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Post Hearing Information Pack of

LEPU SCIENTECH MEDICAL TECHNOLOGY (SHANGHAI) CO., LTD.*

樂普心泰醫療科技(上海)股份有限公司

(a joint stock company incorporated in the People's Republic of China with limited liability)

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LEPU SCIENTECH MEDICAL TECHNOLOGY (SHANGHAI) CO., LTD.*

樂普心泰醫療科技(上海)股份有限公司

(a joint stock company incorporated in the People's Republic of China with limited liability)

[REDACTED]

Number of [REDACTED] : [REDACTED] H Shares (subject to the under the [REDACTED] [REDACTED])
Number of Hong Kong [REDACTED] : [REDACTED] H Shares (subject to [REDACTED])
Number of [REDACTED] : [REDACTED] H Shares (subject to [REDACTED] and the [REDACTED])
[REDACTED] : HK\$[REDACTED] per H Share (payable in full in Hong Kong dollars on application plus [REDACTED] of 1%, SFC transaction levy of 0.0027%, the Stock Exchange trading fee of 0.005% and AFRC transaction levy of 0.00015% and subject to refund)
Nominal value : RMB1.00 per H Share
[REDACTED] : [REDACTED]

Sole Sponsor and [REDACTED]



[REDACTED]

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We are incorporated, and most of our businesses are located, in the PRC. Potential [REDACTED] should be aware of the differences in legal, economic and financial systems between the PRC and Hong Kong and that there are different risk factors relating to [REDACTED] in PRC-incorporated companies. Potential [REDACTED] should also be aware that the regulatory framework in the PRC is different from the regulatory framework in Hong Kong and should take into consideration the different market nature of our H Shares. Such differences and risk factors are set out in “Risk Factors,” “Regulatory Overview,” “Appendix V — Summary of Principal PRC and Hong Kong Legal and Regulatory Provisions” and “Appendix IV — Summary of the Articles of Association of the Company” in this document. Prior to making an [REDACTED] decision, potential [REDACTED] should consider carefully all of the information set out in this document, including the risk factors set out in “Risk Factors.”

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IMPORTANT

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

CONTENTS

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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 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 232 registered patents and 51 pending patent applications in China as well as 14 patents under application in the United States and the European Union.

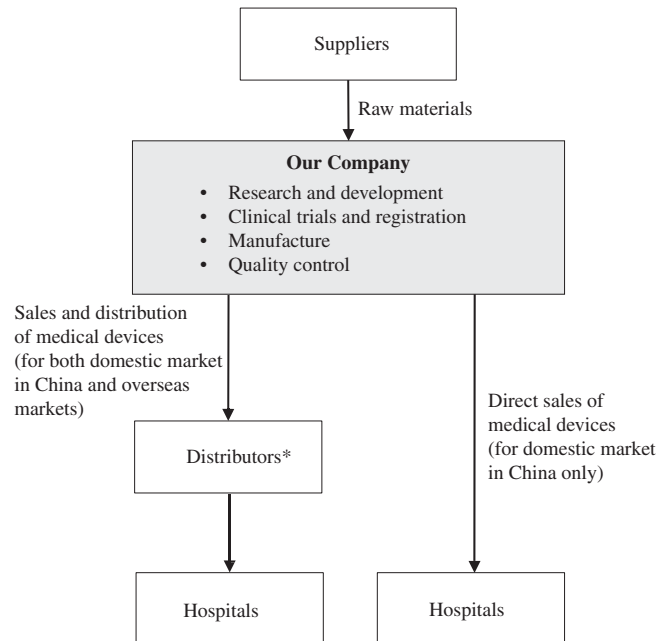
* In China, domestic CHD manufacturers dominated the market with a combined market share of approximately 91.5% in 2021, according to the F&S Report.

** 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.

SUMMARY

OUR BUSINESS MODEL

We have established a 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.

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.





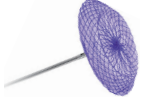

SUMMARY

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. We have 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.





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 and VSD occluder products that had relatively major revenue contributions during the Track Record Period and product candidates.

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

SUMMARY



The following graphs illustrate the product structure of our PDA occluder products that had relatively major revenue contributions during the Track Record Period.

Product Name	Product Structure	
MemoPart [®] PDA Occluder I (Double-rivet)	 Cylinder-shaped	 Cone-shaped
MemoCarna [®] PDA Occluder III (Oxide Coating)	 Cylinder-shaped	 Cone-shaped

See “Business — Occluder Products — CHD Occluder Products” for full details of our CHD occluder products.

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. 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 clinical trial preparation in China.

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.

Product Name	Product Structure
MemoPart [®] PFO Occluder I	
MemoSorb [®] PFO Occluder II (Biodegradable) (product candidate)	

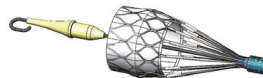
SUMMARY

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® LAA Occluder I together with the delivery system.



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 was in the clinical trial stage as of the Latest Practicable Date. 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 trial stage 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.

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

SUMMARY

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

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

SUMMARY

	Product ⁽¹⁾	Pre-clinical	Clinical Trial ⁽²⁾	Registration ⁽³⁾	Next Milestone/ Actual Launch Time ⁽⁴⁾
Left atrial appendage occluder	MemoLefort® LAA Closure Occluder I	●	Launched	Launched	NMPA Approval in 2020Q2
	LAA Closure Occluder II (Biodegradable)	○	Clinical trial preparation		Clinical Trial in PRC in 2022Q4E
Interatrial shunt device	Interatrial shunt device I		Clinical trial		NMPA Application in 2023Q4E
	Interatrial shunt device II (Biodegradable)		Design stage		Clinical Trial in PRC in 2023Q3E
	Interatrial shunt device III (Radiofrequency ablation shunt device)		Type inspection		Clinical Trial in PRC in 2023Q4E
	Radiofrequency ablation device (Device)		Type inspection		Clinical Trial in PRC in 2023Q4E
Vascular plug	MemoPart® Plug I (Double-rivet)			Launched	CE Mark in 2012 ⁽⁶⁾
	MemoPart® Plug II (Single-rivet)			Launched	CE Mark in 2012 ⁽⁶⁾
	MemoFlex® Plug III (Double-waist)		Clinical trial		NMPA Application in 2023Q4E
Occluder Products ⁽⁵⁾	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)	▲		Registration in progress	NMPA Approval in 2023Q3E
Procedural accessories					

SUMMARY

	Product⁽¹⁾	Pre-clinical	Clinical Trial⁽²⁾	Registration⁽³⁾	Next Milestone/ Actual Launch Time⁽⁴⁾
Heart Valve Products	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
	Mitral valve products	○	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
	Design stage		Clinical Trial in PRC in 2024Q4E		
	Design stage		Clinical Trial in PRC in 2024Q4E		

SUMMARY

	Product ⁽¹⁾	Pre-clinical	Clinical Trial ⁽²⁾	Registration ⁽³⁾	Next Milestone/ Actual Launch Time ⁽⁴⁾
Heart Valve Products	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
	Pulmonary valve product	Transcatheter pulmonary valve replacement system	Design stage		Clinical Trial in PRC in 2024Q4E
Procedural accessories	Balloon dilatation catheter for aortic valve		Clinical trial		NMPA Application in 2022Q4E
	Disposable introducing sheath	▲	Registration in progress		NMPA Approval in 2023Q2E
	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, PFO occluder products and LAA occluder products, are designed to treat the respective heart defects. Our interatrial shunt device (“IASD”) product candidates are designed to reduce left atrial hypertension. Our vascular plugs are designed for rapid vessel occlusion. Our heart valve product candidates, including aortic valve product candidates, mitral valve product candidates, tricuspid valve product candidates and pulmonary valve product candidate, are designed to treat the respective valvular diseases. Our portfolio of products and product candidates also includes occluder related procedural accessories and heart valve related procedural accessories.

SUMMARY

- (2) We plan to commence overseas clinical trial process for various product candidates. Specifically, we plan to commence clinical trial for the following product candidates: MemoSorb® ASD Occluder IV in the European Union and the United States in the fourth quarter of 2024; MemoSorb® VSD Occluder IV in the European Union and the United States in the fourth quarter of 2022 and the fourth quarter of 2023, respectively; MemoSorb® PFO Occluder II in the European Union and the United States in the fourth quarter of 2024; MemoLefort® LAA Occluder I in the European Union in the fourth quarter of 2022; interventional delivery system for biodegradable occluders in the European Union and the United States in the fourth quarter of 2022 and the fourth quarter of 2023, respectively; TAVR system in the European Union in the fourth quarter of 2024; TMVr-A system 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.
- (5) 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.
- (6) “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.

SUMMARY

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 232 registered patents and 51 pending patent applications in China as of the Latest Practicable Date. As of the Latest Practicable Date, we had 30 major product candidates at various development stages, including our biodegradable occluders and heart valve product candidates, which we expect to compete favorably in the market with their unique designs and advanced features. In addition, we had accumulated considerable experience in product registration and launch in the European Union and attained valid CE Marks for nine of our products as of the Latest Practicable Date.

Manufacture. We have accumulated expertise and established practice protocols, which serves to ensure the precision, efficiency and safety of our manufacturing process. We conduct substantially all the key manufacturing procedures in-house except for sterilization.

* 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.

SUMMARY

Commercialization. We have a proven track record of commercializing 14 products in China and 11 products overseas as of the Latest Practicable Date 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.

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) 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.

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.

SUMMARY

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. We had significant amount of goodwill and intangible assets as of the balance sheet dates during the Track Record Period, and potential impairment of intangible assets and/or goodwill could have a material adverse effect on our business, financial condition and results of operations. 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.

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. Sales to our five largest customers in each year/period of the Track Record Period amounted to 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. Purchases from our five largest suppliers in each year/period of the Track Record Period 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.”

SUMMARY

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. See “Industry Overview.”

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

As of the Latest Practicable Date, our sales and marketing team had 63 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.”

SUMMARY

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 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

SUMMARY

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 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)
Gross profit	102,832	88.3	133,113	89.8	197,545	88.8	99,084	89.3	109,482	87.7
Operating profit	60,219	51.7	76,537	51.6	76,387	34.3	45,663	41.1	34,359	27.5
Profit before income tax	60,346	51.8	76,679	51.7	66,027	29.7	44,970	40.5	25,306	20.3
Income tax expense	(8,437)	(7.2)	(7,907)	(5.3)	(7,330)	(3.3)	(3,203)	(2.9)	(1,051)	(0.8)
Profit for the year/period	51,909	44.6	68,772	46.4	58,697	26.4	41,767	37.6	24,255	19.4

SUMMARY

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 occluder products sold overseas through the Retained Lepu Medical Group; and (2) 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[®] ASD Occluder III in May 2020, which started to generate revenue in the second half of 2020; and (2) 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 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[®] ASD Occluder III, MemoCarna[®] PDA Occluder III and MemoCarna[®] VSD Occluder III; partially offset by 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. The sales volume of our LAA occluder products was relatively high in the six months ended June 30, 2021 as our first generation LAA occluder product launched in June 2020 quickly captured the market potential with its compelling therapeutic effects, backed by our continued investments in the related academic promotion activities and market fairs.

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 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.

SUMMARY

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. 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, 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.

SUMMARY

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.”

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 ⁽¹⁾	56,058	48.1	69,677	47.0	99,809	44.8	47,791	43.1	71,270	57.1
VSD occluder products	19,322	16.6	22,076	14.9	19,771	8.9	9,958	9.0	10,287	8.2
PDA occluder products	11,336	9.7	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 ⁽²⁾	349	0.3	110	0.1	85	0.0	36	0.0	66	0.1
Total	116,451	100.0	148,247	100.0	222,583	100.0	110,968	100.0	124,804	100.0

SUMMARY

- (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.

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
Total	116,451	100.0	148,247	100.0	222,583	100.0	110,968	100.0	124,804	100.0

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 ⁽¹⁾	313	89.7	84	76.4	21	25.8	24	66.7	24	36.1
Total	102,832	88.3	133,113	89.8	197,545	88.8	99,084	89.3	109,482	87.7

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

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

SUMMARY

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. The sales volume of our LAA occluder products was relatively high in the six months ended June 30, 2021 as our first generation LAA occluder product launched in June 2020 quickly captured the market potential with its compelling therapeutic effects, backed by our continued investments in the related academic promotion activities and market fairs. 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 June 30,
	2019	2020	2021	2022
	<i>(RMB in thousands)</i>			
Total non-current assets	222,617	226,748	327,174	365,701
Total current assets	85,944	105,762	792,516	860,497
Total non-current liabilities	2,148	1,315	4,526	4,446
Total current liabilities	74,544	77,596	729,973	804,505
Net current assets	11,400	28,166	62,543	55,992
Total equity	231,869	253,599	385,191	417,247

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

SUMMARY

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 June 30,
	2019	2020	2021	2022
Profitability ratios				
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% ⁽¹⁾
Return on total assets	17.8%	21.5%	8.1%	4.1% ⁽¹⁾
Liquidity ratios				
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

[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 Domestic Shares and Unlisted Foreign Shares into H Shares, 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 the section headed “Relationship with Our Controlling Shareholders”, 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.”

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.”

SUMMARY

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 Business and Industry — 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 Our Business and Industry — Risks Relating to Our Operations — 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 Shareholders, our Group and the [REDACTED].”

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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.

[REDACTED]

Lepu Medical, our Controlling Shareholder, is a company listed on the Shenzhen Stock Exchange (stock code: 300003). The [REDACTED] of our Company constitutes a [REDACTED] 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 [REDACTED] 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.”

SUMMARY

[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 [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] to the public and is expected to be 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 profit or loss of the six months ending 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;

SUMMARY

- 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. See “Financial Information — COVID-19 Outbreak and Effects on Our Business.”

RECENT DEVELOPMENT

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.”

SUMMARY

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 and net profit margin 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.

DEFINITIONS

In this document, unless the context otherwise requires, the following terms shall have the following meanings. Certain technical terms are explained in the section headed “Glossary of Technical Terms” in this document.

“30%-controlled company”	has the meaning ascribed to it under the Listing Rules
“Actual Controller”	the individual or entity that can control a company by way of investment relationship, contracts or other arrangements according to the Listing Rules of the ChiNext Board of the Shenzhen Stock Exchange (《深圳證券交易所創業板股票上市規則》) where Lepu Medical, our Controlling Shareholder, is listed
“affiliate”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	the Accounting and Financial Reporting Council
“Anhui Magete”	Anhui Magete Medical Technology Co., Ltd.* (安徽省瑪格特醫療科技有限公司), a limited liability company established in the PRC on November 22, 2016 and an indirect non-wholly owned subsidiary of Lepu Medical
“Articles” or “Articles of Association”	the amended and restated articles of association of our Company, conditionally adopted on June 9, 2021 with effect from the [REDACTED], and as amended from time to time, a summary of which is set out in the section headed “Summary of the Articles of Association of the Company” in Appendix IV to this document
“associate(s)”	has the meaning ascribed thereto under the Listing Rules
“Beijing Sida”	Beijing Sida Medical Devices Company Limited* (北京思達醫用裝置有限公司), a limited liability company established under the laws of the PRC on August 12, 1997 and a wholly-owned subsidiary of Lepu Medical
“BIS”	the Bureau of Industry and Security of the U.S. Department of Commerce

DEFINITIONS

“BIS List”	the Bureau of Industry and Security’s Entity List, Denied Parties List, or List administered by the U.S. Department of Commerce
“Board of Directors”	the board of directors of our Company
“Board of Supervisors”	the board of supervisors of our Company
“business day”	any day (other than a Saturday, Sunday or public holiday in Hong Kong) on which banks in Hong Kong are generally open for normal banking business

[REDACTED]

DEFINITIONS

[REDACTED]

“CDH Supermatrix”	CDH Supermatrix D Limited, a limited liability company incorporated under the laws of Hong Kong on April 27, 2021 and a [REDACTED]
“China” or “PRC”	the People’s Republic of China and for the purposes of this document only, except where the context requires otherwise, excluding Hong Kong, Macau and Taiwan
“CNIPA”	China National Intellectual Property Administration (國家知識產權局)
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Companies (Winding Up and Miscellaneous Provisions) Ordinance”	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Company,” “our Company,” or “the Company”	LEPU ScienTech Medical Technology (Shanghai) Co., Ltd.* (樂普心泰醫療科技(上海)股份有限公司), a joint stock limited liability company established in the PRC on January 29, 2021
“Company Law”	the Company Law of the PRC (中華人民共和國公司法), as amended, supplemented or otherwise modified from time to time
“Comprehensively Sanctioned Countries”	Cuba, Iran, North Korea, Syria, the Crimea Region of Russia/Ukraine and the self-proclaimed Luhansk People’s Republic and self-proclaimed Donetsk People’s Republic regions
“connected person(s)”	has the meaning ascribed to it under the Listing Rules
“connected transaction(s)”	has the meaning ascribed to it under the Listing Rules

DEFINITIONS

“Controlling Shareholders” has the meaning ascribed to it under the Listing Rules and unless the context otherwise requires, refers to Lepu Medical, Dr. Pu and Target Medical. For further details of these entities, see “Relationship with Our Controlling Shareholders”

[REDACTED]

“Countries subject to International Sanctions” any country or territory subject either to a general and comprehensive embargo or a more limited set of export, import, financial or investment restrictions under sanctions related laws or regulation of the Relevant Jurisdiction

“COVID-19” coronavirus disease 2019, a coronavirus known to cause contagious respiratory illness

“CSDC” China Securities Depository and Clearing Corporation

“CSDC (Hong Kong)” China Securities Depository and Clearing (Hong Kong)

“CSRC” China Securities Regulatory Commission (中國證券監督管理委員會)

“Deed of Indemnity” the deed of indemnity entered into by Lepu Medical with and in favor of our Company dated January 27, 2022 to provide certain indemnities, particulars of which are set out in “Appendix VII — Statutory and General Information — D. Other Information — 11. Other Indemnities” to this document

“Director(s)” the director(s) of our Company

“Domestic Share(s)” ordinary Share(s) in the share capital of the Company with a nominal value of RMB1.00 each, which are subscribed for and paid up in Renminbi

DEFINITIONS

“Dr. Pu”	Dr. Pu Zhongjie (蒲忠杰), the Actual Controller of Lepu Medical and one of our Controlling Shareholders
“EIT Law”	Enterprise Income Tax Law of the PRC (中華人民共和國企業所得稅法)
“Entrustment Arrangements”	the entrustment arrangements between Lepu Medical and us in connection with the Entrusted Products, details of which are set out in the section headed “Business — Our Products — Heart Valve Product Candidates — Entrusted Products”
“Entrusted Products”	the TAVR system, TMVCRS and balloon dilatation catheter for aortic valve that the Group entrusted the Retained Lepu Medical Group for its R&D, registration and production pursuant to an asset transfer agreement (including an intellectual property transfer agreement as attached thereto) entered into between Shanghai Shape Memory Alloy and Lepu Medical in January 2021. See “Connected Transaction — Non-exempt Continuing Connected Transactions — 2. Entrusted Products Related Framework Agreement” and “Business — Our Products — Heart Valve Product Candidates — Entrusted Products”
“Entrusted Products Regulatory Restrictions”	the PRC regulatory restrictions in connection with the Entrusted Products entailing the Entrustment Arrangements, details of which are set out in the section headed “Business — Our Products — Heart Valve Product Candidates — Entrusted Products”
“EU”	the European Union
“European Economic Area”	consists of the member states of the European Union (EU) and three countries of the European Free Trade Association (EFTA) (Iceland, Liechtenstein and Norway; excluding Switzerland)
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
“FDA”	U.S. Food and Drug Administration

DEFINITIONS

“FIL”	Foreign Investment Law of the PRC (中華人民共和國外商投資法)
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.
“FSE List”	the list of Foreign Sanctions Evaders maintained by OFAC, which sets forth individuals and entities that are determined to have violated, attempted to violate, conspired to violate, or caused a violation of U.S. sanctions on Syria or Iran, and are prohibited to transact with U.S. persons or within the United States but whose assets/property interest are not subject to blocking
“F&S Report”	the industry report in respect of the [REDACTED] issued by Frost & Sullivan

[REDACTED]

“Group,” “our Group,” “the Group,” “we,” or “us”	the Company and its subsidiaries from time to time or, where the context so requires, in respect of the period prior to our Company becoming the holding company of its present subsidiaries, such subsidiaries as if they were subsidiaries of our Company at the relevant time
“H Share(s)”	(1) overseas listed foreign share(s) in our ordinary share capital, with nominal value of RMB1.00 each in the share capital of our Company, which are to be [REDACTED] for and [REDACTED] in HK dollars, and (2) Domestic Shares and Unlisted Foreign Shares that are [REDACTED] into overseas [REDACTED] shares (境外[REDACTED]股份), all of which an application has been made for [REDACTED] and permission to [REDACTED] on the Stock Exchange

[REDACTED]

“Hefei Hospital”	Hefei High-tech Cardiovascular Hospital* (合肥高新心血管病醫院), a hospital established in the PRC on December 18, 2009, a wholly-owned indirect subsidiary of Lepu Medical
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DEFINITIONS

[REDACTED]

“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the People’s Republic of China
“Hong Kong dollars,” “HK dollars” or “HK\$”	Hong Kong dollars, the lawful currency of Hong Kong

[REDACTED]

“Hong Kong Securities and Futures Ordinance” or “SFO”	Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
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[REDACTED]

DEFINITIONS

[REDACTED]

“Huaihua Haozhi”	Huaihua Haozhi Enterprise Management Partnership (Limited Partnership)* (懷化皓智企業管理合夥企業(有限合夥)), a limited liability partnership established under the laws of the PRC on February 19, 2020 and a [REDACTED]
“IFRS”	International Financial Reporting Standards issued by the International Accounting Standards Board
“independent third party(ies)”	any entity or person who is not a connected person of our Company within the meaning ascribed thereto under the Listing Rules

[REDACTED]

DEFINITIONS

“International Sanctions”	all applicable laws and regulation to economic sanctions, export controls, trade embargoes and wider prohibitions and restrictions on international trade and investment related activities, including those adopted administered and enforced by the U.S. government, the European Union and its member states, the United Nations or the government of Australia
“International Sanctions Legal Advisors”	Hogan Lovells, our legal advisors as to International Sanctions laws in connection with the [REDACTED]

[REDACTED]

“Latest Practicable Date”	October 18, 2022, being the latest practicable date for ascertaining certain information in this document before its publication
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DEFINITIONS

“Lepu Growth”	Beijing Lepu Growth Investment Management Co., Ltd.* (北京樂普成長投資管理有限公司), a limited liability Company incorporated on July 3, 2015 in the PRC and a wholly-owned subsidiary of Lepu Medical
“Lepu India”	LepuCare (India) Vascular Solutions Private Limited, a Company limited shares incorporated on April 30, 2016 in India and a wholly-owned subsidiary of Lepu Medical
“Lepu Medical”	Lepu Medical Technology (Beijing) Co., Ltd.* (樂普(北京)醫療器械股份有限公司), a company listed on the ChiNext Board of the Shenzhen Stock Exchange, stock code: 300003, one of our Controlling Shareholders
“Lepu Medical Group”	Lepu Medical and its subsidiaries

[REDACTED]

“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operates in parallel with the Growth Enterprise Market of the Stock Exchange
“Mandatory Provisions”	the Mandatory Provisions for Articles of Association of Companies to be Listed Overseas (《到境外上市公司章程必備條款》), as amended, supplemented or otherwise modified from time to time, for inclusion in the articles of association of companies incorporated in the PRC to be listed overseas (including Hong Kong), which were promulgated by the former Securities Commission of the State Council (國務院證券委員會) and the former State Commission for Restructuring the Economic Systems (國家經濟體制改革委員會) on August 27, 1994

DEFINITIONS

[REDACTED]

“Non-competition Agreement”	the non-competition agreement entered into among Lepu Medical, Dr. Pu and our Company dated January 27, 2022 in respect of certain non-competition undertakings given by Lepu Medical and Dr. Pu in favor of our Company
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“Ningbo Bingkun”	Ningbo Bingkun Medical Devices Co., Ltd.* (寧波秉琨醫療科技有限公司), a limited liability company established in the PRC on November 24, 2014 and a non-wholly owned subsidiary of Lepu Medical
“Ningbo Jiacheng”	Ningbo Jiacheng Enterprise Management Partnership (Limited Partnership) (寧波嘉呈企業管理合夥企業(有限合夥)), a limited liability partnership established on February 22, 2021 in the PRC and the shareholding platform for the employees of the Retained Lepu Medical Group
“Ningbo Jiadu”	Ningbo Jiadu Enterprise Management Partnership (Limited Partnership) (寧波嘉度企業管理合夥企業(有限合夥)), a limited liability partnership established on February 22, 2021 in the PRC and the shareholding platform for our employees
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局), formerly known as the China Food and Drug Administration
“OFAC”	the U.S. Department of Treasury’s Office of Foreign Assets Control

[REDACTED]

DEFINITIONS

[REDACTED]

“PBOC”	People’s Bank of China (中國人民銀行), the central bank of the PRC
“PRC GAAP”	the Accounting Standards for Business Enterprises (企業會計準則) promulgated by the Ministry of Finance of the PRC
“PRC Legal Advisors”	Haiwen & Partners, PRC legal advisors to our Company
“[REDACTED]”	the [REDACTED] in our Company undertaken by the [REDACTED], details of which are set out in the section headed “History, Reorganization and Corporate Structure — [REDACTED]” in this document
“[REDACTED]”	the [REDACTED], namely Vivo Capital Fund IX, Sequoia Capital China Growth, SHC, Huaihua Haozhi and CDH Supermatrix, details of which are set out in the section headed “History, Reorganization and Corporate Structure” in this document
“[REDACTED] Shareholders Agreement”	the shareholders’ agreement of our Company entered into among Lepu Medical, Dr. Pu, Target Medical, Ningbo Jiadu, Ningbo Jiacheng, Shanghai Shape Memory Alloy, the [REDACTED] and the Company dated May 28, 2021

DEFINITIONS

[REDACTED]

“Primary Sanctioned Activity” any activities in a Sanctioned Country or (1) with; or (2) directly or indirectly benefiting or involving the property or interests in property of, a Sanctioned Target by the Company incorporated or located in a Relevant Jurisdiction or which otherwise has a nexus with such jurisdiction with respect to the relevant activity, such that it is subject to the relevant sanctions law and regulation

“Promoters” the promoters of our Company, namely, Lepu Medical and Target Medical

[REDACTED]

“Regulation S” Regulation S under the U.S. Securities Act

“Relevant Activities” research and development, registration and manufacturing activities relating to the Entrusted Products (to the extent that the then applicable PRC laws and regulations prohibits us from carrying out such activities), details of which are set out in the section headed “Business — Our Products — Heart Valve Product Candidates — Entrusted Products”

“Relevant Jurisdiction” any jurisdiction that is relevant to our Company and has sanctions related law or regulation restricting, among other things, its nationals and/or entities which are incorporated or located in that jurisdiction from directly or indirectly making assets or services available to or otherwise dealing in assets or certain countries, governments, person or entities targeted by such law or regulation

