure the precision, efficiency and safety of our manufacturing process. We conduct substantially all the key manufacturing procedures in-house except for sterilization. Our manufacturing capabilities have served to ensure the originality of our products while maintaining effective quality control and cost control. Our quality control team participates in every aspect of 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 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 also historically collaborated with the Retained Lepu Medical Group to sell our products overseas. 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 “Business — Sales, Distribution and Marketing — Sales Arrangements.” 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. 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 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.

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### OUR BUSINESS MODEL

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 “Business — Sales, Distribution and Marketing — Sales Arrangements” for details.

### COMPETITIVE STRENGTHS

We believe the following competitive strengths have contributed to our success and differentiated us from our competitors: (1) 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, (2) advanced biodegradable technology to capture significant market demand for sought-after therapeutic and safety benefits, (3) most comprehensive product portfolio of heart valve product candidates with early-mover advantages in mitral valve product candidates in China, (4) validated platform backed by strong research and development and manufacturing capabilities, (5) extensive distributor network and effective academic promotion and marketing capability, and (6) experienced and visionary senior management team with strong support from our shareholder.



## SUMMARY

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### GROWTH STRATEGIES

We intend to pursue the following strategies to further grow our business: (1) promote the development and clinical trial progress of our product candidates, (2) continue to enhance research and development capabilities, (3) expand brand exposure and market share in China, (4) expand our global footprint by increasing product development and commercialization and broadening overseas sales channels, (5) selectively pursue strategic investments and acquisitions, and (6) expand our production capabilities to support future growth.

### RISK FACTORS

Our business and the [REDACTED] involved certain risks, which are set out in the section headed “Risk Factors” in this document. Downward changes in the pricing of our products may have a material adverse effect on our business, results of operations and financial condition. Failure to achieve broad market acceptance could have a material adverse impact on our business and results of operations. The research, development and commercialization of our products are heavily regulated in all material aspects. We may be unable to obtain, maintain or renew the regulatory filings and registration certificates required to commercialize our products in a timely manner, or at all. We may not be able to obtain, maintain or renew all the permits, licenses and certificates required for our business and operations. We may not be able to comply with ongoing regulatory obligations which may result in withdrawal of approvals for our products. Potential impairment of intangible assets and/or goodwill could have a material adverse effect on our business, financial condition and results of operations. 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. We may fail to attract, retain and motivate our key executives and other key employees, such as qualified and highly skilled research and development, manufacturing and production, and sales and marketing personnel. In particular, our research and development team for heart valve product candidates was injected into our Group along with the injection of the interventional heart valve business of Lepu Medical, and we did not have such a team prior to the business injection. The viability of our heart valve business is highly relied upon the contribution of our heart valve research and development personnel, and the efforts by our sales and marketing team upon commercialization. As different [REDACTED] may have different interpretations and criteria when determining the significance of a risk, you should carefully read the “Risk Factors” section in its entirety before you decide to [REDACTED] in our Shares.

You should only rely on the information included in this document and the documents issued by our Company to make your [REDACTED] decision and should not rely on any other information, including any forward-looking information published by our Controlling Shareholders.

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## SUMMARY

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### CUSTOMERS AND SUPPLIERS

Our customers are distributors who on-sell our products to hospitals and, to a lesser extent, hospitals to which we sell our products directly. In 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate revenue generated from our five largest customers 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. The Retained Lepu Medical Group was one of our five largest customers in 2019, 2020 and 2021, through which we distributed our products overseas and in China. See “Business — Customers.” The Retained Lepu Medical Group consists of Lepu Medical, one of our Controlling Shareholders, and its subsidiaries, excluding our Group. During the Track Record Period, our suppliers mainly included suppliers of raw materials, components of medical devices 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 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. In 2019 and 2020, the Retained Lepu Medical Group was one of our five largest suppliers, from which we procured certain non-core components and parts. See “Business — Raw Materials and Suppliers — Suppliers.”

There were overlaps among our major customers and major suppliers during the Track Record Period. See “Business — Raw Materials and Suppliers — Overlapping of Customers and Suppliers.”

### MARKET OPPORTUNITIES

The global interventional medical device market targeting structural heart diseases has experienced rapid growth from US\$4.8 billion in 2017 to US\$9.3 billion in 2021 at a CAGR of 18.0%, in terms of sales revenue, and is expected to reach US\$19.8 billion in 2025 at a CAGR of 20.8% from 2021 to 2025, 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 CAGR of 51.0%, according to the same source. 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. CHD occluder products mainly include ASD occluder, VSD occluder, and PDA occluder. Cardioembolic stroke occluder products mainly consist of PFO occluder and LAA occluder. Heart valve products to treat valvular diseases mainly include aortic valve products and mitral valve products.

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## SUMMARY

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CHD. 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%, according to the same source. 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. According to the F&S Report, the incidence of CHD in China was 133,400 in 2021 and is expected to reach 144,800 in 2030; and the global incidence of CHD was 1.7 million in 2021 and is expected to remain relatively stable in 2030.

Cardioembolic stroke. 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%. According to the F&S Report, compared to traditional open surgeries which require large cuts in the skin, medical practitioners can perform interventional therapies targeting structural heart diseases with reduced or no incision. Accordingly, it is a market trend for cardioembolic stroke patients to choose PFO and LAA occluder products, which would bring reduced pain, scarring and complications, lowered risk of infection, and shortened hospital stays and recovery time. According to the same source, the prevalence of cardioembolic stroke in China was 4.5 million in 2021 and is expected to reach 5.7 million in 2030; and the global prevalence of cardioembolic stroke was 19.7 million in 2021 and is expected to reach 29.6 million in 2030.

Valvular 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%. According to the same source, 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%. According to the F&S Report, the prevalence of valvular disease increases with age, and for elderly patients with comorbidities, traditional surgical valvular disease treatment has high risk with slow post-operative recovery. Accordingly, it is a market trend for patients to choose valvular disease interventional devices, such as TAVR and TMVr systems, which provide alternative options with lower risk and more rapid recovery. According to the same source, the prevalence of valvular diseases in China was 37.7 million in 2021 and is expected to reach 42.7 million in 2030; and the global prevalence of valvular diseases was 220.9 million in 2021 and is expected to reach 246.7 million in 2030.

## SUMMARY

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### SALES AND MARKETING

#### Sales and Marketing Strategy

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 educating 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. See “Business — Sales, Distribution and Marketing — Sales and Marketing Strategy.”

## SUMMARY

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As of the Latest Practicable Date, our sales and marketing team had 60 members. 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. See “Business — Sales, Distribution and Marketing.”

### Pricing

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.

The public prices 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. We generally price our products and product candidates upon commercialization by taking into consideration a variety of factors, including pricing guidance set by the government authorities, bargaining power and preferences of hospitals, prices of similar products offered by our competitors, our operating costs and the continuous upgrades of existing products, some of which are beyond our control.

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. See “Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Reform Plan on High-Value Medical Consumables.” 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. However, we cannot assure you that any of our products or product candidates upon commercialization will not be included under the regime in the future. If the PRC government issues pricing guidance for our products and/or product candidates upon commercialization, it may negatively affect the price at which we can sell our products and therefore have a material adverse effect on our business, results

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## SUMMARY

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of operations and financial condition. See “Business — Sales, Distribution and Marketing — Pricing” and “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.”

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. See “Business — Sales, Distribution and Marketing — Pricing.”

### SUMMARY OF HISTORICAL FINANCIAL INFORMATION

The following tables present our summary of consolidated financial information as of and for the years ended December 31, 2019, 2020 and 2021 and the six months ended June 30, 2022. We have derived this summary from our audited financial information set forth in the Accountant’s Report in Appendix I to this document. The financial information of Ningbo Bingkun, a company that was fully disposed of by Shanghai Shape Memory Alloy to Lepu Medical in December 2020, had been excluded from our consolidated financial information during the Track Record Period, on the basis that (1) Ningbo Bingkun had been managed directly by Lepu Medical with its business conducted independently from Shanghai Shape Memory Alloy, (2) Ningbo Bingkun’s operations were not a part of the principal business of our Group, and (3) the exclusion of Ningbo Bingkun’s financial information from that of the Group ensures a meaningful presentation of the results of our Group during the Track Record Period. The consideration of RMB1,098 million at which Ningbo Bingkun was disposed of was determined based on the valuation of Ningbo Bingkun’s equity interests at the time of such disposal according to a valuation report prepared by an independent professional valuer engaged by Lepu Medical.

The summary financial data set forth below should be read together with our consolidated financial statements and the related notes set forth in the Accountant’s Report in Appendix I to this document, as well as the section headed “Financial Information.”

## SUMMARY

### Summary of Consolidated Statements of Profit or Loss

The following table sets forth selected line items of our consolidated statements of profit or loss for the periods indicated.

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
	<i>(RMB in thousands, except for percentages)</i>									
	<i>(Unaudited)</i>									
Revenue	116,451	100.0	148,247	100.0	222,583	100.0	110,968	100.0	124,804	100.0
Cost of sales	(13,619)	(11.7)	(15,134)	(10.2)	(25,038)	(11.2)	(11,884)	(10.7)	(15,322)	(12.3)
<b>Gross profit</b>	<b>102,832</b>	<b>88.3</b>	<b>133,113</b>	<b>89.8</b>	<b>197,545</b>	<b>88.8</b>	<b>99,084</b>	<b>89.3</b>	<b>109,482</b>	<b>87.7</b>
Distribution expenses	(21,760)	(18.7)	(23,146)	(15.6)	(43,072)	(19.4)	(17,383)	(15.7)	(16,626)	(13.3)
General and administrative expenses	(8,981)	(7.7)	(8,383)	(5.7)	(59,874)	(26.9)	(24,457)	(22.0)	(16,402)	(13.1)
Research and development expenses	(25,830)	(22.2)	(38,957)	(26.3)	(41,387)	(18.6)	(16,446)	(14.8)	(19,637)	(15.7)
Net (provision for)/reversal of impairment losses on financial assets	(1,788)	(1.5)	672	0.5	533	0.2	464	0.4	(4,169)	(3.3)
Other income and gains/(losses) – net	15,746	13.5	13,238	8.9	22,642	10.2	4,401	4.0	(18,289)	(14.7)
<b>Operating profit</b>	<b>60,219</b>	<b>51.7</b>	<b>76,537</b>	<b>51.6</b>	<b>76,387</b>	<b>34.3</b>	<b>45,663</b>	<b>41.1</b>	<b>34,359</b>	<b>27.5</b>
Finance income	151	0.1	149	0.1	1,185	0.5	221	0.2	1,645	1.3
Finance costs	(24)	(0.0)	(7)	(0.0)	(11,545)	(5.2)	(914)	(0.8)	(10,698)	(8.6)
Finance income/(costs) – net	127	0.1	142	0.1	(10,360)	(4.7)	(693)	(0.6)	(9,053)	(7.3)
<b>Profit before income tax</b>	<b>60,346</b>	<b>51.8</b>	<b>76,679</b>	<b>51.7</b>	<b>66,027</b>	<b>29.7</b>	<b>44,970</b>	<b>40.5</b>	<b>25,306</b>	<b>20.3</b>
Income tax expense	(8,437)	(7.2)	(7,907)	(5.3)	(7,330)	(3.3)	(3,203)	(2.9)	(1,051)	(0.8)
<b>Profit for the year/period</b>	<b>51,909</b>	<b>44.6</b>	<b>68,772</b>	<b>46.4</b>	<b>58,697</b>	<b>26.4</b>	<b>41,767</b>	<b>37.6</b>	<b>24,255</b>	<b>19.4</b>

Our revenue increased by 27.3% from RMB116.5 million in 2019 to RMB148.2 million in 2020, primarily because (1) revenue generated from CHD occluder products increased by 22.9% to RMB106.6 million in 2020, as a result of an increase in pricing per unit for our CHD

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occluder products sold overseas through the Retained Lepu Medical Group, partially offset by the slight decrease in sales volume of our CHD occluder products in 2020 as a result of the lower demand among hospitals for medical devices driven by a decrease of operations unrelated to COVID-19, as most of the hospitals devoted their resources primarily to dealing with COVID-19 in the first half of 2020; (2) revenue generated from occluder related procedural accessories increased by 10.7% to RMB32.0 million in 2020, as a result of an increase in pricing per unit for our occluder related procedural accessories, partially offset by the slight decrease in sales volume of our occluder related procedural accessories in 2020, generally consistent with the slight decrease in the sales volume of our CHD occluder products in 2020; and (3) revenue generated from PFO and LAA occluder products increased significantly from RMB0.5 million in 2019 to RMB9.5 million in 2020 as a result of the launch of our LAA occluder products in June 2020.