DEFINITIONS

“Relevant Persons”	means our Company, together with our [REDACTED] and shareholders and persons who might directly or indirectly, be involved in permitting the [REDACTED], [REDACTED], [REDACTED] and [REDACTED] of our Shares including the Stock Exchange and related group companies
“Relevant Regions”	Iran, Egypt, Hong Kong, Iraq, Lebanon, Russia (excluding Crimea), Tunisia, Turkey and Ukraine (excluding Crimea)
“Reorganization”	the reorganization of the companies within our Group for the purpose of the [REDACTED] as set out in the section headed “History, Reorganization and Corporate Structure” in this document
“Retained Lepu Medical Group”	Lepu Medical and its subsidiaries, excluding our Group
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“SAFE”	State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“SAMR”	State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局)
“Sanctioned Person”	certain person(s) and identity(ies) listed on OFAC’s Specially Designated Nationals and Blocked Persons List or other restricted parties lists maintained by the United States, the European Union, the United Nations or Australia
“Sanctioned Target”	any person or entity (1) designated on any list of targeted persons or entities issued under the sanctions-related law or regulation of a Relevant Jurisdiction; (2) that is, or is owned or controlled by, a government of a Country subject to International Sanctions; or (3) that is the target of sanctions under the law or regulation of a Relevant Jurisdiction because of a relationship of ownership, control, or agency with a person or entity described in (1) or (2)
“SAT”	State Administration of Taxation (國家稅務總局)
“SDN”	individuals and entities that are listed on the SDN List

DEFINITIONS

“SDN List”	the list of Specially Designated Nationals, and Blocked Persons maintained by OFAC, which sets forth individuals and entities that are subject to its sanctions and restricted from dealings with U.S. persons
“SEC”	the Securities and Exchange Commission of the United States
“Secondary Sanctionable Activity”	certain activity by our Company that may result in the imposition of sanctions against the Relevant Person(s) by a Relevant Jurisdiction (including designation as a Sanctioned Target or the imposition of penalties), even though our Company is not incorporated or located in that Relevant Jurisdiction and does not otherwise have any nexus with that Relevant Jurisdiction
“Sequoia Capital China Growth”	SCC Growth VI Holdco AF, Ltd., an exempted company with limited liability incorporated under the laws of the Cayman Islands on April 12, 2021 and a [REDACTED]
“SFC”	the Securities and Futures Commission of Hong Kong
“Shanghai Shape Memory Alloy”	Shanghai Shape Memory Alloy Co., Ltd.* (上海形狀記憶合金材料有限公司), a limited liability company established under the laws of the PRC on May 5, 1994 and a wholly-owned subsidiary of the Company
“Share(s)”	ordinary share(s) in the share capital of our Company with a par value of RMB1.00 each, comprising our Domestic Shares, our Unlisted Foreign Shares and our H Shares
“Shareholder(s)”	holder(s) of our Share(s)
“SHC”	Shanghai Healthcare Capital Partnership (Limited Partnership) (上海生物醫藥產業股權投資基金合夥企業(有限合夥)), a limited liability partnership established under the laws of the PRC on October 28, 2020 and a [REDACTED]
“Sole [REDACTED]”, “[REDACTED]”, “Sole Sponsor” and “Sole Sponsor-[REDACTED]”	China International Capital Corporation Hong Kong Securities Limited

DEFINITIONS

“Spin-off Circular”	the Circular on Issues Relevant to Regulating Offshore Listing of Subordinate Enterprises of Domestic Listed Companies (關於規範境內上市公司所屬企業到境外上市有關問題的通知) promulgated by the CSRC on July 21, 2004
“SSI List”	the list of the Sectoral Sanctions Identifications parties maintenance by OFAC, which sets forth entities designated by OFAC in Russia’s energy, financial and/or defense sectors that are subject to more limited, sectoral, sanctions imposed under one or more OFAC Directives that prohibit certain (but not all) dealing with U.S. persons or within the United States
	[REDACTED]
“State Council”	State Council of the PRC (中華人民共和國國務院)
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“subsidiary(ies)”	has the meaning ascribed thereto in section 15 of the Companies Ordinance
“substantial shareholder(s)”	has the meaning ascribed to it in the Listing Rules
“Supervisor(s)”	the supervisor(s) of our Company
“Takeovers Code”	The Code on Takeovers and Mergers issued by the SFC, as amended, supplemented or otherwise modified from time to time
“Target Medical”	Beijing Target Medical Technologies Co., Ltd.* (北京天地和協科技有限公司), a limited liability company established in the PRC on November 18, 1999 and a wholly-owned subsidiary of Lepu Medical, one of our Controlling Shareholders
“Track Record Period”	the period comprising the financial years ended December 31, 2019, 2020 and 2021 and the six months ended June 30, 2022
“U.S. dollars” or “US\$”	United States dollars, the lawful currency of the United States

DEFINITIONS

“U.S. Securities Act” United States Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder

[REDACTED]

“United States” or the “U.S.” the United States of America, its territories and possessions, any State of the United States, and the District of Columbia

“Unlisted Foreign Share(s)” ordinary share(s) issued by our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid for in a currency other than Renminbi and not listed on any stock exchange

“Unlisted Foreign Shareholder(s)” holders of the Unlisted Foreign Share(s)

“Vivo Capital Fund IX” Vivo Capital Fund IX, L.P., a limited partnership established under the laws of Delaware of the United States on March 12, 2018 and a [REDACTED]

“%” per cent

Unless otherwise specified, statements contained in this document assume no exercise of the [REDACTED].

In this document, the terms “associate,” “close associate,” “connected person,” “core connected person,” “connected transaction,” “controlling shareholder” and “substantial shareholder” shall have the meanings given to such terms in the Listing Rules, unless the context otherwise requires.

Certain amounts and percentage figures included in this document have been subject to rounding. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them. Any discrepancies in any table or chart between the total shown and the sum of the amounts listed are due to rounding.

All times refer to Hong Kong time unless otherwise specified.

Unless otherwise specified, references to years in this document are to calendar years.

DEFINITIONS

Unless otherwise expressly stated or the context otherwise requires, all data in this document is as of the date of this document.

If there are any inconsistencies between the Chinese names of the PRC laws and regulations or PRC entities mentioned in this document and their English translations, the Chinese names shall prevail.

Translated English names of Chinese natural persons, legal persons, governmental authorities, institutions or other entities for which no official English translation exist are unofficial translations for identification purposes only.

GLOSSARY OF TECHNICAL TERMS

The following is a glossary of certain terms used in this document in connection with us and/or our business. As such, these terms and their meanings may not correspond to standard industry meanings or usage of these terms.

“annulus”	a ring-like structure at the base of a heart valve that supports the valve’s leaflets
“anticoagulant”	an agent that is used to prevent the formation of blood clots
“aorta”	the main and largest artery (see “artery”) in the body, which transports blood from the heart and arises from the left ventricle of the heart, goes up (ascends) a little, bends over (arches), then goes down (descends) through the chest and through the abdomen to where ends by dividing into two arteries called the common iliac arteries that go to the legs
“aortic regurgitation”	a condition where the aortic valve is not able to close completely, causing a backflow of blood from the aorta into the left ventricle during diastole
“aortic stenosis”	the disability to fully open of the aortic valve caused by aortic valve lesions, due to congenital or acquired factors
“aortic valve”	one of the four valves in the heart, which is situated at the exit of the left ventricle of the heart where the aorta begins and lets blood from the left ventricle be pumped up into the aorta but prevents blood once it is in the aorta from returning to the heart
“arrhythmia”	also known as cardiac arrhythmia or heart arrhythmia, is a group of conditions in which the heartbeat is irregular
“atrial fibrillation”	an arrhythmia characterized by the rapid and irregular beating of the atrial chambers of the heart
“atrial septal defect” or “ASD”	a remnant opening, or a defect, between the left and right atria resulting from the abnormal development, absorption and fusion of the atrial septum during embryonic development

GLOSSARY OF TECHNICAL TERMS

“arachnoid”	the middle fibrocellular layer of membranes covering the brain and spinal cord
“artery”	a blood vessel that carries blood high in oxygen content away from the heart to the farthest reaches of the body
“balloon dilatation”	an interventional procedure performed by delivering the balloon to a predetermined site for dilatation
“biodegradable”	a characteristic of a material that is capable of being broken down especially into innocuous products by the action of living organisms
“catheter”	a single-lumen or multi-lumen tubular device that can be partially or fully inserted or implanted into the cardiovascular system for diagnostic and/or therapeutic purposes
“cardioembolic stroke”	a clinical syndrome in which cardiogenic emboli from the heart and aortic arch through blood circulation cause cerebral artery thrombosis and corresponding brain dysfunction
“cardiovascular medical devices”	medical devices that are used to diagnose and treat heart disease
“CE Mark”	a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
“chordae”	thick, strong, tendinous connections between the mitral valve cusps and the papillary muscles
“Class III Grade A hospital(s)”	hospitals of the highest level in China
“Class III Hospitals”	top-level hospitals in China, as hospitals in China are divided into three classes by Ministry of Health (now National Health Commission), among which, Class III hospitals are at the highest level, typically having more than 500 beds, providing high-level specialist medical and healthcare services to several regions and performing advanced teaching and research tasks

GLOSSARY OF TECHNICAL TERMS

“Class III medical device(s)”	in China, medical devices are classified according to a catalogue issued by the NMPA into three different categories, namely Class I, Class II and Class III, depending on the degree of risk associated with each medical device and the extent of regulatory control needed to ensure safety and effectiveness. Class III medical devices involve the highest degree of associated risks and therefore are subject to the largest extent of regulatory control to ensure safety and effectiveness
“congenital heart disease” or “CHD”	the formation of the heart and blood vessels during embryonic development or abnormal development or failure to close the channels that should be automatically closed after birth, resulting in abnormalities in the solid structure or function of the blood vessels in the heart or thoracic cavity
“CROs”	contract research organization, an organization that provides clinical support to the pharmaceutical, biotechnology, and medical device industries on a contract basis
“ductus arteriosus”	a blood vessel in the developing fetus connecting the trunk of the pulmonary artery, which normally closes in one year after birth
“edge-to-edge”	a technique to treat mitral valve or tricuspid valve by suturing the edges of the leaflets at the site of regurgitation
“endothelialization”	the process of developing an endothelium, which consists of an intact layer of vascular endothelial cells
“ePTFE”	expanded polytetrafluoroethylene, with its unique properties, is particularly useful for the production of internal and external medical devices such as catheters, bio-containment vessels, syringes and sutures
“foramen ovale”	a normal opening between the right atrium and left atrium in the fetal heart, which normally closes in one year after birth

GLOSSARY OF TECHNICAL TERMS

“Good Clinical Practice” or “GCP”	an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“Good Manufacturing Practice” or “GMP”	the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification
“Green Path for Innovative Medical Device”	the Special Procedures for Examination and Approval of Innovative Medical Devices (創新醫療器械特別審查程序) in China, pursuant to which priority review and approval will be applicable to certain innovative medical devices
“heart valve”	valves that control blood flow to and from the heart and that include the atrioventricular valves, the aortic valve, and the pulmonary valve
“hemostatic valve”	a valve-like device acting as the stoppage of bleeding or blood flow
“incidence”	the occurrence of new cases of disease or injury, a measure of the probability of occurrence of a given medical condition in a population within a specified period of time
“interatrial shunt device” or “IASD”	an implanted or interventional device that punctures the atrium to form a fistula, which directly reduces left atrial pressures, improves exercise tolerance and potentially improves clinical outcomes and heart failure
“interventional delivery system”	a delivery system designed to attach, load, deliver and deploy interventional medical devices into targets with no need for open-chest surgery
“interatrial septum”	a partition that separates the upper chambers (atria) of the heart
“KOLs”	key opinion leaders, who are professionals that influence their peers’ medical practice, including but not limited to prescribing behavior
“leaflet”	cusps of heart valves

GLOSSARY OF TECHNICAL TERMS

“left atrial appendage” or “LAA”	a long, narrow and curved blind-end structure extending forward and downward along the anterior wall of the left atrium, which has active diastolic and secretory functions
“mitral valve”	a valve in the heart that is situated between the left atrium and the left ventricle, which permits blood to flow from the left atrium into the left ventricle, but not in the reverse direction
“occluder”	a device that closes, obstructs, or prevents the passage of the flow of blood
“oxide coating”	a dense oxide film produced through plasma treatment process
“Patent Cooperation Treaty” or “PCT”	an international patent law treaty concluded in 1970 which provides a unified procedure for filing patent applications to protect inventions in each of its contracting states
“patent ductus arteriosus” or “PDA”	a remnant opening of the ductus arteriosus, which fails to close normally in one year after birth
“patent foramen ovale” or “PFO”	a remnant opening of the fetal foramen ovale, which fails to close normally in one year after birth
“penetration rate”	the penetration rate of a specific therapy or product is calculated by dividing the number of patients who undertook relevant procedures by the number of the patients suffering from the relevant diseases who are able to receive the relevant procedures
“percutaneous”	a procedure that operates through the skin
“polyethylene terephthalate” or “PET”	a common thermoplastic polymer resin of the polyester family
“polytetrafluoroethylene” or “PTFE”	a strong, tough, waxy, nonflammable synthetic resin produced by the polymerization of tetrafluoroethylene
“prevalence”	the proportion of a population with a disease or a particular condition at a specific point in time or over a specified period of time

GLOSSARY OF TECHNICAL TERMS

“pulmonary valve”	one of the four valves in the heart that stands at the opening from the right ventricle in the pulmonary artery trunk, which lets blood head in the right direction (toward the lungs) and keeps it from sloshing back from the pulmonary artery into the heart
“radiofrequency ablation”	a method that use electrodes to generate heat and destroy abnormal tissue
“SAVR”	surgical aortic valve replacement, which involves an open-heart surgery where the heart is stopped and the patient is attached to a bypass to oxygenate the blood to allow access to the aortic valve within the heart
“sheath”	a tube having a lumen which is designed to be inserted into blood vessel to provide a pathway through which a device is delivered
“snare”	a surgical instrument usually consisting of a wire loop used to establish a pathway in arteries and veins for transcatheter therapies for VSD and PDA
“stent”	a short narrow metal or plastic tube often in the form of a mesh that is inserted into the lumen of an anatomical vessel (such as an artery) or passageway to keep it open
“transcatheter”	a medical procedure that performed through the lumen of a catheter either by transapical or by transfemoral access
“transapical”	a medical procedure that performed through the apex (the tip) of the heart
“transfemoral”	a medical procedure that passing through or performed by way of the femoral artery
“TAVR”	transcatheter aortic valve replacement, a catheter-based technique to implant a new aortic valve in a minimally invasive procedure that does not involve open-chest surgery to correct severe aortic stenosis

GLOSSARY OF TECHNICAL TERMS

“TMVr”	transcatheter mitral valve repair, which provides a newer, minimally invasive option for treating the most common form of mitral valve leakage for people who cannot undergo open-heart surgery. It is implanted via a tri-axial transcatheter technique and involves suturing together the anterior and posterior mitral valve leaflets
“TTVI”	transcatheter tricuspid valve intervention, an alternative for treatment of tricuspid regurgitation (TR) and tricuspid stenosis (TS), which can be classified according to their mechanism of action as transcatheter tricuspid valve repairment (TTVr) and transcatheter tricuspid valve replacement (TTVR)
“TTVRS”	transcatheter tricuspid valve repair system, a catheter based technique to repair the tricuspid valve in a minimally invasive procedure that does not involve open-chest surgery to correct tricuspid regurgitation
“tricuspid valve”	one of the four heart valves, the first one that blood encounters as it enters the heart, which stands between the right atrium and the right ventricle, and it allows blood to flow only from the atrium into the ventricle
“TMVCRS”	transapical mitral valve repair system (chordal), a catheter-based system with two configurations, one enabling artificial mitral chordae implantation and the other enabling edge-to-edge chordae repair
“TMVr-A”	transapical mitral valve clip repair, a catheter-based technique to repair the mitral valve in an interventional therapy that does not involve open-chest surgery
“TMVr-F”	transfemoral mitral valve clip repair, a catheter-based technique to repair the mitral valve in an interventional therapy that does not involve open-chest surgery
“type inspection”	the process conducted by medical device manufacturers of delivering product samples to medical device testing laboratories accredited by the relevant government authorities, such as the NMPA, for physical, chemical, biological and other performance testing and inspection to prove that the product samples comply with the regulations of technical requirements or national standards

GLOSSARY OF TECHNICAL TERMS

“vascular plug”	a self-expandable device made of nitinol wire mesh (or other material) which can be cylindered into a sheath and deployed precisely at embolization targets
“ventricular septal defect” or “VSD”	a defect, or a hole, in the septum between the left and right ventricles of the heart, which may lead to abnormal blood circulation and pulmonary hypertension and other complications in severe cases

FORWARD-LOOKING STATEMENTS

Certain statements in this document are forward-looking statements that are, by their nature, subject to significant risks and uncertainties. Any statements that express, or involve discussions as to, expectations, beliefs, plans, objectives, assumptions or future events or performance (often, but not always, through the use of words or phrases such as “will,” “expect,” “anticipate,” “estimate,” “believe,” “going forward,” “ought to,” “may,” “seek,” “should,” “intend,” “plan,” “projection,” “could,” “vision,” “goals,” “objective,” “target,” “schedule,” “predict,” “aim,” “intend,” “consider,” “would,” “continue” and “outlook”) are not historical facts, but are forward-looking and may involve estimates and assumptions and are subject to risks (including the risk factors detailed in this document), uncertainties and other factors some of which are beyond our control and which are difficult to predict. Accordingly, these factors could cause actual results or outcomes to differ materially from those expressed in the forward-looking statements.

Our forward-looking statements have been based on assumptions and factors concerning future events that may prove to be inaccurate. Those assumptions and factors are based on information currently available to us about the businesses that we operate. The risks, uncertainties and other factors, many of which are beyond our control, that could influence actual results include, but are not limited to:

- general political, market and economic conditions, including those related to the PRC;
- any changes in the laws, rules and regulations of the central and local governments in the PRC and other relevant jurisdictions and the rules, regulations and policies of the relevant governmental authorities relating to all aspects of our business;
- our planned projects and goals;
- our ability to control or reduce costs;
- our ability to control our risks;
- our ability to maintain good relationships with business partners;
- our business prospects and expansion plans;
- our ability to successfully implement our business plans and strategies;
- our financial condition and performance, debt levels and capital needs;
- our dividend policy;
- our capital expenditure plans;

FORWARD-LOOKING STATEMENTS

- various business opportunities that we may pursue;
- the actions and developments of our competitors;
- changes or volatility in interest rates, foreign exchange rates, equity prices or other rates or prices, including those pertaining to the PRC and the industry and markets in which we operate; and
- all other risks and uncertainties described in the section headed “Risk Factors” in this document.

Since actual results or outcomes could differ materially from those expressed in any forward-looking statements, we strongly caution [REDACTED] against placing undue reliance on any such forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by the Listing Rules, we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. Statements of or references to our intentions or those of any of our Directors are made as of the date of this document. Any such intentions may change in light of future developments.

All forward-looking statements in this document are expressly qualified by reference to this cautionary statement.

RISK FACTORS

Potential [REDACTED] should read and consider carefully all the information set out in this document, and, in particular, should evaluate the following risks and uncertainties before deciding to make any [REDACTED] in our H Shares. You should pay particular attention to the fact that we conduct our operations in China, the legal and regulatory environment of which in some respects may differ from that in Hong Kong. Any of the risks and uncertainties listed below could have a material adverse effect on our business, results of operations, financial condition or on the [REDACTED] of our H Shares, and could cause you to lose all or part of your [REDACTED]. The risks and uncertainties identified below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business and results of operations.

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.

Our business is subject to numerous risks and uncertainties, including (1) risks relating to our business and industry, which primarily includes risks relating to commercialization and distribution, research and development, manufacture and supply, extensive government regulations, our intellectual properties and our operations, (2) risks relating to doing business in China, and (3) risks relating to the [REDACTED].

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.

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.

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 of operations and financial condition. In addition, the PRC government has adopted a centralized procurement regime in an effort to regulate the prices of certain medical devices, which may exert downward pressure on the said pricing of medical devices that are included under such regime. See “Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Reform Plan on

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High-Value Medical Consumables.” Although 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, we cannot assure you that any of our products or product candidates upon commercialization will not be included under the regime in the future. We may also face downward changes in pricing if additional products of ours are included in the medical insurance reimbursement list, even if we expect such inclusion to increase the sales volume of our products. See “Business — Sales, Distribution and Marketing — Pricing” and “— Our sales depend to a certain extent on the level of insurance reimbursement patients receive for treatments using our products, especially, whether our products are covered in the medical insurance scheme.” Also, when setting the prices for our products, hospitals may gain more bargaining power depending on the availability of alternative products, demands of patients and the preferences of physicians. If hospitals seek to lower retail prices of our products and therefore reduce the profitability of our distributors, our distributors may have less incentive to purchase and promote our products, and we may need to lower the order price we set for our distributors. Furthermore, along with our increasing efforts to promote our product candidates, as well as the continuous development of competing product candidates, awareness of these products is expected to increase. More competing products may become available, which will offer alternatives for hospitals and patients to choose.

In addition, with the development of technologies and increasing competition in the industry, we may experience reduced pricing from our existing products, particularly along with the launch of new products that can replace or further improve the safety and efficacy profile of our existing products, while the manufacturing and material costs may remain constant or increase. If we are unable to successfully introduce more advanced and/or more profitable products to the market, or if we fail to effectively control our operating and manufacturing costs, our business, financial condition and results of operations could be materially and adversely affected.

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

The commercial success of our products depends upon the degree of market acceptance each of such products achieves, particularly among physicians, patients and hospitals. As a treatment recently developed and introduced to the market, interventional therapies involving our occluder products and product candidates and heart valve product candidates may fail to receive broad acceptance from patients or physicians as anticipated. As an alternative, open-chest surgeries may have certain advantages over interventional therapies, given its established market acceptance, comparatively lower price and coverage by governmental and private medical insurance. In addition, physicians could face a learning process to become proficient in the use of our products, which may take longer than expected and therefore affect our ability to market our products.

RISK FACTORS

If any of our products or product candidates upon commercialization fails to gain sufficient market acceptance by physicians, patients, hospitals, third-party payors or others in the industry, the sales of our products will be adversely affected. For example, currently commercialized interventional medical devices, such as the occluder products and heart valve products developed by some of our competitors are well established in the China and overseas markets, and physicians may continue to rely on these treatments to the exclusion of our products and product candidates. In addition, physicians, patients, hospitals, and third-party payors may prefer other novel products to ours. If our products and product candidates upon commercialization do not achieve an adequate level of acceptance, we may not be able to generate significant product sales revenue and to improve profitability. The degree of market acceptance of our products and product candidates (if approved for commercial sale) will depend on a number of factors, including, among others:

- the clinical indications for which our products and product candidates are approved;
- physicians, patients and hospitals considering our products and product candidates upon commercialization as a safe and effective treatment;
- the potential and perceived advantages and disadvantages of our products, product candidates upon commercialization and relevant treatments compared to alternative products and treatments;
- the prevalence and severity of any side effect, adverse event or complication;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our products and product candidates upon commercialization as well as competing products;
- the cost of treatment in relation to alternative treatments;
- pricing and the availability of adequate coverage and reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and/or
- the effectiveness of our sales and marketing efforts.

If any product that we commercialize fails to achieve market acceptance among physicians, patients, hospitals, or others in the industry or if we fail to maintain good relationships with them, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies introduced are more favorably received and more cost effective than our products.

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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.

The interventional medical device market targeting structural heart diseases is intensely competitive and rapidly changing. We face competition from major interventional medical device providers for structural heart diseases worldwide. There are several multi-national and domestic companies having products at or near commercial stage, or pursuing the development and undergoing clinical trials of product candidates targeting the structural heart diseases as our products and product candidates do. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacture and commercialization on interventional medical devices for structural heart diseases.

Our commercialized products may face competition based on factors including, among others, their safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer severe adverse events, or are less expensive than any products that we commercialize or may develop. As a result, we may become obsolete overtime and lose our market share. In terms of product candidates, our competitors may be applying for marketing approvals in China or other countries for medical device products with the same intended use as our product candidates. The ability of the relevant authorities to concurrently review multiple marketing applications for the same type of innovative medical device may be limited. For example, when our product candidates and their competing products are subject to the NMPA's concurrent review, we cannot guarantee that the NMPA's schedule would not be affected, and the registration process of our product candidates may be prolonged. Moreover, our competitors may obtain approval from the NMPA or other comparable regulatory authorities for their products more quickly than we obtain approval for ours, which could result in our competitors establishing a strong market position or gaining acceptance in the same markets that we are targeting before we are able to enter the market. As a result, we may be unable to maintain or enhance our market share or achieve our targeted market share in the industry.

Moreover, some of our competitors, including certain first-movers and multi-national companies, may have greater commercial infrastructure, better financial, technical and personnel resources than we have. Mergers and acquisitions in the medical device industries may result in even more resources being concentrated among a small number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development. Our business and results of operations will suffer if we fail to compete effectively.

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Disruptive technologies and medical breakthroughs may also render our products obsolete or non-competitive. Without the timely introduction of new and improved products, our products could become technologically obsolete or more susceptible to competition and our revenue and operating results would suffer. We may have to make significant investments in new products and advanced technologies to face such competitions. However, technical innovations often require substantial time and investment before we can determine their commercial viability, which could have a material adverse impact on our financial condition. Furthermore, should the new generation of our products succeed in obtaining an approval, it may capture a significant share of our previous generation products and thereby reduce the sales of our previous generation products.

We depend on distributors for a substantial portion of our revenue and our revenue growth. We may fail to maintain or renew relationships with distributors, or further expand our network of distributors.

We rely on third-party distributors to distribute our products. As of June 30, 2022, we had 288 distributors covering all provinces, municipalities and autonomous regions in China. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we generated 91.8%, 92.6%, 93.9%, 94.8% and 97.0% of our total revenue through sales to distributors, respectively. We expect we will continue to rely on distributors for our revenue growth. Our ability to maintain and expand our business depends on our ability to maintain effective distributor networks that ensure timely distribution of our products to the relevant markets where we generate market demand through our sales and marketing activities. We rely on our distribution agreements to manage our distributors. However, all of our distributors, except for the Retained Lepu Medical Group, are independent third parties over whom we have limited control. Moreover, in line with industry practice, we generally do not enter into long-term distribution agreements, and our standard distribution agreement has a term of one year, which may be automatically renewed for three months. In order to maintain our network of distributors, we need to continually renew distribution agreements. However, we cannot guarantee that we will be able to renew such agreements with our preferred distributors on terms favorable to us or at all. If our distributors elect not to renew their agreements with us or otherwise terminate their business relationships with us for various reasons, including in the event that PRC pricing regulations or other factors limit the margins our distributors can obtain through the resale of our products to hospitals, many of which are beyond of control, our business, results of operations and financial condition could be materially and adversely affected.

Sales to our five largest customers in each year/period of the Track Record Period amounted to RMB32.2 million, RMB56.0 million, RMB47.2 million and RMB18.9 million, respectively, representing 27.6%, 37.8%, 21.2% and 15.1% of our total revenue for the same periods, respectively. Sales to the largest customer in each year/period of the Track Record Period amounted to RMB10.2 million, RMB31.0 million, RMB16.0 million and RMB4.4 million, respectively, representing 8.8%, 20.9%, 7.2% and 3.5% of our total revenue for the same periods, respectively. Substantially all of our five largest customers during the Track Record Period were our distributors. If any of our major distributors was to substantially

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reduce the size or amount of the orders they place with us or were to terminate their business relationship with us entirely, we may not be able to obtain orders from other customers to replace any such lost sales on comparable terms or at all. As a result, our sales volume and business prospects could be materially and adversely affected.