Our revenue further increased by 50.1% from RMB148.2 million in 2020 to RMB222.6 million in 2021, primarily because (1) revenue generated from CHD occluder products increased by 24.3% from RMB106.6 million in 2020 to RMB132.5 million in 2021, primarily due to the launch of our MemoCarna<sup>®</sup> ASD Occluder III in May 2020, which started to generate revenue in the second half of 2020; (2) revenue generated from occluder related procedural accessories increased by 29.9% from RMB32.0 million in 2020 to RMB41.6 million in 2021, primarily due to an increase in the sales volume of our occluder related procedural accessories as a result of the increased sales of our integrated intervention delivery system II along with the increased sales of our MemoCarna<sup>®</sup> ASD Occluder III launched in May 2020; and (3) revenue generated from PFO and LAA occluder products increased significantly from RMB9.5 million in 2020 to RMB48.5 million in 2021, primarily due to the launch of our LAA occluder product in June 2020, which started to generate revenue in the second half of 2020.

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, primarily because (1) revenue generated from CHD occluder products increased by 41.4% from RMB64.1 million in the six months ended June 30, 2021 to RMB90.7 million in the six months ended June 30, 2022, primarily attributable to the increased sales volume of our oxide-coated occluder products as they received broad market acceptance, including primarily MemoCarna<sup>®</sup> ASD Occluder III, MemoCarna<sup>®</sup> PDA Occluder III and MemoCarna<sup>®</sup> VSD Occluder III; and (2) revenue generated from occluder related procedural accessories increased by 47.2% from RMB18.4 million in the six months ended June 30, 2021 to RMB27.1 million in the six months ended June 30, 2022, primarily attributable to an increase in the sales volume of our occluder related procedural accessories, especially our integrated intervention delivery system II, along with the increased sales of our oxide-coated occluder products; partially offset by (3) a 75.4% decrease in revenue generated from PFO and LAA occluder products from RMB28.4 million in the six months ended June 30, 2021 to RMB7.0 million in the six months ended June 30, 2022, primarily due to 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 implantation of LAA occluder products and therefore the related sales.

Our cost of sales consisted primarily of raw materials and consumables costs for manufacturing, employee benefit expense for our manufacturing staff and amortization of intangible assets. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, our



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cost of sales was RMB13.6 million, RMB15.1 million, RMB25.0 million, RMB11.9 million and RMB15.3 million, respectively, representing 11.7%, 10.2%, 11.2%, 10.7% and 12.3% of our revenue for the same periods, respectively. Our cost of sales increased during the Track Record Period, generally in line with our business growth and the expansion of our production lines. The decrease in the percentage of revenue for cost of sales from 2019 to 2020 primarily reflected economies of scale as we continued to grow our business and the impact of the COVID-19 outbreak in 2020, which slowed down the increase of our cost of sales.

Our expenses consisted primarily of distribution expenses, general and administrative expenses, and research and development expenses. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, our distribution expenses were 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% of our revenue for the same periods, respectively. The decrease in the percentage of revenue for distribution expenses from 2019 to 2020 primarily reflected economies of scale as we continued to grow our business and a decrease in sales and traveling activities during the COVID-19 outbreak in 2020. The increase in 2021 as compared to 2020 was primarily due to (1) our increased sales and traveling activities mainly driven by the effective containment of the COVID-19 outbreak in China and the new products launched in mid-2020 and 2021, and (2) our enlarged sales and marketing team as we continued to launch new products. The decrease in the six months ended June 30, 2022 as compared to the same period in 2021 primarily reflected decreased sales and traveling activities as a result of the recent regional resurgence of COVID-19 in China. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, our general and administrative expenses were RMB9.0 million, RMB8.4 million, RMB59.9 million, RMB24.5 million and RMB16.4 million, respectively, representing 7.7%, 5.7%, 26.9%, 22.0% and 13.1% of our revenue for the same periods, respectively. The decrease in the percentage of revenue for general and administrative expenses from 2019 to 2020 primarily reflected economies of scale as we continued to grow our business and the decrease in employee benefit expense as a result of the decrease in corporate events and activities during the COVID-19 outbreak in 2020. The significant increase in the percentage of revenue for general and administrative expenses from 2020 to 2021 was primarily due to the one-off [REDACTED] expenses of RMB32.7 million in connection with the [REDACTED], and an increase of RMB13.3 million in employee benefit expense primarily in relation to share-based compensation to motivate our employees. The decrease in the six months ended June 30, 2022 as compared to the same period in 2021 was primarily due to a decrease of RMB12.1 million in [REDACTED] expenses, partially offset by an increase of RMB4.5 million in employee benefit expense primarily in relation to share-based compensation to motivate our employees. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, our research and development expenses were 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% of our revenue for the same periods, respectively. As a percentage of revenue, research and development expenses increased from 2019 to 2020, as we continued to invest in research and development activities at various stages, including product design, animal study, type inspection and pre-clinical trial. The decrease in the percentage of revenue in 2021 was primarily because we began to capitalize the research and development expenses associated with certain product candidates, including primarily a certain

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portion of the employee benefit expense and raw materials and consumables expenses relating to the development of MemoSorb<sup>®</sup> PFO Occluder II, TAVR system, balloon dilatation catheter for aortic valve, MemoSorb<sup>®</sup> ASD Occluder IV, TMVr-A system, TMVCRS and IASD I, as they had fulfilled the prerequisites for clinical trials in the second half of 2020 or 2021 and therefore met the criteria for capitalization. The increase in the percentage of revenue in the six months ended June 30, 2022 as compared to the same period in 2021 was primarily because we continued to invest in R&D activities and incurred share-based compensation to motivate our R&D personnel. See “Financial Information — Discussion of Major Balance Sheet Items — Intangible Assets” and Note 18 to the Accountant’s Report in Appendix I to this document.

Our net profit increased by 32.5% from RMB51.9 million in 2019 to RMB68.8 million in 2020, with the increase in net profit margin from 44.6% in 2019 to 46.4% in 2020, primarily attributable to the combined effect of (1) the increases in our revenue and gross profit margin and (2) the decrease in our distribution expenses and general and administrative expenses as a percentage of our revenue as discussed above.

Our net profit decreased by 14.6% from RMB68.8 million in 2020 to RMB58.7 million in 2021, with the decrease in net profit margin from 46.4% in 2020 to 26.4% in 2021, primarily attributable to the combined effect of the decrease in our gross profit margin and the increases in our general and administrative expenses and distribution expenses as a percentage of our revenue as discussed above.

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, with the decrease in net profit margin from 37.6% in the six months ended June 30, 2021 to 19.4% in the six months ended June 30, 2022, primarily due to the net foreign exchange losses of RMB26.9 million in the six months ended June 30, 2022 primarily in relation to the retranslation of redemption liabilities resulted from exchange rate fluctuations.