In addition, competition for distributors in the medical device market is intense. We compete for desired distributors with other leading medical device manufacturers and importers that may have greater visibility, brand recognition and financial resources, and a broader product portfolio than we do. Our competitors may enter into exclusive distribution agreements that restrict their distributors from selling our products. Consequently, maintaining relationships with existing distributors and replacing distributors may be difficult and time consuming. Further, the implementation of the “two-invoice system” limits the distribution to a single level of distributors from manufacturers to public hospitals or similar systems in the medical device industry. See “Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Two-Invoice System.” Related changes may have a negative impact on us, as there would be a smaller pool of distributors, which may increase the bargaining power of distributors. As the implementation of the “two-invoice system” is still at an early stage, and the interpretation and enforcement of such system in the medical device industry are evolving and subject to uncertainty, we cannot predict how the implementation and enforcement will evolve in different provinces in China, or whether and how that will affect our business and results of operations in the future. If we engage more than one layer of distributors in the provinces or municipal cities that have implemented the two-invoice system, we could risk violating the relevant local regulations and may be subject to regulatory measures imposed by the relevant local government authorities. Any disruption of our distributor network, including our failure to renew our existing distribution agreements with our preferred distributors, could negatively affect our ability to effectively sell our products and would materially and adversely affect our business, results of operations and financial condition.

If our distributors fail to expand or maintain their sales network, or if we fail to educate or manage our distributors effectively, our sales may decline.

We have limited control over the operations and actions of our distributors. We rely on the distribution agreements and the policies and measures we have in place to manage our distributors, including their compliance with laws, rules, regulations and our policies. See “Business — Sales, Distribution and Marketing — Sales to Distributors.” We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors would not breach our agreements and policies. Our distributors could take actions, including one or more of the following, which could have a material adverse effect on our business, prospects and reputation:

- failing to meet the sales targets for our products in accordance with relevant agreements;
- selling products that compete with our products;

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- selling our products outside their designated territories;
- procuring sub-distributors in connection with the sales of our products;
- failing to adequately promote our products;
- failing to maintain the requisite license or otherwise failing to comply with applicable regulatory requirements when selling our products;
- failing to provide proper training and after-sales services to our end-customers; or
- violating anti-corruption, anti-bribery, sanctions, competition or other laws and regulations of China or other jurisdictions.

During the Track Record Period and up to the Latest Practicable Date, we entered into written distribution agreement with each distributor we directly worked with, which would set forth various terms and restrictions, such as designated hospitals and authorized product type. However, we historically sold our products overseas through the Retained Lepu Medical Group, who then distributed our products to sub-distributors in overseas markets. See “Business — Sales, Distribution and Marketing — Sales Arrangements.” We did not require the Retained Lepu Medical Group to seek our approval before engaging such sub-distributors. We did not engage these sub-distributors directly or maintain contractual relationships with them, and instead, mainly relied on the Retained Lepu Medical Group to manage and control such sub-distributors in accordance with regulatory requirements and our policies and measures that the Retained Lepu Medical Group agree to comply with. As a result, we had a more limited control over these sub-distributors. We cannot assure you that the sub-distributors had complied with the distribution requirements under our distribution agreements and policies. Furthermore, as there was no contractual relationship between us and these sub-distributors, we had no direct legal recourse against them if their activities caused harm to our business or reputation. 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.” We have built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution. We cannot assure you, however, that we will be successful in executing this new model in the future. Overseas distribution network is substantially different from our domestic distribution network in many ways. For instance, overseas distributors are primarily importer-distributors who have both the expertise in foreign trade and established distribution and marketing capabilities in local markets. They need to import products from us, and independently conduct promotional and sales activities tailored for the local markets. Therefore, the overseas distribution chain can be longer and more complex as compared to domestic distribution, which could lead to additional uncertainties and adversely affect our business, financial condition and results of operations. Moreover, we also face uncertainties in

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managing our distribution networks across geographical locations and in an environment of multiple languages, cultures, customs, and legal and regulatory systems, which could adversely affect distribution efficiency, which in turn could adversely affect our business, financial condition and results of operations.

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

Our sales may fail to accurately reflect the actual demand of end-customers as a result of our distribution sales model.

We typically set a sales target with our distributors, which is subject to review and amendment upon renewal of distribution agreements. The sales target serves as annual sales goals instead of strict purchase requirements. As a result, there is a risk that the products are not reaching end-customers but remain in our distributor network. We have implemented policies and measures, including close monitoring of our distributors' sales performance and inventory levels and strict product return and exchange policy, to prevent channel-stuffing of our products. However, as our control over distributors is limited, if sales to distributors were higher than actual market demand, certain distributors may decrease their order volume or cease to order additional products from us until they eventually sell the stocked products to end-customers, and as a result, our business and results of operations may be adversely affected.

Failure to effectively expand our sales and marketing capabilities could harm our ability to increase the sales of our products and achieve broader market acceptance.

In addition to the sales through our distributors, we sell our products directly to hospitals. We rely on our sales and marketing team to promote our products and communicate with hospitals and physicians. They also work closely with our research and development team to improve our existing products and introduce new products or enhancements by providing first-hand market trend and customer feedback. The success of our sales and marketing efforts depends on our ability to attract, motivate and retain qualified employees in our sales and marketing team who have, among other things, education background and work experience in the medical device industry. Furthermore, since we expect to commercialize our heart valve product candidates and launch new occluder product candidates, we expect to hire additional employees with relevant experience and knowledge to support our sales and marketing efforts. If we are unable to recruit, develop and retain qualified sales and marketing personnel, or if our new sales and marketing personnel are unable to achieve desired performance levels in a reasonable period of time, we may not be able to increase the sales of our products and achieve broader market acceptance, and our business and results of operations may be negatively affected.

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Moreover, we promote our products through academic marketing, by establishing research and clinical collaboration and training relationships with hospitals, physicians and KOLs. We cannot assure you that we will be able to maintain or strengthen our relationships with these industry participants, or that our efforts to maintain or strengthen such relationships will yield increased sales. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. In addition, we cannot assure you that our academic promotion and marketing strategy will continue to serve as an effective marketing strategy. Industry participants may no longer want to collaborate with us or attend our conferences, and our marketing strategy may no longer be able to yield larger hospital coverage or increased sales commensurate to our efforts spent. In addition, the hospitals, physicians and KOLs that we focus on may not continue to have a significant demand for our products or product candidates. If we are unable to develop new products or generate returns from our relationships with industry participants as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

Further, we historically collaborated together with the Retained Lepu Medical Group to explore sales and marketing opportunities in overseas markets. 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” for details. We have built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution. We also intend to continue integrating our domestic and overseas sales and marketing efforts. However, such integration process may take longer than expected to achieve the full effect, and our overseas sales could decline if we fail to integrate overseas sales and marketing activities in an effective and efficient manner.

We cannot guarantee that we will succeed in expanding our sales network to cover new hospitals.

We plan to expand our sales network to cover more hospitals to increase our market share and penetration in the China market to drive future growth. We may seek to expand our sales network to cover additional hospitals which have limited experience in interventional therapies involving our occluder products and heart valve product candidates and hospitals in emerging markets with relatively limited resources. This marketing strategy could require us to strengthen our sales and marketing efforts, and we may not be able to do so. If we are unable to expand our sales network effectively, our sales volumes and business prospects could be materially and adversely affected.

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We derived a majority of our revenue from the sale of CHD occluder products and occluder related procedural accessories during the Track Record Period, and we expect to continue to do so in the near future. If we are unable to manufacture or sell newly launched products or successfully commercialize our various product candidates, or if demand for these products is reduced, our revenue would significantly decline.

During the Track Record Period, we generated a majority of our revenue from the sale of CHD occluder products and occluder related procedural accessories. Our occluder related procedural accessories primarily include delivery systems and snares mainly related to CHD occluder products. Revenue generated from the sale of CHD occluder products was RMB86.7 million, RMB106.6 million, RMB132.5 million, RMB64.1 million and RMB90.7 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 74.5%, 71.9%, 59.5%, 57.8% and 72.7% of our total revenue for the same periods, respectively. Revenue generated from sales of occluder related procedural accessories was RMB28.9 million, RMB32.0 million, RMB41.6 million, RMB18.4 million and RMB27.1 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 24.8%, 21.6%, 18.7%, 16.6% and 21.7% of our revenue in the same periods, respectively. Among our CHD occluder products, revenue generated from the sale of ASD occluder products was RMB56.1 million, RMB69.7 million, RMB99.8 million, RMB47.8 million and RMB71.3 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, representing 48.1%, 47.0%, 44.8%, 43.1% and 57.1% of our revenue for the same periods, respectively. See “Financial Information — Description of Certain Consolidated Statements of Profit or Loss Items — Revenue — Major Product.” While we are dedicated to diversifying our product portfolio, prior to the broad acceptance of our newly launched products and successful commercialization of our various product candidates, we expect to continue to derive a majority of our revenue from the sale of our occluder products and occluder related procedural accessories in the near future. Continued market acceptance and demand for these products are critical to our revenue. If we are unable to manufacture or sell these products due to commercial, regulatory, intellectual property or any other reasons, or if demand for these products is reduced due to the ever-increasing competition or advances in alternative treatments or products, our revenue would significantly decline.

We are exposed to credit risk in relation to our trade and other receivables.

Our trade receivables consisted of amounts due from our third-party customers or our related-party customers. Our customers include distributors who on-sell our products to hospitals and, to a lesser extent, hospitals. We generally do not grant a credit period to our distributors, including the Retained Lepu Medical Group. Under limited circumstances, we may grant distributors who have a good track record with us a temporary credit period. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had trade receivables of RMB45.3 million, RMB38.3 million, RMB23.9 million and RMB32.9 million, respectively. In 2019, 2020, 2021 and the six months ended June 30, 2022, trade receivables turnover days were 144 days, 122 days, 64 days and 56 days, respectively. See “Financial Information — Discussion

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of Major Balance Sheet Items — Trade Receivables.” We had also recorded other receivables – net of RMB8.6 million, RMB10.7 million, RMB1.8 million and RMB18.9 million, respectively, as of December 31, 2019, 2020 and 2021 and June 30, 2022, representing other receivables due from third parties and related parties. See “Financial Information — Discussion of Major Balance Sheet Items — Prepayments and Other Receivables.”

We are exposed to the risks that our customers or other business partners may delay or even be unable to pay us in accordance with the payment terms included in our agreements in a timely manner, or at all. Although we closely monitor our outstanding trade and other receivables, we cannot assure you that we will be able to fully recover the outstanding amounts in a timely manner, or at all. In addition, as our business continues to scale up, our trade and other receivables may continue to grow, which may increase our credit risk. Any substantial delay in or default of payments from our customers and other business partners could materially and adversely affect our cash flows. Moreover, we could be required to terminate our relationship with distributors in a manner that will impair the effective distribution of our products. Any of the foregoing could materially and adversely affect our business, results of operations and financial condition.

Our failure to honor our obligations in respect of our contract liabilities may lead to our refund obligation, customer dissatisfaction, or even customer disputes with us, which may adversely affect our reputation, business, results of operations and financial condition.

Our contract liabilities consisted primarily of customers’ rights to claim for additional units, volume rebates to customers, and nonrefundable prepayment from customers. We had contract liabilities of RMB12.2 million, RMB15.3 million, RMB14.8 million and RMB14.4 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. The volume rebates are offered to our distributors who outperformed the pre-determined sales levels. The considerations for products that are used as settlement for our unsatisfied performance obligations with respect to the aforementioned claims for additional units and volume rebates have been deferred and accounted for as our contract liabilities. See Note 32 to the Accountant’s Report in Appendix I to this document. If we fail to honor such obligations, we may not be able to recognize the related revenue in a timely manner, if at all, which may adversely affect our business, results of operations and financial condition. The prepayments from customers are generally not refundable. However, if we fail to honor our obligations in respect of our contract liabilities, customers may request to cancel their agreements with us or request a partial or full refund, which may lead to our refund obligation, customer dissatisfaction or even customer disputes with us. In the event that we are required to refund some or all of the prepayments from our customers pursuant to the contract provisions, we may not have the cash or other available resources to fulfill the refund obligation. Even if we are able to fulfill the refund obligation from available resources (including potentially a portion of the net [REDACTED] of this [REDACTED]), we may need to seek additional sources of capital to fund our operations, which funding may not be available when needed or on acceptable terms, if at all. If any of the foregoing circumstances occurs, our business, results of operations, financial condition and reputation may be materially and adversely affected. Furthermore, in the future, customers may elect not to prepay us for our products, in which case

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we would have to find other sources of funding for our operations, capital expenditures and expansion plans, which would be costly as compared to the aforementioned cost-free customer prepayment funding and may not be available when needed or on acceptable terms, if at all.

The growth and success of our business depends on the performance of us and our distributors in tender processes.

Our future growth and success significantly depend on our ability to successfully market our products to hospitals. We participate in public tender processes organized by procurement platforms managed by the government agencies at provincial or municipal level to secure the right to sell our products to the hospitals in such provinces or municipalities. Our distributors do not participate in such public tender processes at the provincial or municipal level. In addition, hospitals may organize public tenders either by themselves or through local governments. The procedures of public tenders organized by hospitals vary from hospital to hospital and from region to region, and there could be uncertainties with respect to the timing of such hospital-organized public tenders. As a result, we primarily depend on experienced local distributors to assist us during such procedures. However, we may not always be able to locate a sufficient number of experienced local distributors to sell our products to hospitals.

Furthermore, even if we could locate a sufficient number of experienced distributors, our bids during the public tender process may not be successful and our products may not be chosen for a number of reasons, including where:

- our prices are not competitive;
- our products fail to meet the technical or quality requirements imposed by the hospitals or are less clinically effective than competing products;
- our reputation is adversely affected by unforeseeable events; or
- our service quality or any other aspect of our operation fails to meet the relevant requirements.

If we fail in the tender process, we may face difficulties in maintaining the existing level of sales of our products, and we may find it difficult to sell our product candidates upon commercialization and our revenue may decline, materially adversely affecting our results of operations and financial condition.

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Our sales depend to a certain extent on the level of insurance reimbursement patients receive for treatments using our products, especially, whether our products are covered in the medical insurance scheme.

Our ability to sell our products depends to a certain extent on the availability of governmental and private health insurance in China and overseas covering treatments using our products. Practice varied among provinces in the PRC for the reimbursement of interventional therapies involving our occluder products and heart valve product candidates. As the national medical insurance reimbursement system in China covers the treatment of CHD, all the occluder products and the related procedural accessories for the treatment of CHD are eligible for the medical insurance reimbursement. Accordingly, as of the Latest Practicable Date, our MemoPart[®] ASD Occluder I, MemoPart[®] VSD Occluder I, MemoPart[®] PDA Occluder I, MemoPart[®] interventional delivery system I, MemoPart[®] Snare I and interventional delivery system II were eligible for medical insurance reimbursement in all the provinces, autonomous regions and municipal cities in China. As of the same date, our MemoCarna[®] ASD Occluder III, MemoCarna[®] PDA Occluder III, MemoLefort[®] LAA Closure Occluder I, MemoCarna[®] VSD Occluder III, integrated interventional delivery system for Plug III, delivery system and interventional delivery system (biodegradable) were subject to medical insurance reimbursement in certain provinces in China. China has a complex medical insurance system which is currently undergoing reform. Governmental insurance coverage or the reimbursement rates in China for treatments using new medical devices such as our products and product candidates are subject to uncertainty and vary from region to region, as local government approvals for such coverage must be obtained in each geographic region. In addition, the PRC government may change, reduce or eliminate the governmental insurance coverage currently available for treatments using our products. See “Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — National Medical Insurance Program.”

We cannot assure you that reimbursement will be available for our products and product candidates upon commercialization and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the prices of our products. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with newly introduced technologies and medical devices. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize the product candidates that we successfully develop.

In the absence of sufficient medical insurance coverage for the use of our products, patients may choose alternative treatment methods, such as open-chest surgeries and drug treatment, and hospitals may recommend such alternative treatments, which would reduce demand for our products and in turn materially and adversely affect our business, results of operations and financial condition. Moreover, we may need to lower the prices of our products in order to have them included in the medical insurance reimbursement list, and such price cut and reimbursement may not necessarily lead to increase in our sales and our results of operations may be adversely affected.

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Lack of sufficient sophisticated physicians that can perform interventional therapies involving our occluder products and heart valve product candidates may adversely affect our business.

Sophisticated physicians that can perform interventional therapies involving our occluder products and heart valve product candidates play a significant role in our business. We involve physicians in our product development stage and solicit their feedback, proposals and suggestions based on their clinical experience. We also rely on influential physicians to endorse the quality of our products and promote their use among hospitals. Additionally, sales volume of our products is largely determined by the number of interventional therapies involving our occluder products and heart valve product candidates performed, and physicians’ performance is key to ensuring the proper implantation and function of our products in human bodies. However, interventional therapies are at a relatively early stage of implementation in China, with qualified physicians primarily employed by Class III hospitals. If the market acceptance of related procedures and the number of qualified physicians fail to grow as expected, our research and development efforts and sales of our products could be adversely affected.

Risks Relating to Research and Development

Our future growth depends substantially on the success of our product candidates.

Our ability to generate revenue from our product candidates and improve profitability in the future substantially depends on our ability to complete the development of our product candidates, obtain the requisite regulatory approvals and successfully commercialize our approved products in a timely manner. 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. We have invested a significant portion of our efforts and financial resources in the development of our existing product candidates. For 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. See “Financial Information — Description of Certain Consolidated Statements of Profit or Loss Items — Research and Development Expenses.” We expect to continue to incur substantial and increasing expenses in developing, registering and commercializing our product candidates. Whether we can generate profit from our research and development activities depends on the successful commercialization of our product candidates, which in turn depends on a variety of facts, including but not limited to:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals;

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- establishment of commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with suppliers;
- ability of our CROs to conduct or assist in conducting our clinical trials safely and efficiently and in accordance with our specified trial protocols;
- performance by any other third party we may retain in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- receipt and maintenance of patent, trade secret and other intellectual property protection and regulatory exclusivity;
- prevention of infringement, misappropriation or other violation of the patent, trade secret or other intellectual property rights of third parties;
- required marketing authorizations and commercial sales launch in China and other targeted markets, if and when approved;
- favorable governmental and private medical reimbursement for our products, if and when approved;
- appropriate pricing of our product candidates and timely collection of payments;
- competition with other occluder products and heart valve products; and
- continued acceptable safety profile following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to obtain approval for our product candidates, and/or to successfully commercialize our approved products, which would materially harm our business and we may not be able to generate sufficient revenue and cash flows to continue our operations.

Clinical development involves lengthy and expensive process with uncertain outcomes.

All of our products and product candidates are classified as Class III medical devices pursuant to a catalogue issued by the NMPA, which involve the highest degree of associated risks and therefore are subject to the largest extent of regulatory control to ensure safety and effectiveness. To obtain product registrations for medical devices of Class III in China, we may need to conduct, at our own expense, adequate and well-controlled clinical trials to demonstrate the safety and efficacy of our products.

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Clinical testing is expensive and can take several years to finish, and its outcome is inherently uncertain. Failures can occur at any stage of the clinical trial process, and clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. We cannot assure you that these trials or procedures can be completed in a timely or cost-effective manner or result in commercially viable products. We may experience numerous unexpected events before and during the clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including but not limited to:

- regulators, institutional review boards or ethics committees may not authorize us or our clinical trial site investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our product candidates may have undesirable side effects, produce negative or inconclusive results, or other unexpected characteristics, and we may decide, or regulators may require us, to conduct additional clinical trials, or even suspend or terminate the product development programs;
- the initial or interim results of clinical trials may not be predictive of the final clinical trial results and may be subject to adjustments;
- the number of patients required for clinical trials of our product candidates may be larger than anticipated;
- we may not be able to reach agreements on acceptable terms with prospective CROs, which can be subject to extensive negotiation and may vary significantly among different CROs;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to delay, suspend or terminate clinical trials of our product candidates for various reasons, many of which are beyond our control, including a finding of lack of clinical response or other unexpected characteristics, a finding that participants are being exposed to unacceptable health risks such as the outbreak of COVID-19;
- regulators or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or the quality may be inadequate.

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In addition, changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Any delay in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenue for that candidate. Any of these occurrences may materially and adversely affect our business, results of operations, financial condition and prospects.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in a timely manner or at all, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

The results of preclinical studies and feasibility clinical trial of our product candidates may not be predictive of the results of confirmatory clinical trial. Product candidates in confirmatory clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and/or feasibility clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in the protocols, and differences in physical conditions of the patient population. We cannot assure that future clinical trial results of our product candidates can lead to favorable results. Even if our future clinical trial results show favorable efficacy, there is a possibility that certain of our product candidates may not suit the conditions of certain patients, and severe adverse events and complications may occur for some patients after the procedure.

If we are required by competent government authorities, such as the NMPA, to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be subject to substantial liabilities;
- be delayed in obtaining regulatory approval for our product candidates, or not be able to obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended, with additional pre-requisites;
- have the product removed from the market after obtaining regulatory approval;

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- be subject to additional post-market study and testing requirements;
- be subject to restrictions on how the product is distributed or used;
- be unable to obtain reimbursement for use of the product; or
- be inferior to products of competitors when being selected by physicians and hospitals.

Any of such events could materially and adversely affect our ability to commercialize the subject product candidates.

We rely on the Entrustment Arrangements to exercise control over the Entrusted Products. Ineffective implementation of the Entrustment Arrangements due to factors beyond our control may adversely affect our business and results of operations.

As part of the Reorganization, we entered into an asset transfer agreement with Lepu Medical in January 2021 whereby the interventional heart valve business of Lepu Medical was injected into our Group to solidify our position as the sole platform under Lepu Medical Group focusing on interventional medical devices primarily targeting structural heart diseases. Among the product candidates under the injected interventional heart valve business, the key research and development work including type inspections and animal tests of certain heart valve product candidates (i.e., the Entrusted Products) had been conducted under the name of Lepu Medical prior to the business injection. Taking into account the Entrusted Products Regulatory Restrictions and for the purpose of maintaining a clear business delineation between our Group and the Retained Lepu Medical Group in interventional heart valve business subsequent to the business injection, we have entered into the Entrustment Arrangements with Lepu Medical as detailed in “Business — Our Products — Heart Valve Product Candidates — Entrusted Products.”

The Entrustment Arrangements were devised for us to gain control of the Entrusted Products to the greatest extent possible under the prevailing regulatory framework and restrictions. On March 11, 2022, the NMPA amended the Catalogue of Medical Device Prohibited from Entrusted Production (《禁止委託生產醫療器械目錄》) (the “Prohibited Catalogue”). According to the Prohibited Catalogue, which became executive on May 1, 2022, Lepu Medical as the medical device registrant would be prohibited from authorizing us to manufacture TAVR system and TMVCRS and they would conduct the manufacturing of such products pursuant to the Entrustment Arrangements. Nevertheless, as Lepu Medical has irrevocably and exclusively authorized us to carry out commercialization and sales activities for each of the Entrusted Products, our interests under the Entrustment Arrangements would not be materially and adversely affected as a result of the Prohibited Catalogue. However, the interpretation and implementation of the prevailing laws and regulations are subject to discretion of government authorities and involve uncertainties which may not be favorable to

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us, and we cannot assure you that there will not be any unfavorable regulations promulgated in the future which may lead to stricter or additional regulatory restrictions applicable to the Entrusted Products as compared to the currently prevailing Entrusted Products Regulatory Restrictions. As a result, we may have to renegotiate with Lepu Medical or we may be prevented from exerting effective control over the Entrusted Products. Furthermore, Lepu Medical, being one of our Controlling Shareholders, has substantial influence over us and conflicts of interest may arise between Lepu Medical and us as further elaborated in “— 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.” There can be no assurance that we will be able to maintain a cooperative relationship with Lepu Medical in effecting the Entrustment Arrangements pursuant to the terms of the asset transfer agreement in the future. Any such ineffective implementation of the Entrustment Arrangements due to factors beyond our control could result in additional costs and diversion of our management’s attention and resources, thereby adversely affecting our business and results of operations.

We rely on third parties to conduct certain aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to successfully register our product candidates and our business could be substantially harmed.

As a common practice in our industry, we have engaged and plan to continue to engage third parties, including leading academic institutions, hospitals, clinics, experienced physicians, and/or CROs, to assist us in designing, implementing and monitoring our pre-clinical research and conducting clinical trials. If we are unable to maintain or enter into agreements with these third parties on favorable terms to us, or if any such engagement with us is terminated, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate, and the development of our product candidates covered by such agreements could be substantially delayed.

In addition, our reliance on third parties would cause us to have less control over the quality, timing and cost of our pre-clinical research and clinical trials than if we conducted these procedures entirely by ourselves. We cannot guarantee that these third parties would devote adequate time and resources to our studies or perform as required under their contractual obligations, adhere to our protocols, act in accordance with regulatory requirements, meet expected deadlines, or timely transfer to us any regulatory information. If such third parties with which we contract for pre-clinical research and clinical trials perform in a sub-standard manner or in a manner that compromises the quality and/or accuracy of their activities and/or the data they obtain, the pre-clinical research and clinical trials of our product candidates may be extended, delayed or terminated, our data generated from such studies may be rejected by applicable regulatory authorities, and the costs in developing relevant product candidates may be increased. As a result, we may be unable to develop and successfully commercialize our product candidates as anticipated, which would have a material adverse effect on our business and prospects.

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If we encounter difficulties or delays in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in line with their respective protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population, the patient eligibility criteria defined in the protocols, the size of the study population required for analysis of the trial’s primary endpoints, the accessibility of trial sites for the patients, the design of the trial, our ability to recruit clinical trial site investigators with competence and relevant experience, the patients’ perceptions as to the potential advantages and side effects of the product candidates being studied in relation to other available products, product candidates or therapies, and the risk that patients enrolled in clinical trials may drop out or fail to return for post-treatment follow-ups at a higher rate than anticipated.

Our clinical trials will likely compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition will reduce the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development and timely commercialization of our product candidates. If we experience delays in the completion of, or even termination of, any clinical trial of our product candidates, our ability to obtain requisite regulatory approvals and then commercialize our products will be delayed. In addition, any delay in completing our clinical trials will increase our costs, slow down our development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may have a material adverse effect our business, results of operations, financial condition and prospects.

We may not be able to develop new products that are competitive in the market, or in a timely manner or at all.

The interventional medical device market targeting structural heart diseases is competitive in China. Our success depends on our ability to anticipate industry trends and continuously identify, develop and market in a timely manner new and advanced products that meet the demand of our customers. We expect the markets for occluder products and heart valve products to evolve towards newer and more advanced products, some of which we do not currently produce. Developing new products in a timely manner can be difficult, particularly because product designs can change with market conditions and hospitals’ and physicians’ preferences. Our research and development efforts may not lead to new products that will be

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commercially successful. We may also experience delays or be unsuccessful in any stage of product development, manufacturing, clinical trials, product registration, marketing or pricing. Even if we are able to launch new products, it takes time for the new products to gain market acceptance. We may not be able to successfully market our new products or our end customers may not be receptive to our new products.

The success of any of our new product offerings will depend on several factors, including our ability to:

- properly identify and anticipate industry trends and market demand;
- complete product development process successfully in a timely manner;
- optimize our manufacturing and procurement processes to predict and control costs;
- manufacture and deliver new products in a timely manner;
- minimize the time and costs required to obtain required regulatory approvals;
- anticipate and compete effectively with other medical device developers, manufacturers and marketers;
- price our new products at both competitive and commercially justifiable levels; and
- increase end-customer awareness and acceptance of our new products.

If we are not successful in producing or selling our new products to meet market demand, or if there is insufficient demand for our new products once they are introduced to the market, our business, results of operations, financial condition and prospects could be materially and adversely affected.

We may not be successful in developing, enhancing or adapting to new technologies and methodologies.

We must keep pace with new technologies and methodologies to maintain our competitive position. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We intend to continue to enhance our technical capabilities in research, development and manufacturing, which are capital- and time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so could harm our business and prospects.

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Risks Relating to Manufacture and Supply

The manufacturing of our products is highly complex and subject to strict quality controls. Our business could be materially and adversely affected if our products and product candidates are not produced in compliance with all the applicable quality standards.

The manufacturing of our products is highly complex and subject to strict quality controls. In addition, quality is extremely important in our industry due to the serious and costly consequences of a product failure. We have established a comprehensive set quality control and assurance procedures in order to prevent quality issues with respect to our products and operation process. See “Business — Quality Control.” Despite our quality control procedures, we cannot eliminate the risk of product defects or failures. Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, defects or other issues in raw materials, or human errors. If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, damages to customer relationship, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

Furthermore, if contaminants are discovered in our supply of our products or product candidates or in the production facilities, such production facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Stability failures and other issues relating to the manufacturing of our products or product candidates could occur in the future. Although closely managed, disruptions can occur during implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions. In addition, as we expand into new markets, we may face unanticipated surges in demands for our products which could strain our production capacity.

If any of the foregoing arises or if we otherwise fail to meet our internal quality standards or those of the NMPA or other applicable regulatory bodies, which include detailed record-keeping requirements, we could become subject to safety alerts, product recalls, license revocation, regulatory fines, product liability claims or other negative effects, which could materially and adversely affect our reputation, business and results of operations.

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We primarily rely on our production facilities in Shanghai to manufacture our products and product candidates. Any disruption to the operation of our production facilities could materially adversely affect our business, results of operations and financial condition.

We manufacture our products and product candidates primarily at our production facilities located in Shanghai. Our facilities may be harmed or rendered inoperable by physical damage from fires, floods, earthquakes, typhoons, power outages, mechanical breakdowns, telecommunications failures, loss of licenses, certifications and permits, changes in governmental planning for the land underlying the facility, and regulatory changes, many of which are beyond our control. Any substantial interruption in manufacturing operations at our production facilities could result in our inability to satisfy the demands of sales and distribution as to our products and of our clinical trials as to our product candidates, or even lead to our failure to fulfill contractual obligations, which could in turn materially and adversely affect our business, results of operations and financial condition.

Advances in manufacturing techniques may render our facility and equipment inadequate or obsolete, and therefore we may also need to develop advanced manufacturing techniques and process controls in order to fully utilize our facilities. If we are unable to do so, if the process to do so is delayed, or if the cost of this scale-up is not economically feasible for us, we may not be able to supply our products in a sufficient quantity to meet future demand, which would limit our development and commercialization activities and our opportunities for growth.

We rely on a limited number of suppliers, and may not be able to secure a stable supply of qualified raw materials at all times or at all.

Principal raw materials for our products are nitinol materials, animal source materials, polymer materials, and sheathes and other metal components. We only procure raw materials from select suppliers that can satisfy our technical specifications and regulatory compliance requirements to ensure the consistently high quality and performance of our products. In order to acquire raw materials in high quality, we currently rely on a limited number of select third-party suppliers to supply raw materials used in our research, development and manufacturing. Although we believe that we have stable and long-term relationship with our existing suppliers and we have maintained a list of qualified suppliers, we cannot assure you that we will be able to secure a stable supply of qualified raw materials at all times going forward. Further, the custom clearance procedures for importing raw materials could be lengthy and thus could adversely affect the timely supply of such raw materials. If any of these suppliers loses its qualification or eligibility for a variety of reasons including its failure to comply with regulatory requirements, or if we encounter lengthy custom clearance procedures to import certain of our raw materials, we may experience delays in the supply of our raw materials and interruption in our manufacturing process.

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General economic conditions could also adversely affect the financial viability of our suppliers, resulting in their inability to provide raw materials used in our manufacturing process. In addition, some of our suppliers are located outside China, and therefore trade or regulatory embargoes imposed by foreign countries or China, especially in light of recent international trade disputes between China and the United States, could result in delays or shortages of our raw materials sourced overseas. See “— Risks Relating to Our Operations — Changes in international trade policies and trade barriers, or the escalation of trade tensions, may have an adverse effect on our business.” If we are unable to identify alternative suppliers or raw materials and secure approval for their use in a timely manner, our business could be materially and adversely affected.

An increase in the market price of our raw materials and components may adversely affect our profitability.

Our production process requires substantial amounts of raw materials and components. We are exposed to risks associated with fluctuations in prices and availability of raw materials. Significant fluctuations in raw material and component prices and availability could disrupt our operations and have a negative impact on our gross margin. During the Track Record Period, the supply of principal raw materials used in our product activities was generally available and sufficient for our demand, and their prices from our suppliers were generally stable. However, we cannot assure you that this will continue to be the case in the future. The prices of raw materials may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, duties and tariffs, natural disasters, disease outbreaks and general economic conditions. A significant increase in the costs of raw materials may increase our cost of sales and negatively affect our profit margins and, more generally, our business, results of operation, financial conditions and prospects.

Failure to manage our inventory effectively would materially and adversely affect our results of operations, financial condition and cash flows.

Our inventory consists of raw materials, and work-in-progress and finished goods. To operate our business successfully and meet our customers’ demands and expectations, we must manage our inventory effectively to ensure immediate delivery when required. We regularly monitor our inventory to ensure timely supply and reduce the risk of overstocking. We maintain our inventory levels based on our internal forecasts which are inherently uncertain. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had inventories of RMB11.1 million, RMB23.3 million, RMB33.4 million and RMB40.3 million, respectively. In 2019, 2020, 2021 and the six months ended June 30, 2022, our inventory turnover days were 277 days, 414 days, 413 days and 435 days, respectively. See “Financial Information — Discussion of Major Balance Sheet Items — Inventories.” We may be exposed to increased inventory risks due to accumulated excess inventory of our products or raw materials, some of which are subject to expiration. Excess inventory levels may increase our inventory holding costs, obsolescence risks or potential impairment loss. On the other hand, if our forecasted demand is lower than actual level, we may not be able to maintain an adequate inventory level of our products or manufacture our products in a timely manner, and may lose sales and market share to our competitors.

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Furthermore, as we will not be able to recoup our cash paid for raw materials during the production process until the finished products are sold to customers and the purchase price is settled, our business is subject to significant working capital requirements given the high inventory level and inventory turnover days. If our inventory level increases substantially in the future, our financial condition and cash flows could be materially and adversely affected.

If we fail to implement our expansion plan as planned, or our expansion plan fails to achieve expected benefits, our business and prospects could be materially and adversely affected.

We plan to enhance the production capacity for our marketed products. We also intend to install several new product lines, including production lines for biodegradable occluder product and product candidates and heart valve product candidates. See “Business — Growth Strategies — Expand our production capabilities to support future growth.” However, we cannot assure you that our expansion plan will be successfully implemented without delays or at all. Our ability to successfully implement our expansion plan is subject to a number of factors. New manufacturing facilities may require prior review by regulatory authorities and/or approval of the manufacturing process and procedures in accordance with applicable requirements. This review may be costly and time-consuming and could delay or halt the launch of our products. The new facilities will also be subject to pre-approval inspection. In addition, we have to demonstrate that the products made at the new facilities are equivalent to or not worse than the products made at the former facilities by verification methods, which are costly and time consuming. Regulatory authorities may also require clinical testing as a way to prove equivalency, which would result in additional costs and delays. In addition, we may not be able to timely recruit sufficient qualified staff to support the increase in production capacity.

Any failure or delay in implementing any part of our expansion plan may result in a lack of production capacity to support our growth and market expansion, which in turn could adversely affect our business, results of operations and financial condition. Moreover, our plans to increase our production capacity require significant capital investment, and the actual costs of our expansion plan may exceed our original estimates, which could materially and adversely affect the realization of expected return on our expenditures. In addition, if we fail to fully utilize the additional production capacity due to any adverse change to the market environment, technologies, relevant policies during the implementation of projects, our business, results of operations and financial condition could be materially and adversely affected.

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Risks Relating to Extensive Government Regulations

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

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

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

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 are required to complete regulatory filings or obtain registration certificates for our products from the NMPA or its local regulatory branches or from the competent regulatory authorities in other jurisdictions where we sell our products. In China, medical devices are classified into Class I, Class II and Class III depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. All of our products and product candidates are or are designed to be Class III medical devices, which are subject to the most strict registration requirements among all classes. According to applicable regulations, Class III medical devices shall be examined by the NMPA, which will issue registration certificates upon approval. In order to obtain such registration certificates, Class III medical devices are required to undergo clinical trials, unless they are exempted from clinical trials under the Catalogues of Medical Device Exempted from Clinical Trials promulgated by the NMPA from time to time. See “Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Registration and Filings of Medical Device Products.” For risks relating to clinical trials, see “— Risks Relating to Research and Development — Clinical development involves lengthy and expensive process with uncertain outcomes.” The registration process can be lengthy, costly and unpredictable. Our product candidates could fail to obtain regulatory approval for numerous reasons, including:

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

In addition, the time required to obtain approval from the regulatory authorities is unpredictable but typically takes years following the commencement of pre-clinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. As of the Latest Practicable Date, two of our product candidates were undergoing regulatory approval process in China. It is possible that none of our existing product candidates or any product candidate we may discover, in-license or acquire and seek to develop in the future will ever obtain such approval.

Furthermore, regulatory authorities outside of China also have requirements for approval of medical devices for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products and product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. The foreign regulatory approval process may include all of the risks associated with obtaining NMPA approval. For these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

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Moreover, 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. In addition, 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 obtained a total of 14 NMPA registration certificates for Class III medical devices and valid CE Marks for nine of our products. The renewal process with the NMPA normally takes two to five months, while the CE Mark renewal process generally takes one to two years. When deciding whether or not to grant renewal, the NMPA or its local branches usually focuses on, among other things, whether the product conforms to latest applicable standards or quality requirements. If the NMPA or its local branches decide not to grant the renewal of our registration certificates, we will not be able to continue to manufacture and sell the relevant products, which would have a material and adverse effect on our business, financial condition and results of operations. Furthermore, our existing CE Marks were granted in April 2021 pursuant to the Medical Device Directive of the European Union (the “MDD”) 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. Compared with the MDD, the MDR has elevated the standards on quality and safety measures and imposed additional continuous compliance requirements on medical device providers. If we fail to renew or obtain CE Marks under the new MDR standards, our overseas product sales would be materially and adversely affected.

We may not be able to obtain, maintain or renew all the permits, licenses and certificates required for our business and operations.

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products in China or export our products outside of China, including but not limited to the Medical Device Registration Certificate (醫療器械註冊證), the Medical Device Production Permit (醫療器械生產許可證), the Medical Device Operation Permit (醫療器械經營許可證) and the Medical Device Export Certificate (醫療器械產品出口銷售證明). We are also required to obtain requisite licenses, approvals and certificates to sell our products in relevant overseas jurisdictions. For details, see “Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices” and “Business — Licenses, Permits and Approvals.”

Such permits, licenses and certificates are subject to periodic reviews and renewals by the relevant government authorities, and the standards of such reviews and renewals may change from time to time. We cannot assure you that the relevant authorities will approve our renewal applications in the future. Any failure by us to obtain the necessary permits, licenses and certificates, or procure such renewals and otherwise maintain all the licenses, permits and certificates required for our business at any time could disrupt our business, which could have a material adverse effect on our business, results of operations and financial condition. In addition, the regulatory framework for the medical device industry in China has undergone significant changes, including, with respect to quality control, supply, pricing and tender process for medical devices. We cannot predict the likelihood, nature or extent of regulatory

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changes that may arise from existing or future legislation in China. If, as a result of any change in the interpretation of existing laws and regulations or the promulgation and implementation of new laws and regulations, we are required to obtain additional permits, licenses or certificates for our operations involving our products and product candidates, we cannot assure you that we will be successful in obtaining these permits, licenses or certificates in a timely manner, or at all. Such changes may also result in increased compliance costs, prevent our successful development, manufacture or commercialization of products in China, or adversely affect our ability to export our products overseas which would adversely affect our business, financial condition and results of operations.

We may not be able to comply with ongoing regulatory obligations which may result in withdrawal of approvals for our products.

Our products and any additional product candidate that are approved by the regulators are and will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging storage, advertising, promotion, sampling, record-keeping, post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China and other applicable jurisdictions where the products are approved. For example, manufacturers and manufacturers' facilities are required to comply with extensive regulatory requirements from the NMPA and/or other comparable authorities. As such, we are and will be subject to continual review and inspections by the regulators in order to assess our compliance with applicable laws and requirements and adherence to commitments we made in any application materials with the NMPA or other authorities. Further, the regulatory approvals for our products and any approval that we expect to receive for our product candidates are and may be subject to limitations on the indicated uses for which our product may be marketed. Products may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The approvals we obtain may also be subject to other conditions which may require potentially costly post-market testing and surveillance to monitor the safety and efficacy of our products or product candidates upon commercialization. Such limitations and conditions could adversely affect the commercial potential of our products and product candidates.

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

- restrictions on the marketing or manufacturing of our products, withdrawal of the relevant products from the market, or voluntary or mandatory product recalls;

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- fines, warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, suspension or revocation of license approvals or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our products and product candidates; and/or
- injunctions or the imposition of civil or criminal penalties.

We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or overseas, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained, which could materially and adversely affect our business and prospects.

We may be subject, directly or indirectly, to applicable anti-kickback laws, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Hospitals and physicians play a primary role in the recommendation and prescription of any product for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback laws, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China, including, without limitation, the Criminal Law of the PRC, the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and the Administrative Measures for the Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》). These laws may impact, among other things, our proposed sales and marketing programs. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC government.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws

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and regulations. If any such action is instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our business and our results of operations. In addition, we are subject to equivalents of each of the healthcare laws described above in other jurisdictions, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. There are ambiguities as to what is required to comply with these requirements, and if we fail to comply with an applicable law requirement, we could be subject to penalties.

If any of the physicians or other providers or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, results of operations and financial condition. We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees or other third parties.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, results of operations and financial condition. We are subject to the anti-bribery laws of various jurisdictions, particularly in China, that generally prohibits companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, such as related onboard and on-going training sessions, we cannot assure you that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities we acquire. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, results of operations, financial condition and liquidity. We could also be adversely affected by any allegation that we violate such laws.

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

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

We receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the patients enrolled in our clinical trials and post-commercialization clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement actions against us, fines, imprisonment of company officers, public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, results of operations, financial condition or prospects.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled patients and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the patients' private or medical records without their consent, they will be held liable for damage caused thereby. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. While we have adopted security policies and measures to protect our proprietary data and patients' privacy, privacy leakage incidents might not be avoided due to hacking, human error, employee misconduct or negligence or system breakdown. We also cooperate with third parties including hospitals, CROs and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. In particular, certain industry-specific laws and regulations may affect the collection and transfer of personal data in China, including the Interim Measures for the

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Administration of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) and the implementation guidelines issued by the Ministry of Science and Technology and Ministry of Health. For details, see “Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — Sampling and Collecting Human Genetic Resources Filing.” It is possible that these laws and regulations may be interpreted and applied in a manner inconsistent with our clinical trial practices, potentially resulting in confiscation of human genetic resource samples and associated data as well as administrative fines. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security and transfer may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damages. Any of the foregoing could have a material adverse effect on our competitive position, business, results of operations, financial conditions and prospects.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or manufacturing activities. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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Risks Relating to Our Intellectual Properties

If we are unable to obtain and maintain patent protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends, in large part, on our ability to protect our proprietary technologies, products and product candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technologies, products and product candidates that we consider commercially important by filing patent applications in China and other countries, relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file, prosecute or maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. We cannot be certain that patents will be issued or granted with respect to our patent applications that are currently pending, or that issued or granted patents will not later be found to be invalid and/or unenforceable, be interpreted in a manner that does not adequately protect our product candidates, or otherwise provide us with any competitive advantage. As a result, we may not be able to prevent competitors from developing and commercializing competing products in all such fields and territories.

A patent may be invalidated or found unenforceable, and a patent application may not be granted for a number of reasons, including known or unknown prior deficiencies in the patent application or the lack of novelty or inventive step of the underlying invention or technology that is claimed in the patent application. We may also fail to identify patentable aspects of our research and development output in time to obtain patent protection. Moreover, the patent position of medical devices companies is generally uncertain because it involves complex legal and factual considerations. Patent applications we have filed may not be granted in the end. As such, we do not know the degree of future protection that we will have on our products and technologies, if any, and a failure to obtain adequate intellectual property protection with respect to our technologies, products and product candidates could have a material adverse impact on our business.

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

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The issuance of a patent is not conclusive as to its inventor, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in China and other countries. We may be subject to a third-party pre-issuance submission of prior art to the CNIPA or other patent offices, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technologies, products or product candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products and product candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the CNIPA or other patent offices to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or found unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies, products and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and senior management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords is limited. We may face competition for any approved product candidates even if we successfully obtain patent protection once the patent term has expired for the product. The issued patents and pending patent applications, if issued, for our products and product candidates are expected to expire on various dates as described in “Appendix VII — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights of Our Group” to this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, a limited number of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent

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applications, such co-owners may be able to license, without accounting to us, their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, results of operations, financial conditions and prospects.

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

Filing, prosecuting, maintaining and defending patents on products and product candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength from those in some other countries. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as the laws of certain other countries do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing medical products made using our patented technologies or inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to certain jurisdictions where we have patent protection but where enforcement rights are not as strong as those in certain other countries. These products may compete with our products and product candidates, and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing with us.

As of the Latest Practicable Date, we owned 232 registered patents and had 51 pending patent applications in China. To facilitate our strategy to enter overseas market, we also had 14 pending patent applications in the United States and the European Union. The research and development of substantially all of the patents that we owned or applied for relied on our internal efforts. The 232 registered patents in China will expire in accordance with the stipulations in the patent registrations. See “Appendix VII — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights of Our Group.” Following the expiration, we may lose the statutory protection and cannot prevent third parties from exploiting such technology and developing and commercializing competing medical devices embodying such technology in the relevant fields or territories. In addition, as of the Latest Practicable Date, we also owned 41 trademarks in China and four trademarks in Hong Kong. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

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Many companies have encountered significant problems in protecting and defending intellectual property rights in countries such as China. The legal system in these countries could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights in these countries. Proceedings to enforce our intellectual property and proprietary rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful. Our patent rights relating to our products and product candidates could be found invalid or unenforceable if being challenged.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Third parties may also raise similar claims before administrative bodies in China or abroad, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our products or product candidates. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property rights. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, found unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any intellectual property disputes or infringement claims which had, or were likely to have any material adverse impact on our Group. However, we may be subject to intellectual property disputes and infringement claims in the ordinary course of business. If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing or commercializing one or more of our product candidates or products in additional jurisdictions. Defense of these claims, regardless of their merit, would incur substantial litigation expenses

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and would substantially divert resources from our business. In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, in the case of willful infringement, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our development or allow commercialization of our product candidates or products in additional jurisdictions. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further develop or commercialize one or more of our product candidates or products in additional jurisdictions, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if our Shareholders perceive these results to be negative, this could have a substantial adverse effect on the [REDACTED] of our H Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the CNIPA and other patent agencies in several stages over the lifetime of the patent. The CNIPA and various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other requirements or duties during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to office actions or examination reports within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. We are not aware of any material non-compliance events during the Track Record Period and up to the Latest Practicable Date. We cannot assume you that any such event will not occur in the future, in which case, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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We may face intellectual property disputes with our business partners.

We may face intellectual property disputes with our business partners. We may from time to time establish or seek strategic alliances that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop and we will seek to enjoy the intellectual property rights through intellectual property delegation, joint intellectual property application or in-licensing arrangements. As of the Latest Practicable Date, we had collaborated with several hospitals and research institutions in China, such as Fuwai Yunnan Cardiovascular Hospital (雲南省阜外心血管病醫院) and the National Engineering Research Center for Biomaterials (國家生物醫學材料工程技術研究中心). We cannot assure that we will not be subject to intellectual property claims brought by our business partners or any third party. We may be subject to injunctions, damages or other reliefs if such claims are successful, which could prevent us from developing and commercializing related product candidates.

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

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technologies and other proprietary information, to maintain our competitive position and to protect our products and product candidates. We seek to protect these trade secrets, in part, by entering into confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, and third parties involved in our research and development activities. We are not aware of any breach or unauthorized disclosure by such parties that had a material adverse effect on our business during the Track Record Period and up to the Latest Practicable Date. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Proving or enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using our trade secrets to compete with us and our competitive position would be compromised. Furthermore, many of our employees, including our senior management, were previously employed at other medical device companies, including our competitors or potential competitors. Some of these employees, including one of our senior management, are subject to proprietary rights, non-disclosure and non-competition obligations in connection with such previous employment. Although we try to ensure that our employees do not use or disclose the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee’s former employer. We are not aware of any material threatened or pending claims related to these matters or concerning the

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agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract our management's attention.

In addition, while we have detailed protocols governing our employees' service inventions and typically require third-party collaborators involved in the development of intellectual property to execute agreements assigning such intellectual property to us at the project proposal and approval stage, we may be unsuccessful in executing such an agreement with each party which in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and distract the attention of our management and scientific personnel.

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

The scope of patent protection in various jurisdictions is uncertain. Changes in either the patent laws, implementing rules and regulations, or their interpretation in China or other countries may diminish our ability to protect our inventions and to obtain, maintain, defend and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing or may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any future granted patents will provide sufficient protection from competitors. The claim scope in a patent application can be significantly reduced before the patent application issues into a patent, and the claim scope can still be reinterpreted after patent issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to uncertainties, and any result unfavorable to us could have a material adverse effect on our business, results of operations, financial condition and prospects.

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Risks Relating to Our Operations

Our future success depends on our ability to retain key executives and to attract, retain and motivate other qualified and highly skilled personnel, and we may experience labor shortages or increases in labor costs.

Our success and future growth depend largely upon the continued services of key executives and other key employees, such as qualified and highly skilled research and development, manufacturing and production, and sales and marketing personnel. We cannot assure you that these key personnel will not voluntarily terminate employment with us. If one or more of our key personnel are unable or unwilling to continue in their present positions, we may not be able to replace them easily or at all and may incur additional expenses to recruit and train new personnel. Experienced personnel in the interventional medical device market targeting structural heart diseases is in high demand, and competition for relevant talents is intense. Many of the companies with which we compete for experienced personnel have greater resources than we have. We cannot assure you that we will be able to maintain an adequate skilled labor force necessary for us to execute our business, nor can we guarantee that we will not incur significant expense as a result of our continued efforts to attract and retain talent in a labor market with a shortage in the supply of skilled personnel. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth could be adversely affected. 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. See “History, Reorganization and Corporate Structure — Our Corporate Development — Business Injection.” We will continue to utilize our established sales force and sales network for occluder business to promote our heart valve business. The viability of our heart valve business is highly relied upon the contribution of our heart valve research and development personnel, especially Ms. Zhang Yuxin, our executive Director, deputy general manager and chief technology officer, and the efforts by our sales and marketing team upon commercialization. The loss of services of any of these personnel could impede the achievement of our research, development and commercialization objectives for heart valve product candidates.

In addition, if any of our executive officers or key employees joins a competitor or forms a competing company, we may face the risks of losing know-how, trade secrets, suppliers, customers and other business partners. We enter into standard confidentiality agreements with all of our full-time employees, which also contain non-compete provisions. Although non-compete agreements are generally enforceable under PRC laws, PRC legal practice regarding the enforceability of such agreements is not as well developed as in countries such as the United States. As a result, we cannot assure you that a PRC court would enforce the non-compete agreements. Moreover, to retain valuable employees, in addition to offering competitive compensation packages, we provide them with well-structured training resources and learning opportunities. These and other measures we have adopted or may adopt in the

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future may lead to increased labor costs and operating and other expenses, and may not be sufficient to counteract more lucrative offers from our competitors. In line with industry practice, we do not maintain key man life insurance for any of our executives, including Ms. Zhang Yuxin, which is not mandatory under PRC laws. If any of them leaves us for any reason, our business and prospects may be materially and adversely affected. We may experience labor shortages, and our business and competitive position would be harmed, which could have a material adverse effect on our results of operations and prospects.

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

Some of our products and product candidates are considered as emerging and relatively novel therapeutics, and may cause unintended or undesirable severe adverse events as a result of a number of factors, many of which are beyond our control. These factors include potential complications not revealed in clinical trials, side effects in isolated cases, defective products not detected by our quality control measures or misuse of our products. Our products and product candidates may also be perceived to cause adverse events when a conclusive determination as to the cause of the adverse events is not obtained or is unobtainable. In addition, our products and product candidates may be perceived to cause severe adverse events if one or more regulators, determine that other companies’ products containing the same or similar key parts or using the same delivery technologies as our products or product candidates cause or are perceived to have caused severe adverse events.

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

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

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Moreover, if our product candidates cause, or are perceived to cause, severe adverse events, it could cause us or regulatory authorities to interrupt, delay or halt clinical trials, affect patient recruitment or the ability of enrolled patients to complete the trial, adversely impact our ability to obtain regulatory approval in China and other jurisdictions where we may seek to commercialize our products, and/or subject us to product liability claims as well as substantial liabilities. Any of the foregoing could materially and adversely affect our reputation and business operations and prospects.

We may be exposed to potential product liability claims and product recalls, and our insurance coverage may be inadequate to protect us from all the liabilities we may incur.

We face an inherent risk of product liability as a result of the commercialization of our products and the clinical testing and any future commercialization of our product candidates. For example, we may be sued if our products or product candidates cause or are perceived to cause injuries or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Such product liability claims may include allegations of defects in manufacturing, defects in design, failure to warn of dangers inherent in the medical device product, negligence, strict liability or breach of warranties. Claims could also be asserted under applicable consumer protection acts. If we cannot successfully defend ourselves against or obtain indemnification from our business partners for product liability claims, we may be subject to substantial liabilities or be required to limit commercialization of our products and product candidates. Even successful defense would require significant financial and management's resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products and loss of revenue;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend against the related claims;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- diversion of management's time and our resources;
- exhaustion of any available insurance and capital resources; and/or
- inability to commercialize any product candidate.

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

Our business and operations have been and may continue to be materially and adversely affected by the COVID-19 outbreak.

An outbreak of respiratory illness caused by COVID-19 has and is continuing to spread rapidly throughout the world. On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization declared the outbreak a “Public Health Emergency of International Concern (PHEIC).” Government efforts to contain the spread of COVID-19 through city lockdowns or “stay-at-home” orders, widespread business closures, restrictions on travel and emergency quarantines, among others, have caused significant and unprecedented disruptions to the global economy and normal business operations across sectors and countries. To date, the spread of COVID-19 continues to affect China, where we conduct most of our business and engage in pre-clinical studies and clinical trials, as well as certain other countries and regions where we sell our products and where our business partners reside.

Our business, including our production plan and pre-clinical studies and clinical trials, as well as our ability to continue to manage our operations effectively, could be impacted by the current pandemic or future continuance or reoccurrence of COVID-19 in numerous ways, including but not limited to: (1) requirements for us to quarantine certain of our employees or facilities or take extra security precautions for our operations, which may result in higher costs; (2) delay in patient enrollment for our clinical trials; (3) diversion of medical resources required for our clinical trials for the treatment of patients with COVID-19; (4) lowered demand by hospitals for our products, as many patients rescheduled their visits to hospitals to avoid cross-infections and most of the hospitals devoted their resources to dealing with COVID-19 in the first half of 2020 and, therefore, reduced the number of unrelated operations; (5) delay in logistics for suppliers of raw materials resulting from temporary restrictions or bans on traveling by local governments to contain the spread of the outbreak; and (6) temporary closure or flexible working hours of competent regulatory authorities, such as administration and registration authorities, which may delay regulatory submissions and required approvals of our product candidates, and could cause us to incur additional costs and affect our ability to execute our operations as planned. We have also experienced extended payment cycles and delayed collection of accounts receivables in the first half of 2020 as a result of the COVID-19 outbreak. In addition, our business and results of operations could also be adversely affected to the extent the COVID-19 outbreak harms the business of our customers, suppliers, distributors and other business partners. See “Financial Information — COVID-19 Outbreak and Effects on Our Business.”