See “Financial Information — Period to Period Comparison of Results of Operations.”

## SUMMARY

### *Revenue by Major Product*

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
<i>(RMB in thousands, except for percentages)</i>										
<i>(Unaudited)</i>										
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 <sup>(1)</sup>	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	9.7	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 <sup>(2)</sup>	349	0.3	110	0.1	85	0.0	36	0.0	66	0.1
<b>Total</b>	<b>116,451</b>	<b>100.0</b>	<b>148,247</b>	<b>100.0</b>	<b>222,583</b>	<b>100.0</b>	<b>110,968</b>	<b>100.0</b>	<b>124,804</b>	<b>100.0</b>

(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.

## SUMMARY

### *Revenue by Sales Channel*

The following table sets forth a breakdown of our revenue by sales channel 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
	<i>(RMB in thousands, except for percentages)</i>									
	<i>(Unaudited)</i>									
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	9,603	8.2	10,988	7.4	13,576	6.1	5,733	5.2	3,785	3.0
<b>Total</b>	<b>116,451</b>	<b>100.0</b>	<b>148,247</b>	<b>100.0</b>	<b>222,583</b>	<b>100.0</b>	<b>110,968</b>	<b>100.0</b>	<b>124,804</b>	<b>100.0</b>

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, RMB11.5 million and RMB2.6 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, accounting for 8.8%, 20.9%, 7.2%, 10.3% and 2.1% of our total revenue in the same periods, respectively. The significant increase in 2020 was primarily due to the increase in pricing per unit for our products sold overseas through the Retained Lepu Medical Group. See “Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement.” 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 “Business — Sales, Distribution and Marketing — Sales Arrangements.” The decrease in the revenue generated from sales to the Retained Lepu Medical Group in 2021 and the six months ended June 30, 2022 was primarily as a result of the intensified impact of the COVID-19 outbreak in overseas markets, in addition to the termination of cooperation with the Retained Lepu Medical Group for overseas distribution.

## SUMMARY

### *Gross Profit and Gross Profit Margin by Product Type*

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	
	Gross profit Amount	margin	Gross profit Amount	margin	Gross profit Amount	margin	Gross profit Amount	margin	Gross profit Amount	margin
	<i>(RMB in thousands, except for percentages)</i>									
	<i>(Unaudited)</i>									
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 <sup>(1)</sup>	313	89.7	84	76.4	21	25.8	24	66.7	24	36.1
<b>Total</b>	<b>102,832</b>	<b>88.3</b>	<b>133,113</b>	<b>89.8</b>	<b>197,545</b>	<b>88.8</b>	<b>99,084</b>	<b>89.3</b>	<b>109,482</b>	<b>87.7</b>

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

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 from 2019 to 2021, 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 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.”

## SUMMARY

### *Sales Volume and Average Selling Price*

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 <sup>(1)</sup>	Sales volume	Average selling price <sup>(1)</sup>	Sales volume	Average selling price <sup>(1)</sup>	Sales volume	Average selling price <sup>(1)</sup>	Sales volume	Average selling price <sup>(1)</sup>
		<i>(RMB)</i>		<i>(RMB)</i>		<i>(RMB)</i>		<i>(RMB)</i>		<i>(RMB)</i>
							<i>(Unaudited)</i>			
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<sup>®</sup> 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<sup>®</sup> 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.” 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<sup>®</sup> ASD Occluder III and the launch of our MemoCarna<sup>®</sup> PDA Occluder III and MemoCarna<sup>®</sup> 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.

## SUMMARY

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.” 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 in the market, according to the F&S Report.

### Summary of Consolidated Balance Sheets

The following table sets forth a summary of our consolidated balance sheet as of the dates indicated.

	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
<b>NON-CURRENT ASSETS</b>				
Property, plant and equipment	68,459	67,196	76,261	82,446
Right-of-use assets	454	216	6,763	5,841
Investment properties	42,673	40,623	39,553	39,102
Goodwill	48,282	48,282	48,282	48,282
Intangible assets	54,259	65,959	136,557	161,649
Financial assets at fair value through other comprehensive income	849	–	–	–
Deferred income tax assets	7,009	3,472	8,571	16,077
Prepayments	632	1,000	11,187	12,304
Total non-current assets	<u>222,617</u>	<u>226,748</u>	<u>327,174</u>	<u>365,701</u>

## SUMMARY

	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
<b>CURRENT ASSETS</b>				
Inventories	11,052	23,319	33,402	40,269
Trade receivables	45,331	38,317	23,869	32,883
Prepayments and other receivables	13,442	20,182	21,765	51,807
Prepaid income tax	–	5,152	–	–
Financial assets at fair value through profit or loss	–	–	–	1,004
Bank deposit with initial term of over three months	–	–	–	70,000
Cash and cash equivalents	16,119	18,792	713,480	664,534
Total current assets	<u>85,944</u>	<u>105,762</u>	<u>792,516</u>	<u>860,497</u>
<b>TOTAL ASSETS</b>	<u><u>308,561</u></u>	<u><u>332,510</u></u>	<u><u>1,119,690</u></u>	<u><u>1,226,198</u></u>
<b>NON-CURRENT LIABILITIES</b>				
Lease liabilities	–	–	4,044	4,294
Deferred income	2,148	1,315	482	152
Total non-current liabilities	<u>2,148</u>	<u>1,315</u>	<u>4,526</u>	<u>4,446</u>
<b>CURRENT LIABILITIES</b>				
Redemption liabilities	–	–	679,986	720,861
Trade and other payables	57,286	62,137	26,300	54,427
Contract liabilities	12,206	15,343	14,783	14,426
Current income tax liabilities	4,683	–	6,761	12,797
Lease liabilities	369	116	2,143	1,994
Total current liabilities	<u>74,544</u>	<u>77,596</u>	<u>729,973</u>	<u>804,505</u>
<b>TOTAL LIABILITIES</b>	<u>76,692</u>	<u>78,911</u>	<u>734,499</u>	<u>808,951</u>
<b>NET CURRENT ASSETS</b>	<u>11,400</u>	<u>28,166</u>	<u>62,543</u>	<u>55,992</u>
<b>EQUITY</b>				
Equity attributable to owners of the Company				
Share capital	–	–	324,295	324,295
Treasury stock	–	–	(671,507)	(671,507)
Other reserves	(98,745)	(146,766)	593,341	601,142
Retained earnings	330,614	400,365	139,062	163,317
<b>TOTAL EQUITY</b>	<u>231,869</u>	<u>253,599</u>	<u>385,191</u>	<u>417,247</u>
<b>TOTAL EQUITY AND LIABILITIES</b>	<u><u>308,561</u></u>	<u><u>332,510</u></u>	<u><u>1,119,690</u></u>	<u><u>1,226,198</u></u>