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While our Director confirmed that, up to the Latest Practicable Date, the COVID-19 outbreak did not have a material adverse effect on our results of operations and financial condition, the effects of the current COVID-19 pandemic or future outbreaks on our business or our industry will depend on a number of factors outside our control, including the extent to which the current pandemic continues to spread, particularly in China and other countries and regions where we sell our products and where our business partners reside, and such effects could be material. The Chinese and global economy is subject to the risk of a general slowdown, which would have a material adverse effect on our results of operations and financial condition in the near term. Moreover, if the outbreak persists or escalates, we may be subject to further negative impact on our business, results of operations and financial condition.

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

We plan to seek product registrations and intellectual property applications in the European Union and the United States. We also plan to expand our sales and increase our brand recognition in global markets, and specifically, to accelerate the commercialization of our future biodegradable occluder products and heart valve products in overseas markets such as the European Union, Southeast Asia and the United States. See “Business — Growth Strategies — Expand our global footprint by increasing product development and commercialization and broadening overseas sales channels.” However, our limited experience in overseas markets may expose us to risks and uncertainties, including the risks associated with the following:

- dealing with regulatory regimes, regulatory bodies and government policies which may differ materially from those in the PRC or with which we may be unfamiliar;
- substantial time which may be required for us to obtain approval for registering and selling our products in additional countries, especially in developed countries;
- commercializing our products in new markets where we have limited experience with the dynamics and no sales and marketing infrastructure;
- reliance on overseas partners or distributors for the distribution, commercialization and marketing of our products;
- product liability litigation and regulatory scrutiny arising from the marketing and sale of products in overseas markets and the costs incurred dealing with such procedures, as well as our ability to obtain insurance to adequately protect us from any resulting liabilities;
- unexpected changes in tariffs, trade barriers and regulatory requirements;

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

We could be adversely affected as a result of any sales we make to certain countries that are, or become subject to, sanctions administered by the United States, the European Union, the United Nations, Australia and other relevant sanctions authorities.

The United States and other jurisdictions or organizations, including the European Union, the United Nations and Australia, have, through executive order, passing of legislation or other governmental means, implemented measures that impose economic sanctions against such countries or against targeted industry sectors, groups of companies or persons, and/or organizations within such countries.

During the Track Record Period, we had sold our non-U.S. origin interventional medical devices to the Retained Lepu Medical Group which on-sold such products to customer/distributors in Iran, a Comprehensively Sanctioned Country. Revenue generated from such transactions with the Retained Lepu Medical Group was minimal compared with our total revenue during the Track Record Period and did not involve any U.S. nexus, and no U.S. dollar payments were received by us for such sales. As advised by our International Sanctions Legal Advisors, we are not subject to sanctions risk that could have a material adverse risk on our business from our past indirect sales of products in Iran on the bases that (1) the transaction value was minimal compared with our total revenue during the Track Record Period, (2) the nature of the sales involved medical products, and (3) we had ceased all such indirect sales to Iran as of June 18, 2021.

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The United States also has enacted secondary sanctions targeting non-U.S. persons who have engaged in certain sanctionable activities related to certain Comprehensively Sanctioned Countries or Sanctioned Persons, including Iran. As advised by our International Sanctions Legal Advisors, given that (1) Section 1244 of the Iran Freedom and Counter-Proliferation Act of 2012 (“IFCA”) contains a humanitarian exception under secondary sanctions for sale of medicine and medical devices to Iran; (2) during the Track Record Period, the counterparties in our sales had not been identified as SDNs; and (3) the nature of the our sales did not involve certain Iranian industries or products targeted by U.S. secondary sanctions, our sales of medical products to Iran do not trigger exposure to U.S. secondary sanctions.

As further advised by our International Sanctions Legal Advisors, (1) our indirect business dealings in Iran will not be considered as unlawful under the restrictive measures adopted by the European Union, the United Nations and Australia; and (2) we did not violate relevant sanctions as a result of Primary Sanctioned Activity or Secondary Sanctionable Activity during the Track Record Period.

As of the Latest Practicable Date, our Directors confirmed that we had not been notified that any International Sanctions penalties would be imposed on us for our historical sales to the Comprehensively Sanctioned Countries. We have no present intention to undertake any future business with persons on the SDN Lists, or any other business that may expose us to sanctions risks including further sales directly or indirectly to Iran. In addition, we have implemented enhanced internal control and risk management measures which we believe enable us to monitor and evaluate our business to address economic sanction risks. See “Business — Risk Management and Internal Control — Internal Control.” Given the scope of the [REDACTED] and the expected [REDACTED] as set out in this document, our International Sanctions Legal Advisors are of the view that the involvement by parties in the [REDACTED] will not implicate any applicable International Sanctions on such parties, including our Company and our subsidiaries, the respective directors and employees of our Company and our subsidiaries, our Company’s or our subsidiaries’ investors, shareholders as well as the Stock Exchange and its related group companies.

However, we are unable to predict the interpretation or implementation of the International Sanctions with respect to any past activities by us. If any government agencies or organizations were to determine that we were deemed to be engaged in prohibited or sanctionable activities targeted by the International Sanctions, we could be subject to certain sanctions or penalties and our reputation and future business prospects could be adversely affected. In addition, because economic sanctions programs are constantly evolving, new requirements or restrictions could come into effect, or relevant regulatory authorities may interpret current sanctions in such a manner that might increase scrutiny on our business or result in one or more of our business activities being deemed to have violated sanctions or being sanctionable. Our internal control and risk management measures may not be able to react timely or comprehensively to such changes. There is no assurance that our activities in any particular country or region will be in compliance with evolving applicable rules and regulations or that they will not result in negative media attention or reputational damage.

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

Our Controlling Shareholders have substantial influence over our business, including matters relating to our management, policies and decisions regarding mergers, expansion plans, consolidations, sales of all or substantially all of our assets, election of directors and other significant corporate actions. As of 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], Lepu Medical and Target Medical will directly hold approximately [REDACTED]% and [REDACTED]% equity interest in our Company, respectively, assuming the [REDACTED] is not exercised. Dr. Pu is the Actual Controller of Lepu Medical. Lepu Medical, Dr. Pu and Target Medical are considered as a group of Controlling Shareholders of our Company. See “Relationship with Our Controlling Shareholders.” This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their H Shares as part of a sale of our Company and might reduce the price of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, our Controlling Shareholders may exercise their substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

Lepu Medical, as a public company in China, has published and may continue to publish, from time to time, reports, projections, valuations and other types of information which may concern us, our business and financial condition, and/or our industry. Lepu Medical may publish such information voluntarily or in response to regulatory or stock exchange requirements or inquiries. Specifically, Lepu Medical, as a company listed on the Shenzhen Stock Exchange, has ongoing obligations to publish information in relation to our Company. We have no control over whether or when, if at all, Lepu Medical may publish any such information that concerns us, nor can we assure you that we will be given the opportunity to review or endorse any such information. As such, we cannot guarantee that any such information regarding us will not have any impact on the perception of us and our business by the [REDACTED] community, the [REDACTED] of our H Shares, or the interest of the [REDACTED] Shareholders.

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 Shareholders, our Group and the [REDACTED].

Prior to the publication of this document, subsequent to the date of this document and after the [REDACTED], there have been, and there may continue to be, announcements, press and media coverage and research analyst reports regarding Lepu Medical and its subsidiaries (including our Group) and the [REDACTED], which may include certain historical and forward-looking financial information about Lepu Medical, including the business and operations that are operated by our Group.

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We are not expected to endorse or participate in the disclosure of any such information. We do not accept any responsibility for any such announcements, press and media coverage or research analyst coverage or the accuracy or completeness of any such information. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information or publication. If any such information appearing in publications other than this document or the documents issued by us is inconsistent or conflicts with the information contained in this document, we disclaim it. You should only rely on the information included in this document and the documents issued by our Company in making your [REDACTED] decision and should not rely on any other information, including any forward-looking information published by our Controlling Shareholders. See “Relationship with our Controlling Shareholders” for further details.

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

We may from time to time establish or seek collaborations, strategic alliances or equity [REDACTED] or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. As of the Latest Practicable Date, we had collaborated with several hospitals and research institutions in China. We face significant competition in seeking appropriate strategic partners, and the negotiation process for collaboration, alliances or licensing arrangements can be complex and time-consuming. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a development stage for collaborative efforts, and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. Furthermore, if and when we collaborate with a third party for development and commercialization of a product candidate, we may be required by our collaborators through commercial negotiation to relinquish some or all of the control over the future success of that product candidate to them. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing Shareholders, or disrupt our management and business. For any product or product candidate that we may seek to in-license from third parties, we may face significant competition from other medical device companies with greater resources or capabilities than us, and any agreement that we do enter may not result in the anticipated benefits.

Furthermore, collaborations involving our products and product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

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- collaborators may not pursue the development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to availability of funding, acquisition of competing products, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay, suspend or terminate clinical trials, provide insufficient funding for clinical trials, abandon a product candidate, repeat or conduct new clinical trials, or require a new design of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigations that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liabilities;
- disputes may arise between us and collaborators that cause delays in or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management's attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the relevant product candidates; and/or
- collaborators may own or co-own intellectual property covering our products and product candidates that results from our collaborations with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, we may not be able to realize the benefit of current or future collaborations, strategic alliances or the license of our third-party products if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such arrangement. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate expected revenue, which would harm our business, results of operations, financial condition and prospects.

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If parties on whom we rely on fail to maintain or renew the necessary permits, licenses and certificates required for the development, production, sales and distribution of our products, our ability to conduct our business could be materially impaired.

Third parties, such as CROs, suppliers and distributors on whom we may rely to develop, produce, promote, sell and distribute our products and product candidates, may be required to obtain, maintain and renew various permits, licenses and certificates. Third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and we cannot assure you that the third parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our such third parties' business, and if parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation of existing laws and regulations change, or new regulations are promulgated and come into effect, requiring parties on whom we rely to obtain any additional permit, license or certificate that was previously not required to operate their respective businesses, we cannot assure you that parties on whom we rely will successfully obtain such permits, licenses or certificates in a timely manner or at all, which in turn will adversely affect our ability to conduct our business.

Non-compliance with law on the part of any third parties with which we conduct business could disrupt our business and adversely affect our results of operations and financial condition.

Third parties with which we conduct business, such as physicians, suppliers and customers, may be subject to regulatory penalties or punishments because of their regulatory compliance failures, which may, directly or indirectly, disrupt our business. Although we conduct review of legal formalities and certifications before entering into contractual relationship with third parties, and take measures to reduce the risks that we may be exposed to in case of any non-compliance by third parties, we cannot be certain whether such third parties have violated any regulatory requirements. For example, physicians may involve in malpractice which can cause certain injuries to patients using our products, and we may not be able to identify and supervise all instances of such malpractice. In such events, even though we have related disclaimers, we may be involved in legal proceedings regarding malpractice and may even be held liable and have to pay damages to compensate such patients. Even though we have the contractual right to seek indemnification from the relevant patients, we cannot assure you that we will be able to enforce such right. As a result, our business, results of operations and financial condition could be materially and adversely affected. Similarly, suppliers may also not be in full compliance with applicable laws and regulations, which may have an adverse effect as to our business, results of operations and financial condition.

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We expect to incur substantial share-based compensation expense pursuant to certain existing limited partnership agreement, and such expense may affect our financial performance and such compensation may result in a dilution of the shareholdings of the shareholders in our Group.

In February 2021, we established partnerships, Ningbo Jiadu, as a shareholding platform, where our employees, including certain senior management members, and certain of our Directors hold interests as limited partners to such partnership. As provided in the relevant limited partnership agreement, the foregoing persons are restricted from selling, transferring or disposing of their respective partnership interest for the first 12 months from the [REDACTED]. On the first [REDACTED] after each of the first and second anniversary of the [REDACTED], 15% of the interest owned by each of them will be released. On the first [REDACTED] after the third anniversary of the [REDACTED], the remaining 70% of the interest owned by each of them will be released. See “History, Reorganization and Corporate Structure — Our Corporate Development — Establishment of Ningbo Jiadu and Ningbo Jiacheng as the shareholding platforms.” Consequently, we expect to incur substantial expenses associated with share-based compensation as a result of the granting of partnership interest in Ningbo Jiadu to our employees and Directors, which will have an adverse effect on our results of operations and financial condition in the relevant periods between the grant date and release date. In addition, we may also grant share-based awards pursuant to share incentive plans or other equity award plans which we may adopt in the future to help us attract and retain key personnel and employees. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations and financial condition, and such compensation may result in a dilution of the shareholdings of the shareholders in our Group.

We are exposed to risks associated with our investments in wealth management products, including the risks of fair value change and uncertainty in valuation of our investments in wealth management products due to the use of unobservable inputs.

We may invest in wealth management products from time to time in our ordinary course of business. The wealth management products we invested in were usually principal-guaranteed and had a short term ranging from one to three months. We have implemented investment and treasury management policies to ensure proper management and risk assessment.

We are subject to the risks that any of our counterparties, such as the banks that issued wealth management products, may not perform their contractual obligations, such as in the event that any such counterparty declares bankruptcy or becomes insolvent. Any material non-performance of our counterparties with respect to the wealth management products we invested in could materially and adversely affect our financial position and cash flow. Furthermore, our investments in wealth management products are subject to overall market conditions, including the capital markets, which expose us to the risk of valuation uncertainty. We recorded interest income on wealth management products of RMB6.7 million in 2021, which was recognized in other income for the same period. Any volatility in the market or

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fluctuations in interest rates may negatively impact the fair value of our wealth management products, which may in turn have a material adverse effect on our financial condition. In addition, we are also exposed to the risks of fair value change and uncertainty in valuation of our investments in wealth management products due to the use of unobservable inputs in relation to the valuation of the level 3 financial assets at fair value through profit or loss. Should any of the estimates and assumptions changed, it may lead to a change in the fair value of the level 3 instruments, which may in turn have a material adverse effect on our financial condition. See Note 3.3 to the Accountant’s Report in Appendix I to this document.

Impairment of goodwill may materially and adversely affect our results of operations.

Our goodwill remained the same at RMB48.3 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, primarily as a result of the acquisition of Shanghai Shape Memory Alloy, our wholly-owned subsidiary, by Lepu Medical, a Controlling Shareholder, in 2008. The value of goodwill is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, we may be required to have a significant write-off of our goodwill and record a significant impairment loss. Furthermore, our determination on whether goodwill is impaired requires an estimation of the recoverable amount of the CGUs to which the goodwill is allocated, which depends on the expected future cash flows from the CGUs and a suitable discount rate to calculate the present value. If we expected future cash flow to decrease, our goodwill may be impaired. Any significant impairment of goodwill could have a material adverse effect on our business, financial condition and results of operations. For more information, see Note 2.10 and Note 17 to the Accountant’s Report in Appendix I to this document.

Impairment of our intangible assets could materially and adversely affect our results of operations.

As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had intangible assets of RMB54.3 million, RMB66.0 million, RMB136.6 million and RMB161.6 million, respectively. Our determination on whether intangible assets are impaired requires an estimation on recoverable amount of the intangible assets, which is based on a number of assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, the carrying amount of the intangible assets may exceed its recoverable amount, and our intangible assets may be impaired. As a result, we may be required to have a significant write-off of our intangible assets and record a significant impairment loss. The impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations. For more information, see Note 2.9 and Note 18 to the Accountant’s Report in Appendix I to this document.

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

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

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our product candidates, while complying with our contractual obligations to third parties; and
- improving our operational, financial and management controls, as well as reporting systems and procedures.

Our future financial performance and our ability to develop and commercialize our products and product candidates and to compete effectively will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of business partners as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and product candidates and, accordingly, may not achieve our research, development and commercialization goals.

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

We, our Shareholders, Directors, Supervisors, officers, employees, distributors, suppliers or other parties we cooperate with may be subject to negative media coverage and publicity from time to time in our ordinary course of business, which could threaten the perception of our reputation as a trustworthy interventional medical device provider. In addition, to the extent we, our Shareholders, Directors, Supervisors, officers, employees, distributors, suppliers or other parties we cooperate with were involved in any legal or administrative proceedings or violate or allegedly violate any laws or regulations, our reputation could be

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materially and adversely affected, which may, in turn, adversely affect our business and results of operations. Any negative publicity regarding our industry could also affect our reputation and customer confidence in our brand and products.

Any negative publicity or allegations may cause us to spend significant time and incur substantial costs, and we may not be able to diffuse them to the satisfaction of our [REDACTED], customers, hospitals and physicians, which could materially and adversely affect our reputation, business, results of operations and financial condition and the [REDACTED] of our H Shares.

Use of social media platforms presents new risks.

Social media increasingly is being used to communicate about our products, product candidates and the diseases our therapies are designed to treat. Social media practices in the medical device and pharmaceutical industries are evolving, which creates uncertainty and risk of non-compliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, our products or product candidates. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

Changes in international trade policies and trade barriers, or the escalation of trade tensions, may have an adverse effect on our business.

During the Track Record Period, certain of our raw materials were sourced overseas, and we also distributed our products in foreign countries and regions. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. China’s political relationships with those foreign countries and regions may affect the prospects of our relationship with third parties, such as customers, suppliers, distributors and business partners. We cannot assure you that our existing or potential partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Any tension, political concern, and trade friction between China and the relevant foreign countries or regions may cause a decline in the demand for our products and adversely affect our business, results of operations, financial condition, cash flows and prospects. In the event that China and/or the relevant foreign countries impose import tariffs, trade restrictions or other trade barriers affecting the importation of raw materials, we may not be able to obtain a steady supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. In addition, any escalation in existing trade tensions or the advent of a trade war, or news and rumors of the escalation of a potential trade war, could affect consumer confidence and have a material adverse effect on our business, results of operations and, ultimately, the [REDACTED] of our H Shares.

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In particular, recent international trade disputes between China and the United States, and the uncertainties created by such disputes may disrupt the transnational flow of goods and significantly undermine the stability of the global and Chinese economy, thereby harming our business. Political tensions between the United States and China have escalated due to, among other things, the COVID-19 outbreak, the National People’s Congress’ passage of Hong Kong national security legislation, sanctions imposed by the U.S. Department of Treasury on certain officials of Hong Kong and the central government of the PRC, and the Trump administration executive orders issued in August 2020 and the new executive order issued by the U.S. President in June 2021 which sought or seek to prohibit certain transactions with, or equity investment in, certain Chinese companies and their respective subsidiaries. Rising political tensions could reduce levels of trades, investments, technological exchanges and other economic activities between the two major economies, which would have a material adverse effect on global economic conditions and the stability of global financial markets. Any of these factors could have a material adverse effect on our business, prospects, financial condition and results of operations.

We historically received government grants and subsidies for our research and development and other activities and we may not receive such grants or subsidies in the future.

We historically received government grants in the form of subsidies received from local government intended to support our research and development activities and business operations. For 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we recognized government grants of RMB9.0 million, RMB5.6 million, RMB7.7 million, RMB4.5 million and RMB2.6 million, respectively. For details, see “Financial Information — Description of Certain Consolidated Statements of Profit or Loss Items — Other Income and Gains/(Losses) – Net.” Our eligibility for government grants is dependent on a variety of factors, including assessment of our improvement on existing technologies, relevant government policies, availability of funding at different granting authorities and research and development progress made by other peer companies. In addition, the policies according to which we historically received government grants may be halted by the relevant government entities at their sole discretion. We cannot assure you that we will continue to receive such government grants or receive similar level of government grants, or at all, in the future. Any loss of or reduction in government grants could have an adverse effect on our results of operations, financial condition and business prospects.

The discontinuation of any of the preferential tax treatments currently available to us could reduce our profitability.

Under PRC tax laws and regulations, Shanghai Shape Memory Alloy enjoys certain preferential tax treatments. The EIT Law and its implementation rules generally impose a uniform income tax rate of 25% on all enterprises, but grant preferential treatment to “High and New Technology Enterprises” (“HNTEs”) to enjoy a reduced enterprise tax rate of 15%. According to the relevant administrative measures, to qualify as an HNTE, Shanghai Shape

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Memory Alloy must meet certain financial and non-financial criteria and complete verification procedures with the administrative authorities. Continued qualification as an HNTE is subject to a three-year review by the relevant government authorities in China, and in practice certain local tax authorities also require annual evaluation of the qualification.

In addition, according to the relevant laws and regulations promulgated by the State Council and the SAT with effect from 2008 onwards, enterprises engaging in research and development activities were entitled to claim 150% of their research and development expenses so incurred as tax deductible expenses when determining their assessable profits for that year (“Super Deduction”). In September 2018, the SAT announced that enterprises engaging in research and development activities would be entitled to claim 175% of their research and development expenses as Super Deduction from January 1, 2018 to December 31, 2020. The Super Deduction ratio has increased to 200% since 2021. During the Track Record Period, Shanghai Shape Memory Alloy enjoyed the preferential tax treatment of Super Deduction.

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%. We cannot assure you that the tax authorities will not, in the future, discontinue any of our preferential tax treatments, potentially with retroactive effect, which would have a negative impact on our business, results of operations and financial condition.

If we become subject to litigation, legal or contractual disputes, governmental investigations or administrative proceedings, our management’s attention may be diverted and we may incur substantial costs and liabilities.

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. As of the Latest Practicable Date, we were not involved in any litigations and legal proceedings that may materially affect our research and development of our product candidates, business and results of operations. On-going or threatened litigation, legal or contractual disputes, governmental investigations or administrative proceedings involving us or our employees may divert our management’s attention, and result in damages, liabilities and legal and other costs. Furthermore, any litigation, legal or contractual disputes, governmental investigations or administrative proceedings which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved.

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If the outcomes of these proceedings are unfavorable to us, we could be required to pay significant legal costs and monetary damages, assume legal and other liabilities and even to suspend or terminate the related business projects. In addition, negative publicity arising from litigation, legal or contractual disputes, governmental investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. As a result, our business, results of operations and financial condition may be materially and adversely affected.

Failure to make adequate contributions to social insurance and housing provident fund for our employees as required by the PRC regulations may subject us to penalties.

Pursuant to the relevant PRC laws and regulations, employers are obligated to directly and duly contribute to the social insurance and housing provident fund for their employees. During the Track Record Period, we failed to timely make full social insurance and housing provident fund contributions for certain of our eligible employees. We estimate that the accumulated shortfall of social insurance and housing provident fund contributions as of December 31, 2019, 2020 and 2021 and June 30, 2022 was approximately RMB0.2 million, RMB0.2 million, RMB0.3 million and RMB0.3 million, respectively, which was immaterial and would not have a material adverse effect on our business. As a result, we did not make any provisions in connection with the foregoing non-compliance during the Track Record Period and up to the Latest Practicable Date.

As advised by our PRC Legal Advisors, we may be required to make up the deficiencies and be subject to late fees and fines for our insufficient contributions to the social insurance and housing provident fund. According to the relevant PRC laws and regulations, for outstanding social insurance contributions that we did not fully pay within the prescribed period, the relevant PRC authorities may demand that we pay the outstanding social insurance contribution within a stipulated deadline and we may be liable for a late payment fee equal to 0.05% of the outstanding contribution amount of each day of delay; if we fail to make such payments within a stipulated deadline, we may be liable to a fine of one to three times of the outstanding contribution amount. In addition, for outstanding housing provident fund contributions that we did not fully pay within the prescribed period, the relevant government authorities may demand that we pay the outstanding housing provident fund contributions by a stipulated deadline. If we fail to rectify by that deadline, we may be subject to an order from the relevant PRC courts for compulsory enforcement. We have adjusted the payment basis of the social insurance and housing provident funds for our employees pursuant to the standards stipulated under the applicable PRC laws and regulations. Our Directors believe that these incidents would not have a material adverse effect on our business and results of operations, considering that (1) we have not received any notice from relevant regulatory authorities regarding any claim for inadequate contributions of our current and former employees, nor any notifications from the relevant authorities requiring us to pay the shortfalls; (2) we were not aware of any employee complaints or claims with respect to social insurance and/or housing provident funds; (3) we would make full payment within the stipulated deadline as required by

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relevant authorities once we received the notifications from the relevant authorities requiring us to pay the shortfalls; and (4) as advised by our PRC Legal Advisors, based on the above and provided that the relevant regulations and policies issued by PRC governments are still in effect, the likelihood that the relevant social insurance authorities would collectively take initiative to recover the historically unpaid social insurance from us and/or impose the administrative penalties on us due to our failure to make full payment of the social insurance is remote, and the likelihood that the relevant housing provident fund authorities would impose the administrative penalties on us due to our failure to make full payment of the housing provident funds is remote. As a result, we did not make any provisions in connection with the non-compliance during the Track Record Period and up to the Latest Practicable Date. However, we cannot assure that the relevant local government authorities will not require us to pay the outstanding amount within a specific time limit or impose late or additional fees or fines on us, which may adversely affect our financial condition and results of operation.

Failure to comply with PRC property laws and relevant regulations may adversely affect our business, results of operations and financial condition.

Historically, two floors we occupied in the same building with a gross floor area of approximately 3,582.17 square meters where our headquarters are located and where we conduct substantially all of our manufacturing activities were renovated without obtaining the construction commencement permit (施工許可證) and going through the construction completion acceptance procedures (竣工驗收) as required by PRC laws and regulations. According to our PRC Legal Advisors, for construction work carried out without construction commencement permit, we are subject to the risk of being required to adopt remedial measures within a certain time limit and being fined 1% to 2% of the contract price of the construction project. As for construction project that is delivered for use without passing the construction completion acceptance procedures, the construction entity may be ordered to rectify, subject to a fine of not less than 2% but not more than 4% of the contract price of the construction, and may also be required to pay compensation where any damage has been caused. We cannot assure you that we will be able to obtain all the outstanding permit and registration for the building we occupied in a timely manner. The aggregate contract price of the above construction is RMB9.08 million and, accordingly, the maximum penalty under relevant laws and regulations would be a fine of RMB544,800. See “Business — Properties — Owned Properties.” While we had not suffered any such fine from the relevant government authorities as of the Latest Practicable Date, we cannot assure you that we will not be subject to penalties or other disciplinary actions in the future.

Under the applicable PRC laws and regulations, parties to a lease agreement are required to register and file the executed lease agreement with the relevant government authorities. As of the Latest Practicable Date, we had not obtained lease registration for 14 properties under six lease agreements we leased in China. As advised by our PRC Legal Advisors, while failure to complete the lease registration will not affect the legal effectiveness of the lease agreements under PRC law, relevant real estate administrative authorities may require parties to the lease agreements to complete registration within a prescribed period of time and failure to do so may

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subject the parties to fines ranging from RMB1,000 to RMB10,000 for each non-registered lease. See "Business — Properties — Leased Properties." While we had not received any such request or suffered any such fine from the relevant government authorities as of the Latest Practicable Date, we cannot assure you that we will not be subject to penalties or other disciplinary actions for our past and future non-compliance.

Our internal IT systems may fail or suffer security breaches.

Despite the implementation of security measures, our internal IT systems are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, personal information of our employees, and intellectual property and proprietary business information. In addition, we manage and maintain our data utilizing on-site systems and outsourced suppliers. These data encompass a wide variety of business-critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or suppliers that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or loss of revenue. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of data maintained in the information systems and networks of our Company and our suppliers, such as personal information of our employees, and company confidential data. In addition, outside parties may attempt to penetrate our systems or those of our suppliers or fraudulently induce our personnel or the personnel of our suppliers to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our suppliers occurs, the market perception of the effectiveness of our security measures could be harmed and our

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reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely.