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## SUMMARY

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Our net current assets increased from RMB11.4 million as of December 31, 2019 to RMB28.2 million as of December 31, 2020, primarily due to the increase in inventories of RMB12.3 million, generally consistent with our business growth. Our net current assets increased from RMB28.2 million as of December 31, 2020 to RMB62.5 million as of December 31, 2021, primarily due to (1) an increase in cash and cash equivalents of RMB694.7 million, as a result of the capital contribution by [REDACTED] and cash received for the disposal of Ningbo Bingkun, partially offset by dividend paid to Lepu Medical, and (2) a decrease in trade and other payables of RMB35.8 million as a result of our enhanced efforts in settling related party amounts, partially offset by redemption liabilities of RMB680.0 million in connection with financial instruments with preferred rights held by [REDACTED], which were reclassified from non-current liabilities to current liabilities as they were due and payable within one year as of December 31, 2021 pursuant to the [REDACTED] Shareholders Agreement. The preferred rights granted to the [REDACTED] will lapse upon the completion of the [REDACTED] and, accordingly, the redemption liabilities will be reclassified as equity. See “History, Reorganization and Corporate Structure — Our Corporate Development” and “Financial Information — Liquidity and Capital Resources — Current Assets and Current Liabilities.” Our net current assets decreased to RMB56.0 million as of June 30, 2022, primarily due to an increase in redemption liabilities of RMB40.9 million as a result of interest expense on redemption liabilities and foreign exchange losses in relation to the retranslation of redemption liabilities resulted from exchange rate fluctuations.

We had net assets of RMB231.9 million, RMB253.6 million, RMB385.2 million and RMB417.2 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. Our net assets increased from RMB231.9 million as of December 31, 2019 to RMB253.6 million as of December 31, 2020, primarily due to an increase in retained earnings of RMB69.8 million, along with our net profit recognized in 2020, partially offset by a decrease in other reserves of RMB48.0 million, primarily as a result of the recognition of the deemed distribution to Lepu Medical representing our cash payments in connection with Shanghai Shape Memory Alloy’s investment in Ningbo Bingkun and the deemed contribution from Lepu Medical representing our cash receipts in connection with the disposal of Ningbo Bingkun by Shanghai Shape Memory Alloy. Our net assets increased from RMB253.6 million as of December 31, 2020 to RMB385.2 million as of December 31, 2021, primarily due to (1) an increase in other reserves of RMB740.1 million, representing the share premium and capital reserve as arisen from our share issuance in 2021 and the deemed contribution as discussed above, and (2) an increase in share capital of RMB324.3 million, representing the fully paid-up registered capital in connection with our share issuance in 2021, partially offset by (1) a decrease of treasury stock of RMB671.5 million, primarily as a result of the recognition of redemption liabilities in connection with financial instruments with preferred rights held by the [REDACTED], and (2) a decrease in retained earnings of RMB261.3 million, primarily as a result of our net profit earned in 2021 and our dividend paid to Lepu Medical in January 2021. Our net assets increased from RMB385.2 million as of December 31, 2021 to RMB417.2 million as of June 30, 2022, primarily due to (1) an increase in retained earnings of RMB24.3 million, primarily as a result of our net profit earned in the six months ended June 30, 2022, and (2) an increase in other reserves of RMB7.8 million, primarily as a result of capital reserve in relation to the recognition of share-based compensation. See Note 26, Note 27 and Note 30 to the Accountant’s Report in Appendix I to this document.

## SUMMARY

### Summary of Consolidated Statements of Cash Flows

The following table sets forth a summary of our consolidated statements of cash flows for the periods indicated.

	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	<i>(RMB in thousands)</i>				
	<i>(Unaudited)</i>				
Net cash flows generated					
from operating activities	54,475	59,097	105,278	61,753	52,665
Net cash flows used in					
investing activities	(13,074)	(8,463)	(85,171)	(31,951)	(102,765)
Net cash flows (used in)/					
generated from financing					
activities	(41,864)	(47,961)	672,226	673,275	(2,228)
Net increase/(decrease) in					
cash and cash equivalents	(463)	2,673	692,333	703,077	(52,328)
Cash and cash equivalents at					
beginning of the					
year/period	16,582	16,119	18,792	18,792	713,480
Exchange gains on cash and					
cash equivalents	–	–	2,355	2,912	3,382
Cash and cash equivalents at					
end of the year/period	<u>16,119</u>	<u>18,792</u>	<u>713,480</u>	<u>724,781</u>	<u>664,534</u>

Our primary uses of cash are to fund the daily operations of our business. During the Track Record Period, we financed our capital expenditures and working capital requirements principally with cash generated from our operations and financing activities. Our cash and cash equivalents increased significantly from RMB18.8 million as of December 31, 2020 to RMB713.5 million as of December 31, 2021, primarily due to net cash generated from financing activities of RMB672.2 million in 2021. Net cash generated from financing activities was RMB672.2 million in 2021, primarily due to (1) capital contributions by the [REDACTED] of RMB609.7 million, (2) a deemed contribution of RMB446.1 million primarily in relation to the disposal of Ningbo Bingkun, and (3) capital contribution from Ningbo Jiacheng and Ningbo Jiadu of RMB51.3 million, partially offset by (1) dividends paid to Lepu Medical of RMB320.0 million, (2) a deemed distribution of RMB72.2 million in connection with the injection of interventional heart valve business, and (3) settlements to related parties of RMB45.9 million. See “Financial Information — Liquidity and Capital Resources — Cash Flows.” Our cash and cash equivalents decreased to RMB664.5 million as of June 30, 2022, primarily due to placement of bank deposit with initial term of over three months of RMB70.0 million.

## SUMMARY

### Key Financial Ratios

	As of/for the year ended December 31,			As of/for the six months ended
	2019	2020	2021	June 30, 2022
<b>Profitability ratios</b>				
Gross profit margin	88.3%	89.8%	88.8%	87.7%
Net profit margin	44.6%	46.4%	26.4%	19.4%
Return on equity	22.9%	28.3%	18.4%	12.1% <sup>(1)</sup>
Return on total assets	17.8%	21.5%	8.1%	4.1% <sup>(1)</sup>
<b>Liquidity ratios</b>				
Current ratio	1.2	1.4	1.1	1.1
Quick ratio	1.0	1.1	1.0	1.0

(1) These figures have been provided on an annualized basis solely for the purpose of being comparable to prior years, and may not be indicative of actual results.

Our return on equity increased from 22.9% for 2019 to 28.3% for 2020, primarily due to the increase in our net profit. Our return on equity decreased from 28.3% for 2020 to 18.4% for 2021, primarily due to an increase in our equity, including primarily the increase in share capital along with the business and capital injection of Shanghai Shape Memory Alloy from Lepu Medical and the increase in other reserves along with the share premium arisen from the share issuance to the [REDACTED]. Our return on total assets increased from 17.8% for 2019 to 21.5% for 2020, primarily due to the increase in our net profit. Our return on total assets decreased from 21.5% for 2020 to 8.1% for 2021, primarily due to an increase in our cash and cash equivalents as a result of the capital contribution by [REDACTED] and cash received for the disposal of Ningbo Bingkun, partially offset by the dividend paid to Lepu Medical. The decreases of our return on equity and return on total assets in the six months ended June 30, 2022 were primarily due to the decrease in net profit, which in turn was mainly attributable to net foreign exchange losses primarily in relation to the retranslation of redemption liabilities resulted from exchange rate fluctuations. Our current ratio and quick ratio remained relatively stable during the Track Record Period.

See “Financial Information — Key Financial Ratios.”

## SUMMARY

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[REDACTED]

### OUR CONTROLLING SHAREHOLDERS

As at the Latest Practicable Date, Lepu Medical, together with its wholly-owned subsidiary Target Medical, held 86.34% equity interest in our Company, with Lepu Medical and Target Medical directly holding 85.48% and 0.86% equity interests in our Company, respectively. Immediately following the completion of the [REDACTED] and [REDACTED] of [REDACTED], Lepu Medical and Target Medical will directly hold approximately [REDACTED]% and [REDACTED]% equity interest in our Company, respectively, assuming the [REDACTED] is not exercised. Lepu Medical, Dr. Pu and Target Medical are considered as a group of Controlling Shareholders of our Company. Our Controlling Shareholders confirmed that, as of the Latest Practicable Date, save as disclosed in this document, they do not have any interest in a business, apart from the business of our Group, which competes or is likely to compete, directly or indirectly, with our business, and requires disclosure under Rule 8.10 of the Listing Rules. Furthermore, Lepu Medical and Dr. Pu entered into the Non-competition Agreement with our Company on January 27, 2022 in favor of us. See “Relationship with Our Controlling Shareholders.”

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## SUMMARY

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We expect that there will be certain continuing connected transactions between the Group and our Controlling Shareholders and their respective associates. See “Waivers from Strict Compliance with the Listing Rules — Continuing Connected Transactions” and “Connected Transactions.”

### **Letter of Queries from Shenzhen Stock Exchange to Lepu Medical**

On May 31, 2021, Lepu Medical received a letter from the Shenzhen Stock Exchange regarding Lepu Medical’s annual report of 2020 (the “Queries”). In particular, the Shenzhen Stock Exchange requested for the procedures and methods adopted for the goodwill impairment tests and the methods in determining the recoverable amounts in respect of a number of companies acquired by Lepu Medical, including Shanghai Shape Memory Alloy. In correspondence, Lepu Medical published an announcement (the “Announcement”) on June 6, 2021, which included the forecasted revenue, expenses and profit margin of Shanghai Shape Memory Alloy for the six years ending December 31, 2026 (the “Relevant Financial Information”).

During the preparation of the Announcement, Lepu Medical’s auditors considered the same set of cash flow projections that was adopted by our management in performing the goodwill impairment test for Shanghai Shape Memory Alloy for the three financial years ended December 31, 2020. Save for the provision of the historical financial information of Shanghai Shape Memory Alloy, none of the management of Shanghai Shape Memory Alloy was involved in the preparation of the responses to the Queries or the Relevant Financial Information or the review or publication of the Announcement, and hence none of them had any knowledge of the assumptions, bases, methods or qualifications adopted in the preparation of the Relevant Financial Information. We recorded the same amount of goodwill relating to the acquisition of Shanghai Shape Memory Alloy in our historical financial information as set out in the Accountant’s Report contained in Appendix I to this document as Lepu Medical did for the preparation of the Relevant Financial Information. Details of the key assumptions and parameters used for calculating the recoverable amount of the cash generating unit (the “CGU”) of Shanghai Shape Memory Alloy for the purpose of impairment review for goodwill are disclosed in Note 17 of the Accountant’s Report which was issued by the Reporting Accountant in accordance with Hong Kong Standard on Investment Circular Reporting Engagement 200 “Accountants’ Report on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants. The Reporting Accountants’ opinion on the historical financial information of the Group as a whole for the Track Record Period is set out on page I-2 of Appendix I to this document. The Relevant Financial Information may involve risks and uncertainties, which could significantly affect anticipated results in the future and the Group’s results may eventually differ from the Relevant Financial Information. See “Risk Factors — Risks Relating to Our Operations — Our Controlling Shareholders may have substantial influence over our Company and their interests may not be aligned with the interests of our other Shareholders” and “Risk Factors — Risks Relating to the [REDACTED] — You should only rely on the information included in this document and the documents issued by our Company to make your [REDACTED] decision and should not rely on any particular statements in other published announcements, news reports and/or research analyst reports relating to our Controlling Shareholder, our Group and the [REDACTED].”

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## SUMMARY

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It is a regular practice of the Shenzhen Stock Exchange to issue post-vetting inquiries on annual reports of issuers listed on the Shenzhen Stock Exchange. According to Lepu Medical, it has not received any follow-up queries in this regard from the Shenzhen Stock Exchange as of the Latest Practicable Date. Based on its past experience in communication with the Shenzhen Stock Exchange, Lepu Medical believes that such absence of follow-up queries demonstrates that the Queries have been addressed to the satisfaction of the Shenzhen Stock Exchange while no written confirmation pertaining to such clearance would normally be issued by the Shenzhen Stock Exchange, and our Directors concur with such view.

### SPIN-OFF

Lepu Medical, our Controlling Shareholder, is a company listed on the Shenzhen Stock Exchange (stock code: 300003). The [REDACTED] of our Company constitutes a spin-off from a domestic listed company as defined under the Spin-off Circular and is subject to the conditions set out in the Spin-off Circular and the approval from the CSRC. The [REDACTED] of our Company was approved by Lepu Medical’s shareholders at an annual general meeting on May 26, 2021 and by the CSRC on November 11, 2021. There is no other approval from Lepu Medical’s shareholders or regulatory authorities in the PRC required of Lepu Medical in connection with our [REDACTED]. See “Relationship with Our Controlling Shareholders.”