Our future acquisitions and investments may subject us to risks and uncertainties.

We plan to actively seek opportunities for strategic acquisitions or investments to strengthen our research and development capabilities, expand our product portfolio, and enhance our market position. Such endeavors may involve significant risks and uncertainties, including distraction of management from current operations, the inability to generate sufficient revenue to offset the costs and expenses of acquisitions, and risks relating to market acceptance, loss of key acquired personnel, difficulties in integrating diverse corporate cultures, and increased costs to integrate managerial, operational, financial, and administrative systems. We currently plan to use approximately [REDACTED]% of the [REDACTED] from the [REDACTED], or approximately HK\$[REDACTED] million, to fund potential strategic investment and acquisitions within the next five years that could complement and expand our product portfolio and technologies. As of the Latest Practicable Date, we had not identified any specific acquisition targets, formed any specific acquisition plans or entered into any agreements with potential targets. See “Business — Growth Strategies” and “Future Plans and [REDACTED] — [REDACTED].”

We cannot assure you that all the proposed investment and our future investments will be consummated in a timely manner or at all, or that we will realize the economic or commercial benefits from such investment as anticipated. We may be unable to successfully complete an acquisition deal due to reasons including unsuccessful negotiation, even if we identify suitable acquisition targets. In addition, we may be unable to manage an acquired entity profitably or successfully integrate its operations with our own. These factors could harm our ability to achieve anticipated levels of profitability at operations we have acquired or invested in, or realize other anticipated benefits of an acquisition or investment, or even successfully complete an acquisition deal, and could adversely affect our business, results of operations and financial condition. Any acquisition or investment may also cause us to assume liabilities, increase our expenses and working capital requirements, or subject us to litigation, which would reduce our return on invested capital. Failure to manage the acquisitions and investments we make could materially harm our business and results of operations by bringing significant net cash outflows for financing activities, with limited, if any, increase in our revenue.

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Future acquisitions of businesses, technologies or know-how could materially and adversely affect our business, financial condition and results of operations if we fail to integrate the acquired businesses or technologies successfully into our existing operations or if we discover previously undisclosed liabilities.

To enhance our growth, we may acquire businesses, technologies or know-how that we believe would benefit us in terms of product development, technology advancement or distribution network. Our ability to grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financing. Even if we complete acquisitions, as we have limited experience with significant acquisitions, we may experience:

- difficulties in integrating any acquired companies, technologies, or personnel into our existing business, particularly integrating different business operations, financial and risk management, quality control procedures and management, customer service and other business functions;
- delays or failure in realizing the benefits of the acquired company, technologies or know-how;
- diversion of our management’s time and attention from other business concerns;
- higher costs of integration than we anticipated;
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions; or
- difficulties in implementing and enforcing our management and internal control mechanisms as well as quality assurance program that timely and adequately respond to our expanded scope of operations.

If we invest in businesses that operate outside of China, these risks may increase because of our limited experience in operating overseas.

An acquisition could also materially impair our results of operations through use of substantial amounts of cash, potentially dilutive issuances of equity securities, increasing operating expenses and cash requirements, significant depreciation and amortization expenses related to acquired intangible or other assets, impairment losses, deferred compensation charges, adverse tax consequences, significant diversion of management’s attention, incurrence of debt on unfavorable terms, assimilation of operations and exposure to potential unknown liabilities of the acquired business. We may also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance and product liabilities in businesses we acquire which we did not uncover prior to such acquisition. Therefore, we may become subject to penalties, lawsuits or other liabilities. Any difficulties in the integration of acquired businesses, technologies or know-how or unexpected penalties, lawsuits or liabilities in connection with such businesses, technologies or know-how could have a material adverse effect on our business, results of operations and financial condition.

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Our insurance coverage may not be adequate, which could expose us to significant costs and business disruption.

Our operations are subject to hazards and risks associated with our research and manufacturing operations, which may cause significant harm to persons or damage to properties. We maintain different types of insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. For example, we maintain insurance policies that cover losses arising from accidents and natural calamities in respect of our machinery, equipment, inventories and other fixed assets in our research and manufacturing facilities. We also maintain insurance policies covering clinical trial liability and are in the process of securing an insurance policy against product liability claims. For details, see “Business — Insurance.” In line with industry practice in China, we have elected not to maintain certain types of insurances such as key man life insurance, which is not mandatory under PRC laws. We cannot assure you that our insurance policies will be adequate to cover all losses incurred. In particular, our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Losses incurred and associated liabilities may have a material adverse effect on our results of operation if such losses or liabilities are not covered by our insurance policies.

We may need additional capital, and we may be unable to obtain such capital in a timely manner or on acceptable terms, or at all.

We may require additional capital beyond those generated by the [REDACTED] from time to time to grow our business, to better serve our customers, develop and enhance our products, and improve our operating infrastructure. Accordingly, we may need to sell additional equity or debt securities or obtain a credit facility. Future issuances of equity or equity-linked securities could significantly dilute our existing Shareholders, and any new equity security we issue could have rights, preferences and privileges superior to those of holders of our ordinary shares. The incurrence of debt financing would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations or our ability to pay dividends to our Shareholders.

Our ability to obtain additional capital is subject to a variety of uncertainties, including:

- our market position and competitiveness in the interventional medical device market targeting structural heart diseases;
- our future profitability, overall financial condition, and results of operations;
- general market conditions for capital raising activities by companies in the interventional medical device market targeting structural heart diseases in China, which in turn depends on the prospect of this industry; and
- economic, political and other conditions in China and globally.

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We may be unable to obtain additional capital in a timely manner or on acceptable terms, or at all. If we are unable to obtain adequate financing on terms satisfactory to us when we require it, our ability to continue to support our business growth could be significantly impaired, and our business and prospects could be adversely affected.

A severe or prolonged downturn in the global or Chinese economy could materially and adversely affect our business, results of operations, financial condition and prospects.

The global macroeconomic environment is facing challenges, including the end of quantitative easing by the U.S. Federal Reserve, the economic slowdown in the Eurozone since 2014 and uncertainties over the impact of Brexit. The Chinese economy has shown slower growth compared to the previous decade since 2012 and the trend may continue. There is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world’s leading economies, including the United States and China. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa, which have resulted in market volatility. There have also been concerns over the relationship between China and other countries, including the surrounding Asian countries. Recent international trade disputes, including tariff actions announced by the United States, China and certain other countries, and the uncertainties created by such disputes may cause disruptions in the international flow of goods and services and may adversely affect the Chinese economy as well as global markets and economic conditions. In addition, the recent market panics over the global outbreak of COVID-19 and the drop of oil price materially and negatively affected the global financial markets in March 2020, which may cause slowdown of the world’s economy. Economic conditions in China are sensitive to global economic conditions, as well as changes in domestic economic and political policies and the expected or perceived overall economic growth rate in China. Any severe or prolonged slowdown in the global or Chinese economy may materially and adversely affect our business, results of operations, financial condition and prospects.

Any catastrophe, including outbreaks of health pandemics and other extraordinary events, could have a negative impact on our business operations.

We are vulnerable to natural disasters and other calamities. Fire, floods, typhoons, earthquakes, power loss, telecommunications failures, wars, riots, terrorist attacks or similar events may give rise to server interruptions, breakdowns, system failures or Internet failures, which could cause the loss or corruption of customer data, malfunctions of software, hardware and equipment as well as adversely affect our ability to manufacture our products and provide our services.

Our business could also be adversely affected by the effects of COVID-19, Ebola virus diseases, H1N1 flu, H7N9 flu, avian flu, Severe Acute Respiratory Syndrome (SARS), or other epidemics. Our business operation could be disrupted if any of our employees is suspected of having any of the aforementioned epidemics or another contagious disease or condition, since it could require our employees to be quarantined and/or our offices to be disinfected. In addition, our business, results of operations and financial condition could be adversely affected to the extent that any of these epidemics harms the economy of China and other overseas markets in general.

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RISKS RELATING TO DOING BUSINESS IN CHINA

The economic, political and social conditions in China could affect our business, results of operations, financial condition and prospects.

We generate a substantial portion of our revenue from our operations in China. Accordingly, our business, financial condition, results of operations and prospects are subject to and influenced by the economic, political and social conditions in China. Economic reforms begun in the late 1970s have resulted in significant economic growth in China. However, any economic reform policies or measures in China may from time to time be modified or revised. China’s economy differs from the economies of most developed countries in many respects, including with respect to the degree of government involvement, control of foreign exchange, allocation of resources, as well as the overall level of development. While China’s economy has experienced significant growth in the past 30 years, growth has been uneven across different regions and among different economic sectors. In addition, the rate of growth has been slowing since 2012, and the impact of COVID-19 on China’s and global economies was severe and may persist in the future.

The PRC government exercises significant control over China’s economic growth through the allocation of resources, controlling payment of foreign currency denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our results of operations and financial condition may be adversely affected by government control over capital investments or changes in tax regulations. In addition, in the past, the PRC government has implemented certain measures, including interest rate adjustment, to control the pace of economic growth. These measures may cause decreased economic activities in China, which may adversely affect our business and results of operations. In addition, the increased global focus on social, ethical and environmental issues may lead to China’s adoption of more stringent standards in these areas, which may adversely impact the operations of China-based companies including us. We cannot predict future changes in China’s economic, political and social conditions and the effect that new government policies would have on our business and prospects. Any actions and policies adopted by the PRC government could adversely affect our business, results of operations, financial condition and competitive position.

Uncertainties with respect to the PRC legal system could have a material adverse effect on our business, results of operations and financial condition.

Our business and operations are primarily conducted in China and are governed by applicable PRC laws, rules and regulations. The PRC legal system is based on written statutes and their interpretation by the Supreme People’s Court. Prior court decisions may be cited for reference, but have limited weight as precedents. Since the late 1970s, the Chinese government has significantly enhanced China’s legislation and regulations to provide protection to various

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forms of foreign investments in China. However, since these laws and regulations are relatively new and the PRC legal system continues to rapidly evolve, the interpretations of many laws, rules and regulations are not always uniform and enforcement of these laws, rules and regulations involves uncertainties, which may limit legal protections available to us.

Even if we endeavor to comply with relevant laws and regulations, we may not always be able to do so due to a lack of detailed implementation rules by relevant government authorities. In addition, some government authorities (including local government authorities) may not consistently apply regulatory requirements issued by themselves or other PRC government authorities, making strict compliance with all regulatory requirements impractical, or in some circumstances, impossible. For example, we may have to resort to administrative and court proceedings to enforce the legal protection that we enjoy either by law or contract. However, since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into with our customers, suppliers, distributors and business partners. In addition, such uncertainties, including the inability to enforce our contracts, together with any development or interpretation of PRC laws adverse to us, could materially and adversely affect our business and operations. Furthermore, intellectual property rights and confidentiality protections in China may not be as effective as in the United States or other countries. Accordingly, we cannot predict the effect of future developments in the PRC legal system, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. These uncertainties could limit the legal protections available to us and other foreign investors, including you. In addition, any litigation or regulatory enforcement action in China may be protracted and may result in substantial costs and the diversion of resources and management’s attention, which in turn could have a material adverse effect on our results of operations and financial condition.

Government control of currency conversion could limit our ability to utilize our revenue effectively, to pay dividends and other obligations, and affect the value of our H Shares.

The PRC government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. Our revenue and expenses are substantially denominated in Renminbi, and the [REDACTED] from the [REDACTED] and any dividends we pay on our H Shares will be in Hong Kong dollars. Under China’s existing foreign exchange regulations, following the completion of the [REDACTED], we will be able to make current account foreign exchange transactions, including paying dividends in foreign currencies without prior approval from the SAFE.

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However, in the future, the PRC government may take measures, at its discretion, to restrict access to foreign currencies for capital account and current account transactions under certain circumstances. If such measures are implemented, we may not be able to pay dividends in foreign currencies to holders of our H Shares. Foreign exchange transactions under our capital account are subject to significant foreign exchange controls and require SAFE’s approval. These limitations could affect our ability to obtain foreign exchange through offshore financing.

Furthermore, the [REDACTED] from the [REDACTED] are expected to be deposited in currencies other than Renminbi until we obtain necessary approvals from relevant PRC regulatory authorities to convert these [REDACTED] into onshore Renminbi. If the [REDACTED] cannot be converted into onshore Renminbi in a timely manner, our ability to deploy these [REDACTED] efficiently may be affected as we will not be able to invest these [REDACTED] on RMB denominated assets onshore or deploy them in uses onshore where Renminbi is required. All of these factors could materially and adversely affect our business results of operations, financial condition and prospects.

Fluctuations in exchange rates could adversely affect our results of operations and the value of your [REDACTED].

Fluctuations in the exchange rate of Renminbi against Hong Kong dollar, U.S. dollar and other foreign currencies are affected by, among other things, the policies of the PRC Government and changes in China’s and international political and economic conditions.

The [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. As a result, any appreciation of Renminbi against U.S. dollar, Hong Kong dollar or any other foreign currencies may result in a decrease in the value of our foreign currency-denominated assets and our [REDACTED] from the [REDACTED]. Conversely, any depreciation of Renminbi may adversely affect the value of, and any dividends payable on our H Shares in foreign currencies. In 2021, we recorded net foreign exchange gains of RMB5.2 million from retranslation of U.S. dollar-denominated bank balances and redemption liabilities. In the six months ended June 30, 2021 and 2022, we recorded net foreign exchange losses of RMB1.8 million and RMB26.9 million, respectively, from retranslation of redemption liabilities resulted from exchange rate fluctuations. There are limited instruments available for us to reduce our foreign currency risk exposure at reasonable cost in China, and we have not utilized, and may not in the future utilize, any such instrument. All of these factors could materially and adversely affect our business, results of operations, financial condition and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

RISK FACTORS

[REDACTED] of our H Shares may become subject to PRC taxation on dividends received from us and gains from the disposition of our H Shares.

Non-Chinese resident individual holders of H Shares whose names appear on the register of members of H Shares (“Non-Chinese Resident Individual Holders”), are subject to Chinese individual income tax on dividends received from us. Pursuant to the Circular on Questions Concerning the Collection of Individual Income Tax Following the Repeal of Guo Shui Fa [1993] No. 045 (Guo Shui Han [2011] No. 348) (《關於國稅發[1993]045號文件廢止後有關個人所得稅徵管問題的通知》(國稅函[2011]348號)) dated June 28, 2011 and issued by the SAT, the tax rate applicable to dividends paid to Non-Chinese Resident Individual Holders of H Shares varies from 5% to 20% (usually 10%), depending on whether there is any applicable tax treaty between China and the jurisdiction in which the Non-Chinese Resident Individual Holder of H Shares resides, as well as the tax arrangement between China and Hong Kong. Non-Chinese Resident Individual Holders who reside in jurisdictions that have not entered into tax treaties with the PRC are subject to a 20% withholding tax on dividends received from us. See “Appendix VI — Taxation and Foreign Exchange” to this document. In addition, under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) and its implementation regulations, Non-Chinese Resident Individual Holders of H Shares are subject to individual income tax at a rate of 20% on gains realized upon the sale or other disposition of H Shares. However, pursuant to the Circular Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) issued by the Ministry of Finance and the SAT on March 30, 1998, gains of individuals derived from the transfer of listed shares of enterprises may be exempt from individual income tax. Based on our knowledge, as of the Latest Practicable Date, the Chinese tax authorities have not in practice sought to collect individual income tax on such gains. If such tax is collected in the future, the value of such non-Chinese resident individual holders’ [REDACTED] in H Shares may be materially and adversely affected.

Under the EIT Law and its implementation regulations, a non-Chinese resident enterprise is generally subject to enterprise income tax at a rate of 10% with respect to its Chinese-sourced income, including dividends received from a Chinese company and gains derived from the disposition of equity interests in a Chinese company. This rate may be reduced under any special arrangement or applicable treaty between the China and the jurisdiction in which the non-Chinese resident enterprise resides. Pursuant to the Circular on Questions Concerning Withholding of Enterprise Income Tax for Dividends Distributed by Resident Enterprises in China to Non-resident Enterprises Holding H-shares of the Enterprises (Guo Shui Han [2008] No. 897) (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》(國稅函[2008]897號)) promulgated by the SAT on November 6, 2008, we intend to withhold tax at 10% from dividends payable to non-Chinese resident enterprise holders of H Shares (including [REDACTED] Nominees). Non-Chinese resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty or arrangement will be required to apply to the Chinese tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be

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subject to the Chinese tax authorities’ approval. See “Appendix VI — Taxation and Foreign Exchange” to this document. There are uncertainties as to the interpretation and implementation of the EIT Law and its implementation rules by the Chinese tax authorities, including whether and how enterprise income tax on gains derived upon the sale or other disposition of H Shares will be collected from non-Chinese resident enterprise holders of H Shares. If such tax is collected in the future, the value of such non-Chinese resident enterprise holders’ [REDACTED] in H Shares may be materially and adversely affected.

Payment of dividends is subject to restrictions under PRC law.

Under PRC law, dividends may be paid only out of distributable profits. Distributable profits are defined as our profits after taxes as determined under PRC GAAP less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make. As a result, we may not have sufficient, if any, distributable profits to enable us to make dividend distributions to our Shareholders in the future, including periods for which our financial statements indicate that our operations have been profitable. Any distributable profits not distributed in a given year are retained and available for distribution in subsequent years.

Moreover, because the calculation of distributable profits under PRC GAAP is different from the calculation under IFRS in certain respects, our subsidiaries may not have distributable profits as determined under PRC GAAP, even if they have profits for that year as determined under IFRS. Even though there are no material differences between our distributable profit during the Track Record Period under PRC GAAP and IFRS, we may not receive sufficient distributions from our subsidiaries in the future. Failure by our subsidiaries to pay dividends to us could have a negative impact on our cash flow and our ability to make dividend distributions to our Shareholders in the future, including those periods in which our financial statements indicate that our operations have been profitable.

It may be difficult to effect service of process, enforce foreign judgments or bring original actions against us, our Directors, Supervisors and senior management residing in China.

We are a company incorporated under the laws of China, and a majority of our assets are located in China. In addition, most of our Directors, Supervisors and senior management reside within China, and the assets of our Directors, Supervisors and senior management are likely to be located within China. As a result, it may be difficult or impossible for you to effect service of process within Hong Kong, the United States or elsewhere outside China upon us or these persons, or to bring an action in Hong Kong against us or these individuals. Moreover, China does not have treaties with most of the other jurisdictions that provide for the reciprocal recognition and enforcement of judicial rulings and awards.

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On July 14, 2006, the Supreme People’s Court of China and Hong Kong entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgements in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “2006 Arrangement”). Pursuant to such arrangement, a party with a final judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China, and vice versa. However, it is subject to the parties in the dispute agreeing to enter into a choice of court agreement in writing under the 2006 Arrangement.

On January 18, 2019, the Supreme People’s Court of China and Hong Kong entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the “2019 Arrangement”), the commencement date of which shall be announced after the Supreme People’s Court promulgates judicial interpretations and relevant procedures are completed in Hong Kong. The 2019 Arrangement will supersede the 2006 Arrangement and afford greater clarity and certainty for reciprocal recognition and enforcement of judgments in civil and commercial matters. The 2006 Arrangement will remain applicable to a “choice of court agreement in writing” entered into before the 2019 Arrangement taking effect. However, there remains uncertainties as to the outcome of any applications to recognize and enforce such judgments and arbitral awards in China.

Furthermore, an original action may only be brought in China against us or our Directors, Supervisors and senior management if the actions are not required to be arbitrated by PRC laws and upon satisfaction of the conditions for commencing a cause of action pursuant to the PRC civil procedure law. As a result of the conditions set forth in the PRC civil procedure law and the discretion of the PRC courts to determine whether the conditions are satisfied and whether to accept the action for adjudication, it is uncertain whether [REDACTED] will be able to bring an original action in China in this manner.

The custodians or authorized users of our controlling non-tangible assets, including chops and seals, may fail to fulfill their responsibilities, or misappropriate or misuse these assets.

Under the PRC law, legal documents for corporate transactions, including agreements and contracts are executed using the chop or seal of the signing entity or with the signature of a legal representative whose designation is registered and filed with relevant PRC market regulation administrative authorities.

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In order to secure the use of our chops and seals, we have established internal control procedures and rules for using these chops and seals. In any event that the chops and seals are intended to be used, the responsible personnel will submit a formal application, which will be verified and approved by authorized employees in accordance with our internal control procedures and rules. In addition, in order to maintain the physical security of our chops, we generally have them stored in secured locations accessible only to authorized employees. Although we monitor such authorized employees, the procedures may not be sufficient to prevent all instances of abuse or negligence. There is a risk that our employees could abuse their authority, for example, by entering into a contract not approved by us or seeking to gain control of one of our subsidiaries or our affiliated entities or their subsidiaries. If any employee obtains, misuses or misappropriates our chops and seals or other controlling non-tangible assets for whatever reason, we could experience disruption to our normal business operations. We may have to take corporate or legal action, which could involve significant time and resources to resolve and divert management from our operations, and we may not be able to recover our loss due to such misuse or misappropriation if the third party relies on the apparent authority of such employees and acts in good faith.

RISKS RELATING TO THE [REDACTED]

There has been no prior [REDACTED] for our H Shares, and the [REDACTED] and [REDACTED] of our H Shares may be volatile.

Prior to the [REDACTED], there has been no [REDACTED] market for our H Shares. The [REDACTED] for our H Shares was the result of negotiations between us, the Sole [REDACTED] and the [REDACTED] on behalf of the [REDACTED], and the [REDACTED] may differ significantly from the [REDACTED] for our H Shares following the [REDACTED]. We have applied for [REDACTED] of, and permission to [REDACTED] in, our H Shares on the Stock Exchange. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and [REDACTED] for our H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED] or that the [REDACTED] of our H Shares will not decline following the [REDACTED]. Furthermore, the [REDACTED] and [REDACTED] of our H Shares may be volatile. The following factors may affect the [REDACTED] and [REDACTED] of our H Shares:

- actual or anticipated fluctuations in our operating performance and revenue;
- news regarding recruitment or departure of key personnel by us or our competitors;
- announcements of competitive developments, acquisitions or strategic alliances in our industry;
- potential litigation or regulatory investigations;

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- general market conditions or other developments affecting us or our industry;
- the operating and stock price performance of other companies in our industry, and other events or factors beyond our control; and
- the release of [REDACTED] or other transfer restrictions on our outstanding H Shares or sales or perceived sales of H Shares by us or other Shareholders.

Moreover, the capital market has from time to time experienced significant price and trading volume fluctuations that were unrelated or not directly related to the operating performance of the underlying companies in the market. These broad market and industry fluctuations may have a material and adverse effect on the [REDACTED] and [REDACTED] of our H Shares.

An active and liquid [REDACTED] market for our H Shares may not develop.

Prior to the [REDACTED], our H Shares were not traded on any other market. We cannot assure you that an active and liquid [REDACTED] for our H Shares will be developed or be maintained after the [REDACTED]. Liquid and active [REDACTED] usually result in less price volatility and more efficiency in carrying out [REDACTED]’ purchase and sale orders. The [REDACTED] of our H Shares could vary significantly as a result of a number of factors, some of which are beyond our control. In the event of a drop in the [REDACTED] of our H Shares, you could lose a substantial part or all of your [REDACTED] in our H Shares.

Any [REDACTED] of Domestic Shares and Unlisted Foreign Shares and subsequent [REDACTED] into H Shares in the future could dilute your shareholding under H Shares, increase the supply of our H Shares in the [REDACTED] and negatively impact the [REDACTED] of our H Shares.

On December 29, 2017, the CSRC issued a press release in connection with the launch of the H share full circulation pilot project (H股全流通試點項目) (the “Pilot Project”). A participating company, which is an H share company listed on the Stock Exchange, in the Pilot Project would be allowed to convert certain of its domestic shares into H shares, which are eligible to be listed and traded on the Stock Exchange. On November 14, 2019, the CSRC announced to fully promote its “full circulation” reform of the H shares by covering both qualified H share companies already listed on the Stock Exchange and companies planning initial public offerings of the H shares on the Stock Exchange.

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We have obtained the approval from the CSRC for the [REDACTED] of [REDACTED] Domestic Shares and [REDACTED] Unlisted Foreign Shares into [REDACTED] H Shares, and the [REDACTED] H Shares may be [REDACTED] on the Stock Exchange upon completion of the [REDACTED]. Such [REDACTED] will increase the number of H Shares to [REDACTED] H Shares (assuming the [REDACTED] is not exercised) and in the case that there is any [REDACTED] of Domestic Shares and subsequent [REDACTED] into H Shares in the future, your shareholding under the class of holders of our H Shares will be diluted. Further, according to the PRC Company Law, the Shares [REDACTED] by our Company prior to the [REDACTED] (including a total of [REDACTED] Domestic Shares and [REDACTED] Unlisted Foreign Shares held by existing Shareholders) are restricted from [REDACTED] within one year from the [REDACTED]. Such restriction from [REDACTED] will limit the number of H Shares [REDACTED] on the [REDACTED], which will in turn adversely affect the [REDACTED] of the H Shares during such restriction period. Any future [REDACTED] (after the expiration of the restrictions set out above) of [REDACTED] H Shares by relevant Shareholders in the [REDACTED] may affect the [REDACTED] of our H Shares.

Since there will be a gap of several days between [REDACTED] and [REDACTED] of our H Shares, holders of our H Shares are subject to the risk that the [REDACTED] of our H Shares could fall during the period before [REDACTED] of our H Shares begins.

The [REDACTED] of our H Shares is expected to be determined on the [REDACTED] Date. However, our H Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be [five] Hong Kong business days after the [REDACTED] Date. As a result, [REDACTED] may not be able to sell or otherwise [REDACTED] in our H Shares during that period. Accordingly, holders of our H Shares are subject to the risk that the [REDACTED] of our H Shares could fall before [REDACTED] begins, as a result of unfavorable market conditions or other adverse developments that could occur between the time of [REDACTED] and the time [REDACTED] begins.

Because the [REDACTED] of our H Shares is substantially higher than the consolidated [REDACTED] book value per Share, purchasers in the [REDACTED] may experience immediate dilution.

As the [REDACTED] of our H Shares is higher than the consolidated [REDACTED] assets per Share immediately prior to the [REDACTED], [REDACTED] of our H Shares in the [REDACTED] will experience an immediate dilution in [REDACTED]. Our existing Shareholders will receive an increase in the [REDACTED] of their Shares. Please refer to Appendix II to this document for details. In addition, holders of our Shares may experience further dilution of their interest if the [REDACTED] exercise the [REDACTED] or if we [REDACTED] additional shares in the future to raise additional capital.

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The [REDACTED] and [REDACTED] of our H Shares may be volatile, which could result in rapid and substantial losses for our Shareholders.

The [REDACTED] of our H Shares may be highly volatile and could be subject to significant fluctuations. In addition, the [REDACTED] of our Shares may fluctuate, which may cause significant [REDACTED] variations. Some of the factors that could negatively affect the [REDACTED] of our H Shares, or result in fluctuations in the [REDACTED] or [REDACTED] of our H Shares following the [REDACTED] include:

- variations in our operating and financial results, such as turnovers, earnings and cash flow;
- our failure to execute our strategies;
- an unexpected business interruption resulting from operational breakdowns, natural disasters, or major changes in our key personnel or senior management;
- adverse market reaction to any indebtedness that we may incur or securities that we may issue in the future;
- changes in market valuations of similar companies;
- changes or proposed changes in laws or regulations, or differing interpretations thereof, affecting our ability to obtain or maintain regulatory approval for our products;
- inadequate protection of our intellectual property rights or legal proceedings brought against us for infringement of third parties’ intellectual property rights;
- unexpected costs of litigations and unfavorable outcomes of claims arising out of defective products and safety related governmental investigations and actions; and
- general political, financial, social and economic conditions.