### [REDACTED]

We completed the [REDACTED] by way of increase and subscription of registered capital in June 2021. Our [REDACTED] who remain as existing Shareholders of our Company as of the Latest Practicable Date will be restricted from trading for 12 months from the [REDACTED]. For further details regarding the identities of the [REDACTED], key terms of these [REDACTED] and the [REDACTED] rights, see “History, Reorganization and Corporate Structure — [REDACTED].”

### DIVIDEND

During the Track Record Period and up to the Latest Practicable Date, we paid dividend of RMB320.0 million to Lepu Medical in January 2021. After completion of the [REDACTED], our Shareholders will be entitled to receive dividends we declare. Our Company currently does not have a dividend policy. Any amount of dividends we pay will be at the discretion of our Directors and will depend on our future operations and earnings, our development pipeline, capital requirements and surplus, general financial conditions, contractual restrictions and other factors that our Directors consider relevant. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the relevant laws. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. Dividends declared in the past may not be indicative of our future dividend policy. Our Directors have the absolute discretion to recommend any dividend. We cannot assure you that our Company will be able to declare dividends of any amount each year or in any year. See “Financial Information — Dividend Policy.”

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## SUMMARY

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### [REDACTED] EXPENSES

We expect to incur a total of approximately RMB[REDACTED] million of [REDACTED] expenses in connection with the [REDACTED], representing approximately [REDACTED]% of the gross [REDACTED] from the [REDACTED] (assuming an [REDACTED] of HK\$[REDACTED], being the mid-point of the indicative [REDACTED] between HK\$[REDACTED] and HK\$[REDACTED], and assuming that the [REDACTED] is not exercised), comprising [REDACTED] related expenses of approximately RMB[REDACTED] million and non-[REDACTED] related expenses of approximately RMB[REDACTED] million. Among the estimated [REDACTED] expenses, approximately RMB[REDACTED] million is directly attributable to the [REDACTED] and is expected to be capitalized and deducted from our Group’s equity upon the completion of the [REDACTED], and approximately RMB[REDACTED] million has been or is expected to be reflected in our consolidated statements of profit or loss, of which approximately RMB[REDACTED] million of the [REDACTED] expenses in relation to the service already performed has been reflected in our consolidated statements of profit or loss of 2021 and the six months ended June 30, 2022, and the remaining amount of approximately RMB[REDACTED] million is expected to be reflected in our consolidated statements of profit or loss of the six months ended December 31, 2022. The [REDACTED] expenses above are our best estimate as of the Latest Practicable Date and for reference only. The actual amount may differ from this estimate.

### [REDACTED]

We estimate that we will receive [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED] million, after deducting the estimated [REDACTED] and other fees and expenses payable by us in connection with the [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative range of the [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per H Share, and that the [REDACTED] is not exercised. We intend to use the [REDACTED] from the [REDACTED] for the following purposes and in the amounts set out below, subject to changes in light of our evolving business needs and changing market conditions:

- approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, will be used to fund our research and development activities within the next five years;
- approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, will be used for our sales and marketing activities within the next five years;
- approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, will be used to expand our production capacity and strengthen our manufacturing capabilities within the next five years;

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## SUMMARY

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- approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, will be used to fund potential strategic investments and acquisitions within the next five years; and
- approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, will be used for our working capital and general corporate purposes.

For further details, see “Future Plans and [REDACTED] — [REDACTED].”

### COVID-19 OUTBREAK AND EFFECTS ON OUR BUSINESS

A novel strain of coronavirus, later named COVID-19, has severely impacted China and many other countries and regions. The PRC government has had imposed quarantine measures across the country since late January 2020. Local governments have also imposed temporary restrictions or bans on traveling to contain the spread of the COVID-19. On January 30, 2020, the world health organization declared the outbreak of COVID-19 a public health emergency of international concern (PHEIC). On March 11, 2020, amid the escalating situation, the world health organization further characterized COVID-19 as a pandemic. With measures taken by the PRC government, there has been a significant decrease in the number of existing confirmed COVID-19 cases in China since mid-February 2020. The Chinese government gradually lifted domestic travel restrictions and other quarantine measures, and economic activities began to recover and return to normal nationwide during the second quarter of 2020. The resurgence of COVID-19 across various cities in China, including the recent outbreak in Shanghai in the first half of 2022, did not have any material adverse effect on us as a result of the effective government measures to contain the spread and our contingency plans to minimize its negative impact. Our Directors have carried out a holistic review of the impact of the COVID-19 on our operations and confirmed that as of the Latest Practicable Date, COVID-19 did not bring permanent interruption to our operations based on the following grounds:

#### Impact on Our Business

Since the outbreak of COVID-19, a series of precautionary and control measures have been implemented worldwide to contain the virus. Government efforts to contain the spread of COVID-19, including city lockdowns or “stay-at-home” orders, widespread business closures, restrictions on travel and emergency quarantines, have caused significant and unprecedented disruptions to the global economy and normal business operations across sectors and countries. In addition, these mandated quarantine measures, such as workplace closures and restrictions on traveling, had adversely affected the demand and supply of medical devices during the COVID-19 outbreak. As a result, the medical device industries in China and overseas have been negatively impacted, which in turn adversely affected our business, results of operations and financial condition. For example, we experienced a slight decrease in sales volume of our products in 2020 as compared to that in 2019, primarily due to (1) the reduced demand among hospitals in China for medical devices driven by the decrease of operations unrelated to COVID-19, as most of the hospitals devoted their resources primarily to dealing with COVID-19 in the first half of 2020; and (2) the reduced scale of international trade amid COVID-19. Specifically, we have experienced certain negative impact on the distribution of our products in overseas markets, primarily reflected in (1) the reduced demand among hospitals in certain overseas markets, primarily including Brazil and India, where hospitals



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devoted their resources primarily to dealing with COVID-19, and (2) the delay in logistics and the increase in logistics expenses resulting from less frequent flights amid the temporary government-mandated travel restrictions or bans to contain the spread of the COVID-19. In addition, we experienced a decrease in revenue generated from products sold overseas in 2021 as a result of the intensified impact of the COVID-19 outbreak in overseas markets. We also incurred increased distribution expenses in 2021 as compared to those in 2020, primarily due to our increased sales activities driven by the effective containment of the COVID-19 outbreak in China. In the six months ended June 30, 2022, we experienced a decrease in revenue generated from sales of 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 implantation of LAA occluder products and therefore the related sales. In addition, our trade receivables increased from December 31, 2021 to June 30, 2022, primarily due to (1) the extended payment cycle caused by the regional resurgence of COVID-19, (2) the relatively loosened credit policy to some of our trusted customers to boost our recovery following the containment of COVID-19, and (3) the increased scale of our business.

We expect that our business will not be severely disrupted in the long run for the following reasons. Firstly, COVID-19 has been largely contained in China, where we conduct most of our business. The Chinese government gradually lifted domestic travel restrictions and other quarantine measures, and economic activities began to recover and return to normal nationwide. The resurgence of COVID-19 across various cities in China, including the recent outbreak in Shanghai in the first half of 2022, did not have any material adverse effect on us. While the production and shipment of our products and the procurement of raw materials experienced temporary interruptions since April 2022 as a result of government measures to contain the recent outbreak in Shanghai, we managed to get the government approval for operation resumption by the end of April 2022 in accordance with relevant regulations and began to recover and return to normal business operations thereafter. In the six months ended June 30, 2022, our overall revenue continued its steady growth despite the outbreak. Second, the demand of medical devices would bounce back in the long term because the COVID-19 outbreak merely delayed operations in a short term rather than eliminate patients’ needs for operations and medical devices.

### **Impact on Our Operations**

Our offices have resumed operation since February 2020 in accordance with the local government policies. During the recent COVID-19 outbreak in certain regions of China, especially in Shanghai where our headquarters and manufacturing facilities are located, we have implemented flexible working hour arrangements such as rotational shifts in response to local government’s temporary quarantine and lockdown measures. Moreover, the production and shipment of our products experienced temporary interruptions since April 2022 as a result of government measures to contain the recent outbreak in Shanghai. We managed to get the government approval for operation resumption in Shanghai by the end of April 2022 and began to recover and return to normal business operations thereafter. As of the Latest Practicable Date, we had not experienced any material interruption to our business operations.

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We have been granted property tax and land use tax exemptions of approximately RMB0.4 million from January 2022 through June 2022, according to relevant government relief policies during the regional resurgence of COVID-19 in Shanghai in the first half of 2022.

### **Impact on Our Employees**

In response to COVID-19, we have implemented an interim policy requiring our management members and employees to declare their recent travel history. Returnees from recent travels are required to quarantine themselves at home and should only return to office upon receiving further notice from us. As of the Latest Practicable Date, we were not aware of any confirmed case of COVID-19 among our staff.

We did not experience any material employee loss due to the COVID-19 outbreak as of the Latest Practicable Date. We have been permitted to reduce the employer’s contribution of social insurance premiums for our employees by approximately RMB1.5 million from February 2020 through December 2020, according to relevant government relief policies during the COVID-19 outbreak.

### **Impact on Our Supply Chain**

Our suppliers include primarily suppliers of raw materials, components of medical devices and machinery and equipment, and institutions that provided testing or clinical trial related services. 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. Specifically, the procurement of raw materials experienced temporary interruptions in April 2022 as a result of government measures to contain the recent outbreak in Shanghai. We managed to get the government approval for operation resumption in Shanghai by the end of April 2022 and began to recover and return to normal business operations thereafter. The procurement of raw materials resumed normal in May 2022 through our online communications with suppliers and engagement of new suppliers. In 2019, 2020, 2021 and the six months ended June 30, 2022, our raw materials turnover days were 286 days, 582 days, 442 days and 421 days, respectively. The increase in 2020 as compared to that of 2019 was primarily because 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 Precautionary Measures**

We have adopted several precautionary measures to maintain a hygienic working environment, including purchasing disinfection products, distributing masks and infrared thermometer.

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However, we cannot be entirely certain as to when the COVID-19 outbreak will be fully contained and its impact will be eradicated. Any prolonged outbreak may adversely affect our business and financial performance. We are closely monitoring the development of the COVID-19 outbreak and continuously evaluating any potential impact on our business, results of operations and financial condition. See “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Operations — Our business and operations have been and may continue to be materially and adversely affected by the COVID-19 outbreak.”

### RECENT DEVELOPMENT AND NO MATERIAL ADVERSE CHANGE

One of our PRC operating subsidiaries, Shanghai Shape Memory Alloy, was qualified as a High and New Technology Enterprise (高新技術企業) in 2017 and subsequently extended its High and New Technology Enterprise certificate in 2020 for a period of three years to 2023. As a High and New Technology Enterprise, Shanghai Shape Memory Alloy enjoys a lower enterprise income tax (“EIT”) rate of 15% instead of the standard EIT rate of 25% in China. If the preferential tax treatments are discontinued or not verified by the local tax authorities, and the affected entity fails to obtain preferential tax treatments based on other qualifications, it will become subject to the standard PRC enterprise income tax rate of 25%, which would bring a negative impact on our financial condition. For the risks relating to preferential tax treatments, see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Operations — The discontinuation of any of the preferential tax treatments currently available to us could reduce our profitability.”

Our fully biodegradable MemoSorb® VSD Occluder IV was approved by the NMPA in February 2022 and obtained the relevant medical device production permit in June 2022. We have started to generate revenue from the sales of MemoSorb® VSD Occluder IV since the second half of 2022. In particular, we have collaboratively consummated the first implantation of our fully biodegradable VSD occluder upon commercialization in July 2022, which marked its successful launch.

We currently expect an increase in our expenses and a corresponding decrease in our net profit (after excluding [REDACTED]) for 2022, primarily because (1) we have recorded foreign exchange losses of RMB26.9 million primarily in relation to the retranslation of redemption liabilities resulted from exchange rate fluctuations for the six months ended June 30, 2022, and expect to continue to face uncertainty with respect to exchange rate fluctuations for the second half of 2022, and (2) we have recorded finance costs of RMB10.7 million primarily representing interest expense on redemption liabilities for the six months ended June 30, 2022, and expect to continue to incur finance costs in this regard for the second half of 2022. See “Risk Factors — Risks Relating to Doing Business in China — Fluctuations in exchange rates could adversely affect our results of operations and the value of your [REDACTED].”

Our Directors confirm that, up to the date of this document, save as disclosed above, there has been no material adverse change in our financial or trading position since June 30, 2022 (being the date on which the latest audited consolidated financial information of our Group was prepared) and there is no event since June 30, 2022 which would materially affect the information shown in our consolidated financial statements included in the Accountant’s Report in Appendix I to this document.