We have significant discretion as to how we will use the [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return. For details of our intended [REDACTED], see “Future Plans and [REDACTED].” However, our management will have discretion as to the actual application of our [REDACTED]. You are entrusting your funds to our management, upon whose judgment you must depend, for the specific use we will make of the [REDACTED] from this [REDACTED].

RISK FACTORS

Future sales or perceived sales or [REDACTED] of substantial amounts of our securities in the [REDACTED], including any future [REDACTED] in China or [REDACTED] of our Domestic Shares and Unlisted Foreign Shares into H Shares, could have a material and adverse effect on the prevailing [REDACTED] of our H Shares and our ability to raise additional capital in the future, or may result in dilution of your shareholdings.

Future sales of substantial amounts of our H Shares or other securities relating to our H Shares in the public [REDACTED], or the [REDACTED] of new H Shares or other securities relating to our H Shares, or the perception that such [REDACTED] or [REDACTED] may occur could all cause a decline in the [REDACTED] of our H Shares. Future [REDACTED], or perceived [REDACTED], of substantial amounts of our securities or other securities relating to our H Shares, including part of any future [REDACTED], could also materially and adversely affect the prevailing [REDACTED] of our H Shares and our ability to raise capital in the future at a time and at a [REDACTED] which we deem appropriate.

Our Domestic Shares and Unlisted Foreign Shares may be [REDACTED] into H Shares, and such [REDACTED] H Shares may be [REDACTED] or [REDACTED] on an overseas stock exchange, provided that prior to the [REDACTED] and [REDACTED] of such [REDACTED] shares, any requisite internal approval processes shall have been duly completed and the approval from the relevant Chinese regulatory authorities, including the CSRC, shall have been obtained (the “Arrangement”). In addition, such [REDACTED], [REDACTED] and [REDACTED] shall in all respects comply with the regulations prescribed by the State Council’s securities regulatory authorities and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. The Arrangement applies only to Domestic Shares and Unlisted Foreign Shares. All of our Domestic Shares and Unlisted Foreign Shares are subject to the Arrangement and may be [REDACTED] into H Shares upon the approval of the relevant regulatory authorities, including the CSRC and the Stock Exchange.

We may not be able to pay any dividends on our H Shares.

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. We cannot guarantee when and in what form dividends will be paid on our H Shares following the [REDACTED]. The declaration of dividends is proposed by the Board and is based on, and limited by, various factors, including without limitation, our business and financial performance, capital and regulatory requirements, and general business conditions. We may not have sufficient or any profits to enable us to make dividend distributions to our Shareholders in the future, even if our financial statements indicate that our operations have been profitable. For details, see “Financial Information — Dividend Policy.”

RISK FACTORS

If securities or industry analysts do not publish research reports about our business, or if they adversely change their recommendations regarding our H Shares, the [REDACTED] and [REDACTED] of our H Shares may decline.

The [REDACTED] of our H Shares may be influenced by research reports that industry or securities analysts publish about us or our business. If one or more analysts who cover us downgrade our H Shares or publish negative opinions about us, the [REDACTED] of our H Shares would likely decline regardless of the accuracy of the information. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which, in turn, could cause the [REDACTED] or [REDACTED] of our H Shares to decline.

Forward-looking statements contained in this document are subject to risks and uncertainties.

This document contains forward-looking statements with respect to our business strategies, operating efficiencies, competitive positions, growth opportunities for existing operations, plans and objectives of management, certain [REDACTED] information and other matters.

The words “anticipate,” “believe,” “could,” “potential,” “continue,” “expect,” “intend,” “may,” “plan,” “seek,” “will,” “would,” “should” and the negative of these terms and other similar expressions identify a number of these forward-looking statements. These forward-looking statements, including, among others, those relating to our future business prospects, capital expenditure, cash flows, working capital, liquidity and capital resources are necessary estimates reflecting the best judgment of our Directors, Supervisors and senior management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. As a result, these forward-looking statements should be considered in light of various important factors, including those set out in “Risk Factors” in this document. Accordingly, such statements are not a guarantee of future performance and you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to this cautionary statement.

The industry data and forecasts in this document obtained from various government publications and the industry report have not been independently verified.

This document includes industry data and forecasts that we obtained from various government publications and the industry report that we believe are reliable. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, we cannot assure you of the accuracy or completeness of information obtained from these sources. We have not independently verified any of the data, forecasts and other statistics from such sources, nor have we ascertained that the underlying economic assumptions relied upon in those sources.

RISK FACTORS

Also, these facts, forecasts and other statistics have not been independently verified by the [REDACTED], their respective directors and advisors or any other parties involved in the [REDACTED] and none of them make any representation as to the accuracy or completeness of such information in respect of the F&S Report and the information therein. Moreover, such facts, forecasts and other statistics may not be prepared on a comparable basis or may not be consistent with other information compiled within or outside China.

You should read the entire document carefully and we strongly caution you not to place any reliance on any information contained in press articles and other media regarding us and the [REDACTED].

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

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

In preparation for the [REDACTED], our Company has sought the following waivers from strict compliance with the relevant provisions of the Listing Rules:

WAIVER IN PRESENCE OF MANAGEMENT IN HONG KONG

Pursuant to Rule 8.12 of the Listing Rules, we must have sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong. Pursuant to Rule 19A.15 of the Listing Rules, the requirement in Rule 8.12 may be waived by having regard to, among other considerations, our arrangements for maintaining regular communication with the Stock Exchange.

Since most of the business operations of our Group are managed and conducted outside of Hong Kong, and all of the executive Directors of our Company ordinarily reside outside Hong Kong, our Company considers that it would be practically difficult and commercially unreasonable and undesirable for our Company to arrange for two executive Directors to be ordinarily resident in Hong Kong, either by means of relocation of existing executive Directors or appointment of additional executive Directors. Therefore, our Company does not have, and does not contemplate in the foreseeable future that we will have sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 of the Listing Rules.

Accordingly, pursuant to Rule 19A.15 of the Listing Rules, we have applied for, [and the Stock Exchange has granted,] a waiver from strict compliance with the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules, subject to the following conditions. We will ensure that there is an effective channel of communication between us and the Stock Exchange by way of the following arrangements:

- **Authorized representatives:** we have appointed Ms. Chen Juan (陳娟) and Ms. Zhang Yuxin (張昱昕) as the authorized representatives (“Authorized Representatives”) for the purpose of Rule 3.05 of the Listing Rules. The Authorized Representatives will act as our principal channel of communication with the Stock Exchange and would be readily contactable by phone, facsimile and email to deal promptly with enquiries from the Stock Exchange. Accordingly, the Authorized Representatives will be able to meet with the relevant members of the Stock Exchange to discuss any matters in relation to our Company within a reasonable period of time. The Company will also inform the Stock Exchange promptly in respect of any change in the Authorized Representatives. Please see “Directors, Supervisors and Senior Management” for more information about our Authorized Representatives;
- **Joint company secretaries:** In addition to the appointment of the Authorized Representatives, Ms. Ng Ka Man (吳嘉雯), one of our joint company secretaries and a Hong Kong resident, will, among other things, act as our Company’s additional channel of communication with the Stock Exchange and be able to answer enquiries from the Stock Exchange. Ms. Ng will maintain contact with our Directors, Supervisors and senior management through various means, including regular meetings and telephone discussions whenever necessary;

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

- **Directors:** to facilitate communication with the Stock Exchange, we have provided the Authorized Representatives and the Stock Exchange with the contact details (such as mobile phone numbers, office phone numbers, facsimile number and e-mail addresses, to the extent possible) of each of our Directors such that the Authorized Representatives would have the means for contacting all our Directors promptly at all times as and when the Stock Exchange wishes to contact our Directors on any matters. In the event that any Director expects to travel or otherwise be out of office, he/she will provide the phone number of the place of his/her accommodation to the Authorized Representatives. To the best of our knowledge and information, each Director who does not ordinarily reside in Hong Kong possesses or can apply for valid travel documents to visit Hong Kong and can meet with the Stock Exchange within a reasonable period upon request of the Stock Exchange;
- **Compliance advisor:** we have appointed Halcyon Capital Limited as our compliance advisor (the “Compliance Advisor”) upon [REDACTED] pursuant to Rules 3A.19 and 19A.05 of the Listing Rules for a period commencing on the [REDACTED] and ending on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED]. The Compliance Advisor will have access at all times to our Authorized Representatives, the Directors, the Supervisors and other senior management and act as the additional channel of communication with the Stock Exchange and answer enquiries from the Stock Exchange. The contact details of the Compliance Advisor have been provided to the Stock Exchange. We will also inform the Stock Exchange promptly in respect of any change in the Compliance Advisor; and
- **Hong Kong legal advisor:** we will retain a Hong Kong legal advisor to advise us on the on-going compliance requirements, any amendment or supplement to and other issues arising under the Listing Rules and other applicable laws and regulations in Hong Kong after the [REDACTED].

WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES

Pursuant to Rule 8.17 of the Listing Rules, we must appoint a company secretary who satisfies the requirements under Rule 3.28 of the Listing Rules. According to Rule 3.28 of the Listing Rules, we must appoint as our company secretary an individual, who, by virtue of his or her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of company secretary.

Pursuant to Note 1 to Rule 3.28 of the Listing Rules, the Stock Exchange considers the following academic or professional qualifications to be acceptable:

- a Member of The Hong Kong Institute of Chartered Secretaries;

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

- a solicitor or barrister (as defined in the Legal Practitioners Ordinance); and
- a certified public accountant (as defined in the Professional Accountants Ordinance).

In addition, pursuant to Note 2 to Rule 3.28 of the Listing Rules provides that, in assessing “relevant experience,” the Stock Exchange will consider the individual’s:

- length of employment with the issuer and other issuers and the roles he/she played;
- familiarity with the Listing Rules and other relevant laws and regulations including the SFO, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code and Mergers and Share Buy-backs;
- relevant training taken and/or to be taken in addition to be the minimum requirement under Rule 3.29 of the Listing Rules; and
- professional qualifications in other jurisdictions.

We have appointed Mr. Qin Xue (秦學) (“Mr. Qin”) as our joint company secretary. He has extensive experience in accounting and finance matters but presently does not possess any of the qualification required under Rules 3.28 and 8.17 of the Listing Rules, we have appointed Ms. Ng Ka Man (吳嘉雯) (“Ms. Ng”) of TMF Hong Kong Limited as the other joint company secretary, working closely with Mr. Qin. Ms. Ng is an associate member of the Hong Kong Institute of Chartered Secretaries and The Institute of Chartered Secretaries and Administrators in the United Kingdom, and therefore meets the qualification requirements under Note 1 to Rule 3.28 of the Listing Rules and is in compliance with Rule 8.17 of the Listing Rules.

The joint company secretaries will be jointly discharging the duties and responsibilities of a company secretary. Ms. Ng will be assisting Mr. Qin in gaining the relevant experience required under Rules 3.28 and 8.17 of the Listing Rules. Also, Mr. Qin will be assisted by (1) the Compliance Advisor of our Company for the first full financial year starting from the [REDACTED], particularly in relation to Hong Kong corporate governance practice and compliance matters; and (2) the Hong Kong legal advisor of our Company, on matters regarding our Company’s ongoing compliance with the Listing Rules and the applicable Hong Kong laws and regulations. In addition, Mr. Qin will endeavor to attend relevant trainings and familiarize himself with the Listing Rules and duties required of a company secretary of an issuer [REDACTED] on the Stock Exchange. We have applied to the Stock Exchange for, [and the Stock Exchange has granted], a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules such that Mr. Qin may be appointed as a joint company secretary of our Company.

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

Pursuant to the Guidance Letter HKEX-GL108-20, the waiver will be for a fixed period of time (the “Waiver Period”) and on the following conditions: (1) the proposed company secretary must be assisted by a person who possesses the qualifications or experience as required under Rule 3.28 and is appointed as a joint company secretary throughout the Waiver Period; and (2) the waiver can be revoked if there are material breaches of the Listing Rules by the issuer. [The waiver is valid for an initial period of a three-year period on the condition that Ms. Ng, as a joint company secretary of our Company, will work closely with, and provide assistance to, Mr. Qin in the discharge of his duties as a joint company secretary and in gaining the relevant experience as required under Rule 3.28 of the Listing Rules and to become familiar with the requirements of the Listing Rules and other applicable Hong Kong laws and regulations. The waiver will be revoked immediately if Ms. Ng ceases to provide assistance to Mr. Qin as the joint company secretary for the three-year period after [REDACTED].]

Our Company will further ensure that Mr. Qin has access to the relevant training and support that would enhance his understanding of the Listing Rules and the duties of a company secretary of an issuer [REDACTED] on the Stock Exchange, and to receive updates on the latest changes to the applicable Hong Kong laws, regulations and the Listing Rules. Prior to the end of the three-year period, the qualifications and experience of Mr. Qin and the need for on-going assistance of Ms. Ng will be further evaluated by our Company. We will liaise with the Stock Exchange to enable it to assess whether Mr. Qin, having benefited from the assistance of Ms. Ng for the preceding three years, will have acquired the skills necessary to carry out the duties of company secretary and the “relevant experience” within the meaning of Rule 3.28 Note 2 of the Listing Rules so that a further waiver will not be necessary.

For further information regarding the qualifications of Mr. Qin and Ms. Ng, see “Directors, Supervisors and Senior Management.”

CONTINUING CONNECTED TRANSACTIONS

We have entered into, and expect to continue, certain transactions that will constitute non-exempt and partially-exempt continuing connected transactions of our Company under the Listing Rules upon [REDACTED] as described in the section headed “Connected Transactions” of this Document. Our Directors consider that strict compliance with the applicable requirement under the Listing Rules would be impractical, unduly burdensome and would impose unnecessary administrative costs on our Company. Accordingly, we have applied for, [and the Stock Exchange has granted to us,] a waiver from strict compliance with the applicable requirements under Chapter 14A of the Listing Rules once the H Shares are [REDACTED] on the Stock Exchange in respect of such non-exempt and partially-exempt continuing connected transactions. For further details, see “Connected Transactions.”

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

WAIVER IN RELATION TO THE PUBLIC FLOAT REQUIREMENTS

Rule 8.08(1)(a) of the Listing Rules requires that there shall be an open market for the securities for which [REDACTED] is sought, and that a sufficient public float of an issuer’s [REDACTED] securities shall be maintained. This normally means that at least 25% of the issuer’s total issued share capital must at all times be held by the public. Pursuant to Rule 8.08(1)(d) of the Listing Rules, the Stock Exchange may, subject to certain conditions and at its discretion, accept a lower percentage of between 15% and 25% in the case of issuers with an expected market capitalization at the time of [REDACTED] of over HK\$10 billion.

We have applied to the Stock Exchange to request the Stock Exchange to exercise its discretion under Rule 8.08(1)(d) of the Listing Rules, and the Stock Exchange [has granted] our Company a waiver from strict compliance with the requirements of Rule 8.08(1)(a) of the Listing Rules, pursuant to which, the public float of the Company may fall below 25% of the issued share capital of the Company (assuming the [REDACTED] is not exercised) or such higher percentage of Shares held by the public (if the [REDACTED] is fully or partially exercised).

The Stock Exchange has agreed to grant the requested waiver on the conditions that:

- (i) the minimum public float of the Company should be at the highest of (a) [REDACTED]; (b) such percentage of Shares held by the public after completion of the [REDACTED]; and (c) such percentage of Shares held by the public after the exercise of the [REDACTED];
- (ii) we will make appropriate disclosure of the lower percentage of public float required by the Stock Exchange in this document;
- (iii) have an expected market capitalization at the time of the [REDACTED] of the [REDACTED] on the Stock Exchange of over HK\$10 billion;
- (iv) we will as soon as practicable announce the percentage of H Shares held by the public immediately after completion of the [REDACTED] (but before the exercise of the [REDACTED]) and upon any exercise of the [REDACTED], such that the public will be informed of the minimum public float requirement applicable to the Company;
- (v) we will confirm sufficiency of public float in the successive annual reports of the Company after the [REDACTED];
- (vi) we will implement appropriate measures and mechanisms to ensure continual maintenance of the minimum percentage of public float prescribed by the Stock Exchange; and
- (vii) we will continue to comply with Rules 8.08(2) and 8.08(3) of the Listing Rules.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

<u>Name</u>	<u>Address</u>	<u>Nationality</u>
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Executive Directors

Ms. CHEN Juan (陳娟)	Room 1401, No. 1287, Lane 1288 Shensong Road Songjiang District Shanghai PRC	Chinese
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Ms. ZHANG Yuxin (張昱昕)	Room 1905, Building 30 Xinyue Homeland Chuangxin Road Changping District Beijing PRC	Chinese
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Non-executive Directors

Mr. FU Shan (付山)	Flat D, 9/F, BLK 7, The Visionary, 1 Ying Hong Street Tung Chung, New Territories Hong Kong	Chinese
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Mr. ZHENG Guorui (鄭國銳)	Room 8602, Court 19 Shuiku Road Changping District Beijing PRC	Chinese
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Independent Non-executive Directors

Ms. CHAN Ka Lai Vanessa (陳嘉麗)	2/F No. 70, Tai Wan Village Sai Kung New Territories Hong Kong	Chinese
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DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Mr. ZHENG Yufeng (鄭玉峰)	Room 502, Unit 4, Building No. 9 District 3 Xiaojiahe Faculty Residential Peking University Haidian District Beijing PRC	Chinese
Mr. LIU Daozhi (劉道志)	Room 801, No. 10 Lane 199, Baiyang Road Pudong New District Shanghai PRC	Australian

SUPERVISORS

Name	Address	Nationality
Mr. WANG Xinglin (王興林)	58 Yanxitai, Jushan Road Haidian District Beijing PRC	Chinese
Ms. WANG Xiaoyong (王曉勇)	402, Unit 2, Building No. 18 Shitao Tianlang Chengnanjie Road Changping District Beijing PRC	Chinese
Mr. QIAN Weidong (錢衛東)	Room 503, No. 14, Lane 1079 Dakang Road Baoshan District Shanghai PRC	Chinese

Further information, see "Directors, Supervisors and Senior Management."

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

**Sole Sponsor, [REDACTED], Sole
Sponsor-[REDACTED] and Sole
[REDACTED]**

China International Capital Corporation
Hong Kong Securities Limited
29/F, One International Finance Centre
1 Harbour View Street
Central
Hong Kong

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Legal Advisors to the Company

As to Hong Kong law and U.S. law:

Wilson Sonsini Goodrich & Rosati

Suite 1509, 15/F Jardine House

1 Connaught Place Central

Hong Kong

As to PRC law:

Haiwen & Partners

20/F, Fortune Financial Center

5 Dong San Huan Central Road

Chaoyang District

Beijing 100020

PRC

As to international sanctions law:

Hogan Lovells

11th Floor, One Pacific Place

88 Queensway

Hong Kong

**Legal Advisors to the Sole Sponsor and
the [REDACTED]**

As to Hong Kong law and U.S. law:

Herbert Smith Freehills

23/F, Gloucester Tower

15 Queen's Road Central

Central

Hong Kong

As to PRC law:

Jingtian & Gongcheng

34th Floor, Tower 3

China Central Place

77 Jianguo Road

Chaoyang District

Beijing

China

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Reporting Accountants and Independent Auditor

PricewaterhouseCoopers
Certified Public Accountants
Registered Public Interest Entity Auditor
22/F, Prince’s Building
Central
Hong Kong

Industry Consultant

**Frost & Sullivan (Beijing) Inc.,
Shanghai Branch Co.**
25th Floor, Wheelock Square
Nanjing West Road
Jingan District
Shanghai
PRC

Independent Property Valuer

**Jones Lang LaSalle Corporate Appraisal
and Advisory Limited**
7/F, One Taikoo Place
979 King’s Road
Hong Kong

[REDACTED]

CORPORATE INFORMATION

Registered Address	Room 201 Building 41 No. 258, Xinzhuan Road Songjiang District Shanghai PRC
Address of Head Office in PRC	1/F, 5/F Building 41 No. 258, Xinzhuan Road Songjiang District Shanghai PRC
Principal Place of Business in Hong Kong	31/F, Tower Two Times Square 1 Matheson Street Causeway Bay Hong Kong
Company's Website	http://www.scientechmed.com/ <i>(the information contained on the website does not form part of this document)</i>
Joint Company Secretaries	Mr. Qin Xue (秦學) No. 2403, Gate 4, Building 1 Muxidi South Lane Xicheng District Beijing PRC Ms. Ng Ka Man, <i>HKICS, ICSA</i> 31/F, Tower Two, Times Square 1 Matheson Street Causeway Bay Hong Kong

CORPORATE INFORMATION

Authorized Representatives

Ms. Chen Juan (陳娟)
Room 1401, No. 1287, Lane 1288
Shensong Road
Songjiang District
Shanghai
PRC

Ms. Zhang Yuxin (張昱昕)
Room 1905, Building 30
Xinyue Homeland
Chuangxin Road
Changping District
Beijing
PRC

Audit Committee

Ms. CHAN Ka Lai Vanessa (陳嘉麗)
(Chairperson)
Mr. Zheng Yufeng (鄭玉峰)
Mr. Zheng Guorui (鄭國銳)

Remuneration Committee

Mr. Zheng Yufeng (鄭玉峰) *(Chairperson)*
Ms. Chen Juan (陳娟)
Mr. Fu Shan (付山)

Nomination Committee

Ms. Chen Juan (陳娟) *(Chairperson)*
Mr. Zheng Guorui (鄭國銳)
Mr. Liu Daozhi (劉道志)

Compliance Advisor

Halcyon Capital Limited
11/F, 8 Wyndham Street
Central
Hong Kong

[REDACTED]

CORPORATE INFORMATION

Principal Banks

**Industrial and Commercial Bank of
China, Songjiang Tech City Branch**

Level 1, 668 Xinzhuan Road
Songjiang District
Shanghai
PRC

Bank of Shanghai, Wusong Branch

153 Songbin Road
Shanghai
PRC

**China Merchants Bank
Xinsong Road Branch**

365 Xinsong Rd
Minhang District
Shanghai
PRC

Bank of Ningbo, Songjiang Branch

Level 1, 175 Renmin North Road
Songjiang District
Shanghai
PRC

INDUSTRY OVERVIEW

This section contains certain information and statistics relating to our industry which is derived from official government sources. In addition, this section and elsewhere in the document contain information extracted from a report prepared by Frost & Sullivan⁽¹⁾, commissioned by us for purposes of this document. However, the information derived from official government sources has not been independently verified by us, the Sole Sponsor, or any other party involved in the [REDACTED], and no representation is given as to its accuracy. Except as otherwise noted, all the data and forecast in this section are derived from the F&S Report.

OVERVIEW OF STRUCTURAL HEART DISEASES

Cardiovascular disease, or heart disease, is a general term that describes heart abnormalities, including primarily coronary heart diseases, arrhythmia, and structural heart diseases. Structural heart disease includes primarily CHD, valvular disease, cardiomyopathy, and complications caused by other conditions, such as atrial fibrillation, which increases the risk of, among others, cardioembolic stroke and myocardial infarction.

CHD refers to the formation of the heart and blood vessels during embryonic development or abnormal development or failure to close the channels that should be automatically closed after birth, resulting in abnormalities in the solid structure or function of the blood vessels in the heart or thoracic cavity. CHD includes primarily ASD, VSD, and PDA. ASD refers to the remnant opening, or a defect, between the left and right atria resulting from the abnormal development, absorption and fusion of the atrial septum during embryonic development. It causes the blood in the left atrium to flow into the right atrium and right ventricle, and then flows to the pulmonary artery. VSD refers to the opening, or a defect between the left and right ventricles resulting from incomplete development of the ventricular septum during the embryonic period. It causes blood to flow abnormally from the left ventricle to the right

⁽¹⁾ We commissioned Frost & Sullivan, a market research and consulting company, which is an independent third party, to conduct research and analysis of, and to produce a report on medical device market study of cardiovascular occluder and transcatheter valve therapies for the period from 2017 to 2030 (the “F&S Report”). The F&S Report has been prepared by Frost & Sullivan independent of the influence of our Group and other interested parties. We have agreed to pay Frost & Sullivan a total fee of RMB650,000 for the preparation and use of the F&S Report, and we believe that such fees are consistent with the market rate. Frost & Sullivan is a consulting firm founded in Hong Kong and provides professional industry consulting services across multiple industries. Frost & Sullivan’s services include industry consultancy services, commercial due diligence, and strategic consulting.

In compiling and preparing the report, Frost & Sullivan conducted both primary and secondary research using a variety of resources. Primary research involved interviewing key industry experts and leading industry participants. Secondary research involved analyzing data from various publicly available data sources, including but not limited to the National Bureau of Statistics, National Medical Products Administration, Food and Drug Administration, National Health Commission of the PRC, the International Monetary Fund, World Health Organization. The market projections in the F&S Report are based on the following key assumptions: (1) the overall social, economic and political environment in China is expected to remain stable during the forecast period; (2) China’s economic and industrial development is likely to maintain a steady growth trend over the next decade; (3) related key industry drivers are likely to continue driving the growth of the medical device market in China during the forecast period, such as the increasing number of surgeries, growing acceptance of domestic products, supportive government programs and policies, increasing amount of research and development expenditures, increasing patient affordability; (4) the negative impact caused by COVID-19 outbreak in 2020, 2021 and 2022 on the industry is expected to be limited, taking into account the impact of the COVID-19 outbreak and estimating market growth for 2020, 2021 and 2022 in a conservative manner based on the industry and economic recovery in China since the second quarter of 2020; and (5) there is no extreme force majeure or industry regulation in which the market may be affected dramatically or fundamentally.

INDUSTRY OVERVIEW

ventricle, and then to the pulmonary artery. PDA refers to a remnant opening of the normal blood vessel between the pulmonary artery and the aorta during the fetal period, which failed to be closed normally after birth. It causes the poorly oxygenated blood to flow in the wrong direction, which weakens the myocardium, leading to heart failure and other complications.

Cardioembolic stroke refers to a clinical syndrome in which cardiogenic emboli from the heart and aortic arch through blood circulation cause cerebral artery thrombosis and corresponding brain dysfunction. LAA is a small, ear-shaped sac in the muscle wall of the left atrium. Blood is likely to clot in the LAA to form thrombus in patients with atrial fibrillation. LAA occlusion procedures prevent the formation and breaking off of thrombus, which serves to prevent cardioembolic stroke. PFO is a small hole between the right and the left atrium. Every baby is born with a PFO, which usually closes very soon after birth. When a PFO fails to close, blood may bypass the lung and go directly from the right atrium to the left atrium. This may cause thrombus in the venous system and right atrium to flow into the left heart system from the right heart through the open foramen ovale and reach the brain, which leads to cerebral venous thrombosis, causing stroke.

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. The aortic valve governs blood flow between the heart and the aorta, and thereby the blood vessels to the rest of the body. The pulmonary valve controls the flow of blood from the heart to the lungs. The mitral and tricuspid valves control the flow of blood between the atria and the ventricles. Valvular disease includes primarily aortic valve disease, mitral valve disease, and tricuspid valve disease. Aortic valve disease is a condition in which the valve between the main pumping chamber of one’s heart, the left ventricle, and the main artery to the body, the aorta, does not work properly. Major types of aortic valve disease include aortic stenosis and aortic regurgitation.

Mitral valve disease is a condition in which the mitral valve, located between the heart’s left upper chamber and the left lower chamber, does not close properly or open completely. Major types of mitral valve disease include mitral stenosis and mitral regurgitation, which may lead to complications such as pulmonary hypertension, atrial fibrillation, and thromboembolism. Tricuspid valve disease is a condition in which the valve between the right ventricle and right atrium does not close properly. Major types of tricuspid valve diseases include tricuspid stenosis and tricuspid regurgitation, which may lead to symptoms such as shortness of breath, atrial fibrillation and atrial flutter. Among the different types of valvular diseases, aortic valve disease and mitral valve disease are most common.

GLOBAL AND CHINA’S INTERVENTIONAL MEDICAL DEVICE MARKETS TARGETING STRUCTURAL HEART DISEASES

Overview

Interventional therapy targeting structural heart diseases is a technique that enters the heart cavity or blood vessel through a blood vessel puncture route for structural heart disease diagnosis or treatment. Medical practitioners use puncture needles, catheters, and other interventional devices to introduce specific devices into human body lesions by natural orifices or small incision made from minimally invasive procedures.

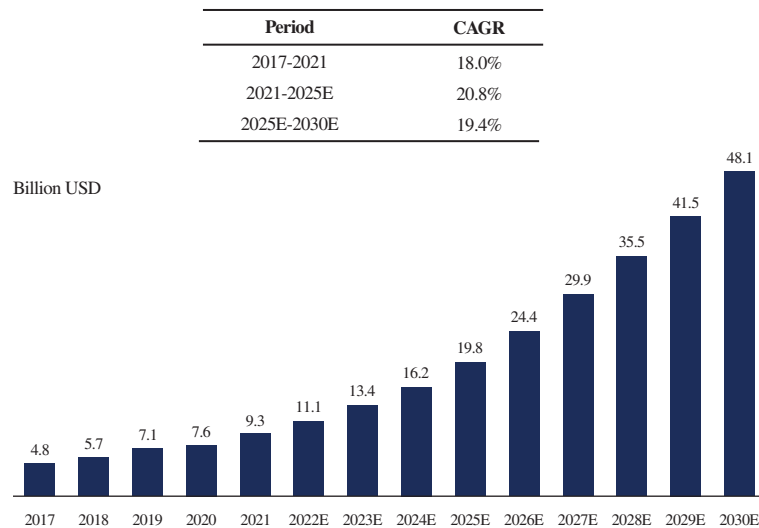
INDUSTRY OVERVIEW

Eligible patients for interventional therapy targeting structural heart diseases primarily include surgery inoperable patients, patients with no improvement after drug treatment, or patients without significant improvement after surgery. Globally, the number of eligible patients for interventional therapy targeting structural heart diseases increased from approximately 25.9 million in 2017 to approximately 29.4 million in 2021, and is expected to reach 34.2 million in 2025. In China, the number of eligible patients for interventional therapy targeting structural heart diseases increased from approximately 4.8 million in 2017 to approximately 5.3 million in 2021, and is expected to reach 6.0 million in 2025. Driven by the large patient pool, the rising disposable income per capita, and the supportive regulatory framework, it is expected that China will experience a significant growth in interventional therapy targeting structural heart diseases in the future.

Market Size

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. The following chart sets forth the historical and forecasted growth of the global interventional medical device market targeting structural heart diseases.

**Global Interventional Medical Device Market
Targeting Structural Heart Diseases, 2017-2030E**

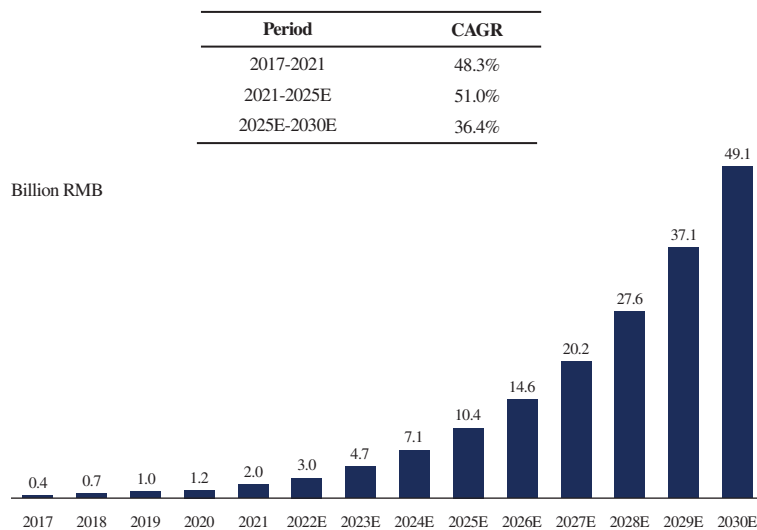


Source: F&S Report

INDUSTRY OVERVIEW

In China, the number of eligible patients for interventional therapy targeting structural heart diseases increased from approximately 4.8 million in 2017 to approximately 5.3 million in 2021 and is expected to reach approximately 6.0 million in 2025. The market size of China’s interventional medical device market targeting structural heart diseases grew from RMB0.4 billion in 2017 to RMB2.0 billion in 2021 at a CAGR of 48.3%, and is expected to reach RMB10.4 billion in 2025 at a CAGR of 51.0% from 2021 to 2025. The following chart sets forth the historical and forecasted growth of China’s interventional medical device market targeting structural heart diseases.

China’s Interventional Medical Device Market Targeting Structural Heart Diseases, 2017-2030E



Source: F&S Report

Market Drivers and Trends

Key growth drivers and trends of global and China’s interventional medical device markets targeting structural heart diseases include the following:

- Increasing substitution of open surgeries with interventional therapies.* Compared to traditional open surgeries which require large cuts in the skin, medical practitioners can perform interventional therapies with reduced or no incision. Patients will experience less pain, scarring and complications, lowered risk of infection, and shortened hospital stays and recovery time.

INDUSTRY OVERVIEW

- *Growing acceptance of domestic products in China.* Because domestic players continue to increase their investment in research and development and manufacturing, high quality and cost-effective domestic interventional medical devices have gained increasing recognition and growing competitiveness against imported products, which we believe have contributed and will continue to contribute to the market acceptance of our products.
- *Product upgrades and innovation.* Advancement in material science, PCI technology, and clinical practices drive innovative interventional therapies. Leveraging PCI technology, biodegradable stents can achieve “intervention without implantation” and contribute to vascular reconstruction with better long-term safety.
- *AI technologies empower interventional therapies.* Under the governmental support and the scientific innovation of the AI technology, the innovative commercialized applications of vascular AI have emerged, improving existing interventional therapies and indirectly boosting the interventional medical devices market.

MAIN PRODUCT CATEGORIES OF INTERVENTIONAL MEDICAL DEVICE MARKET TARGETING STRUCTURAL HEART DISEASES

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 include primarily ASD occluder, VSD occluder, and PDA occluder. Cardioembolic stroke occluder products include primarily PFO occluder and LAA occluder. Heart valve products to treat valvular diseases include primarily aortic valve products and mitral valve products.

CHD Occluder Products

Overview

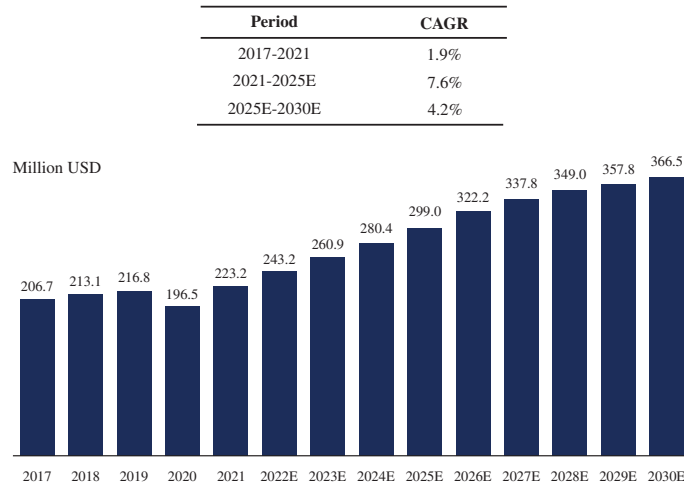
CHD interventional occlusion is a method of puncturing the peripheral blood vessels and pushing the delivery catheter and occluder to the corresponding part of the congenital heart development defect with the assistance of X-ray fluoroscopy guidance and bedside cardiac color Doppler ultrasound. It is a minimally invasive treatment technology for cardiovascular blocking for treating ASD, VSD, and PDA.

INDUSTRY OVERVIEW

Market Size

The following chart sets forth the historical and projected sales revenue of the global CHD occluder products market for the periods indicated.

Global CHD Occluder Products Market, 2017-2030E



Source: F&S Report

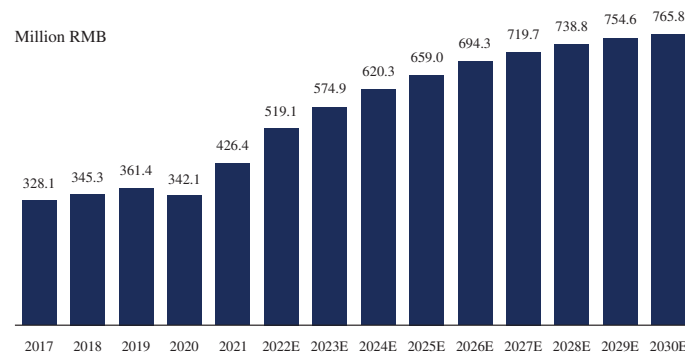
Note: The size of the global CHD occluder products market only includes the market size of three main CHD occluders, namely ASD occluder, VSD occluder and PDA occluder.

The following chart sets forth the historical and projected sales revenue of China’s CHD occluder products market for the periods indicated. The decline of the market size in 2020 was primarily as a result of the reduced demand among hospitals for medical devices as a result of the decrease of operations, as most of the hospitals devoted their resources primarily to dealing with COVID-19 in the first half of 2020. The market size increased in 2021 as a result of the increased demand for medical devices along with the effective containment of COVID-19 and the launch of an increasing number of CHD occluder products. 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.

INDUSTRY OVERVIEW

China’s CHD Occluder Products Market, 2017-2030E

Period	CAGR
2017-2021	6.8%
2021-2025E	11.5%
2025E-2030E	3.1%



Source: F&S Report

Note: The size of China’s CHD occluder products market includes the market size of three main CHD occluders, namely ASD occluder, VSD occluder and PDA occluder, and the market size of the related procedural accessories.

Market Driver and Future Trends

Key growth driver and future trends of global and China’s CHD occluder products markets include the following:

- *Supportive medical insurance policy in China.* CHD patients are mainly in the underdeveloped central and western regions in China. At present, the reimbursement ratio of the new rural cooperative medical insurance for major illnesses is different from the reimbursement ratio of large cities in the southeast coastal area, which is generally higher than other regions. The Chinese government seeks to increase the reimbursement ratio from the current level and scope; therefore, we expect CHD occluder products will become more affordable for patients in central and western regions in China.
- *High market potential in China.* At present, there are approximately 150,000 newborns with CHD in China each year. However, compared with the high treatment rate of CHD in Europe and the United States, the current treatment of CHD patients in China is low, and so is the penetration rate of CHD occluder products in China. The domestic market for CHD occluder devices is expected to proliferate in the future, which we believe will provide further demand for our CHD occluder products.

INDUSTRY OVERVIEW

- *Technology development.* The treatment for CHD has a remarkable change in the past decade due to the evolution of the medical device. Interventional therapy has become the primary treatment option for CHD patients because such therapy has better outcomes and fewer complications than other treatment options.
- *Increasing substitution of open surgeries with interventional therapies.* Compared to traditional open surgeries which require large cuts in the skin, medical practitioners can perform interventional therapies with reduced or no incision. CHD patients will have reduced associated pain, scarring and complications, lowered risk of infection, and shortened hospital stays and recovery time.

Competitive Landscape

In China, domestic CHD manufacturers dominated the market with market share of approximately 91.5% in 2021, with the remaining approximately 8.5% occupied by international CHD manufacturers. The following charts set forth the top five players in China’s occluder products market, in terms of revenue recognized for the sales in China in 2021. We are the largest manufacturer of CHD occluder products and the related procedural accessories in China, and we believe that we will continue to remain competitive in the market, leveraging our broad product portfolio of marketed and pipeline products.

Top Five Players in China’s CHD Occluder Products Market, 2021

Ranking	Company	Sales revenue	Market share by sales revenue
		<i>(RMB million)</i>	
1	Our Company	162.2	38.0%
2	Company A ⁽¹⁾	146.0	34.2%
3	Company B ⁽²⁾	52.9	12.4%
4	Company C ⁽³⁾	36.4	8.5%
5	Company D ⁽⁴⁾	9.1	2.1%
	Subtotal	406.5	95.3%

Source: F&S Report

- (1) Company A is a public company listed on the Hong Kong Stock Exchange primarily focusing on developing, manufacturing and marketing interventional medical devices for cardiovascular and peripheral vascular diseases. Company A had revenue of approximately RMB925.3 million in 2021 and total assets of approximately RMB3,183.7 million as of December 31, 2021.
- (2) Company B is a private company headquartered in Beijing primarily focusing on the R&D, production and sales of interventional medical devices for congenital heart diseases.
- (3) Company C is a public company listed on the New York Stock Exchange with a portfolio of nutrition, diagnostics, medicines and medical devices. Company C had net sales of approximately US\$43.1 million in 2021 and total assets of approximately US\$75.2 million as of December 31, 2021.
- (4) Company D is a private company located in Shanghai primarily focusing on the R&D, manufacturing and sales of cardiovascular and cerebrovascular interventional medical devices.

INDUSTRY OVERVIEW

Cardioembolic Stroke Occluder Products

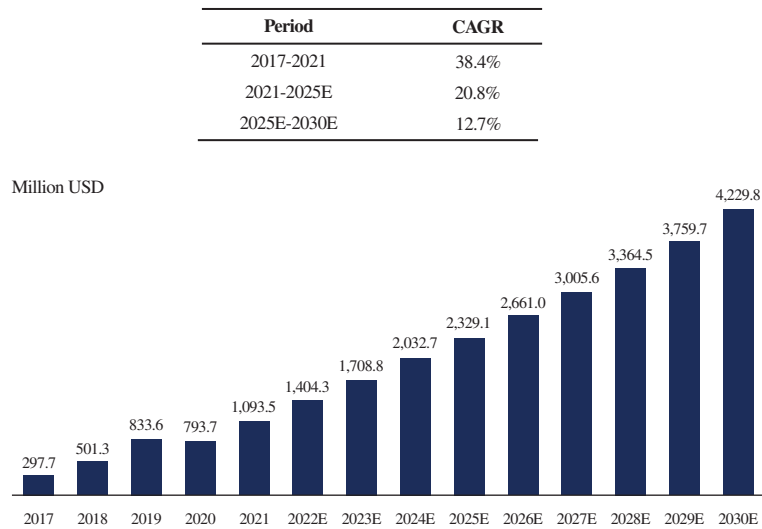
Overview

Interventional occlusion is a method for the prevention of cardioembolic stroke and related symptoms, including migraine, peripheral arterial embolism, and decompression sickness. Cardioembolic stroke occluder products primarily include PFO and LAA occluder products.

Market Size

The following chart sets forth the historical and projected sales revenue of the global cardioembolic stroke occluder products market for the periods indicated. The decline of the market size in 2020 was primarily due to the COVID-19 impact.

Global Cardioembolic Stroke Occluder Products Market, 2017-2030E



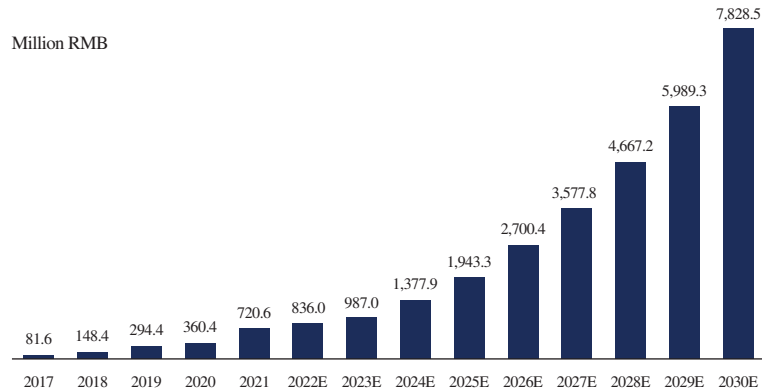
Source: F&S Report

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. The following chart sets forth the historical and projected sales revenue of China’s cardioembolic stroke occluder products market for the periods indicated.

INDUSTRY OVERVIEW

China’s Cardioembolic Stroke Occluder Products Market, 2017-2030E

Period	CAGR
2017-2021	72.4%
2021-2025E	28.1%
2025E-2030E	32.1%



Source: F&S Report

Market Driver and Future Trends

Key growth driver and future trends of global and China’s cardioembolic stroke occluder products markets include the following:

- *Growing demand in China.* The number of PFO occlusion procedures in China is increasing rapidly. As the evidence for migraine and paradoxical embolism becomes more apparent with the PFO occlusion, the demand for PFO occluder products is expected to grow. PFO occlusion procedures are minimally invasive, which offer an option for patients with other severe symptoms and other complications.
- *PFO occluder products will become biodegradable in the future.* Compared with metal implants, biodegradable PFO occluder products can degrade over time into carbon dioxide and water to provide better long-term safety. Accordingly, biodegradable PFO occluder products will become popular in the industry, which we believe will contribute to the market acceptance of our biodegradable PFO occluder product upon commercialization.
- *Increasing substitution of open surgeries with interventional therapies.* 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. Cardioembolic stroke patients will have reduced pain, scarring and complications, lowered risk of infection, and shortened hospital stays and recovery time.

INDUSTRY OVERVIEW

- Poor adherence to medication.* Atrial fibrillation is the most common type of sustained cardiac arrhythmia and a significant risk factor for stroke. Gold standard stroke prevention is lifelong anticoagulation, which is not suitable for all patients. Overall, 90% and 57% of thrombi found in non-valvular and valvular atrial fibrillation patients, respectively, are in the LAA, making it a target for stroke prevention. LAA occlusion devices are a mechanical alternative to oral anticoagulation.

PFO Occluder

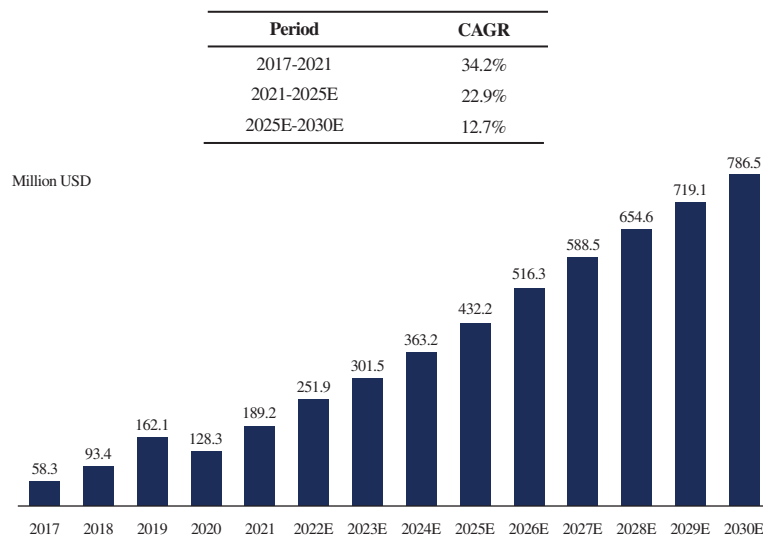
Overview

PFO occluder is a medical device that is delivered along the blood vessel to the patient’s PFO. A medical practitioner implants the PFO occluder into the patient’s PFO through a catheter from a small incision in the patient’s thigh groin. Once a medical practitioner confirms that the position is correct, the PFO occluder is opened, expands and forms on both sides of the interatrial septum, and releases the occluder.

Market Size

The following chart sets forth the historical and projected sales revenue of the global PFO occluder products market for the periods indicated. The decline of the market size in 2020 was primarily due to the COVID-19 impact.

Global PFO Occluder Products Market, 2017-2030E



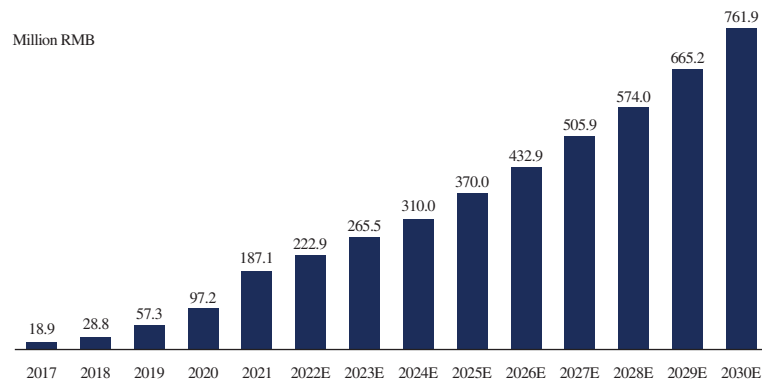
Source: F&S Report

INDUSTRY OVERVIEW

In 2021, the penetration rate of PFO occluder products in China was approximately 42.4%. The penetration rate of PFO occluder products in China is expected to grow to 59.9% by 2025. The following chart sets forth the historical and projected sales revenue of China’s PFO occluder products market for the periods indicated. The decline of the market size in 2020 was primarily due to the COVID-19 impact.

China’s PFO Occluder Products Market, 2017-2030E

Period	CAGR
2017-2021	77.3%
2021-2025E	18.6%
2025E-2030E	15.5%



Source: F&S Report

Competitive Landscape

PFO occluder therapy is still at an emerging stage, with only four players, including those with product candidates in the clinical trial stage, in China’s PFO occluder products market and only eight players in global PFO occluder products market with commercialized products as of the Latest Practicable Date. We had obtained one CE Mark for our PFO occluder product as of the Latest Practicable Date, and we expect to obtain the NMPA approval for our biodegradable PFO occluder product in the fourth quarter of 2023.

INDUSTRY OVERVIEW

The following chart sets forth the existing players in China’s PFO occluder products market with commercialized products or product candidates in the clinical trial stage as of the Latest Practicable Date.

Existing Players in China’s PFO Occluder Products Market

Company	Product	Registration Date/ Current Stage	Materials
AGA Medical Corporation	AMPLATZER PFO Occluder	NMPA approval in 2016	Alloy
Starway Medical Technology Inc.	PFO Occluder	NMPA approval in 2017	Alloy
Our Company	MemoSorb	Registration preparation stage	Fully biodegradable materials
Shanghai Mallow Medical Instrument Co., Ltd.	PFO Occluder	Clinical trial stage	Biodegradable materials

Source: F&S Report

LAA Occluder

Overview

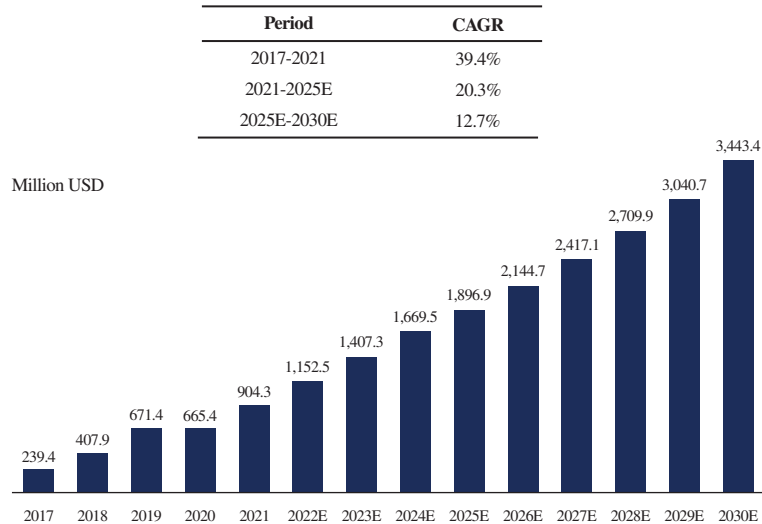
LAA occluder is a medical device that blocks LAA to prevent the formation and breaking off of thrombus, thereby preventing cardioembolic stroke. Patients may use LAA occlusion when there is no improvement after the drug treatment. For patients who have a high risk of bleeding and embolism, and are not suitable for long-term oral anticoagulant therapy, implantation of the LAA occluder is a better option for them. Through interventional therapy, a medical practitioner implants the LAA occluder into the patient’s LAA to treat the cardioembolic stroke.

INDUSTRY OVERVIEW

Market Size

The following chart sets forth the historical and projected sales revenue of the global LAA occluder products market for the periods indicated.

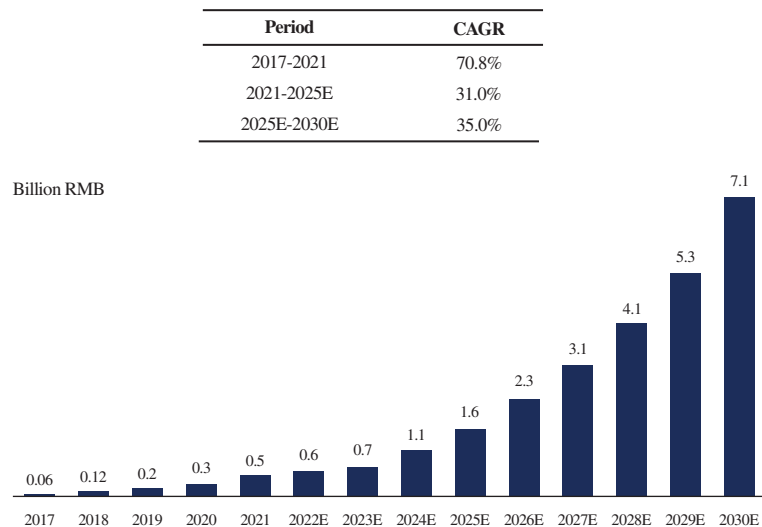
Global LAA Occluder Products Market, 2017-2030E



Source: F&S Report

In 2021, the penetration rate of LAA occluder products in China was approximately 5.9%, as compared to 44.9% in the United States and 14.6% in Europe, respectively. The penetration rate of LAA occluder products in China is expected to grow to 19.4% by 2025. The following chart sets forth the historical and projected sales revenue of China’s LAA occluder products market for the periods indicated.

China’s LAA Occluder Products Market, 2017-2030E



Source: F&S Report

INDUSTRY OVERVIEW

Competitive Landscape

LAA occluder therapy is still at an emerging stage, with only seven major players in China’s LAA occluder products market and four major players in global LAA occluder products market with commercialized products as of the Latest Practicable Date. We had obtained one NMPA registration certificate for our LAA occluder product as of the Latest Practicable Date, and our biodegradable LAA occluder product candidate was in the stage of clinical trial preparation.

The following chart sets forth the existing players in China’s LAA occluder products market with commercialized products as of the Latest Practicable Date.

Existing Players in China’s LAA Occluder Products Market

Company	Product	Registration Date	Materials
Our Company	MemoLefort	NMPA approval in 2020	Alloy
Shanghai Push Medical Device Technology Co., Ltd.	LACbes	NMPA approval in 2019	Alloy
Lifetech Scientific (Shenzhen) Co., Ltd.	LAmbre	NMPA approval in 2017	Alloy
	LAXible	NMPA approval in 2021	Alloy
St. Jude Medical, Inc.	AMPLATZER Amulet	NMPA approval in 2015	Alloy
Boston Scientific Corporation	WATCHMAN	NMPA approval in 2013	Alloy
Shanghai HeartCare Medical Technology Co., Ltd.	Laager	NMPA approval in 2022	Alloy
Shenzhen Salubris Pharmaceuticals Co., Ltd.	LAMax	NMPA approval in 2022	Alloy

Source: F&S Report

INDUSTRY OVERVIEW

Heart Valve Products

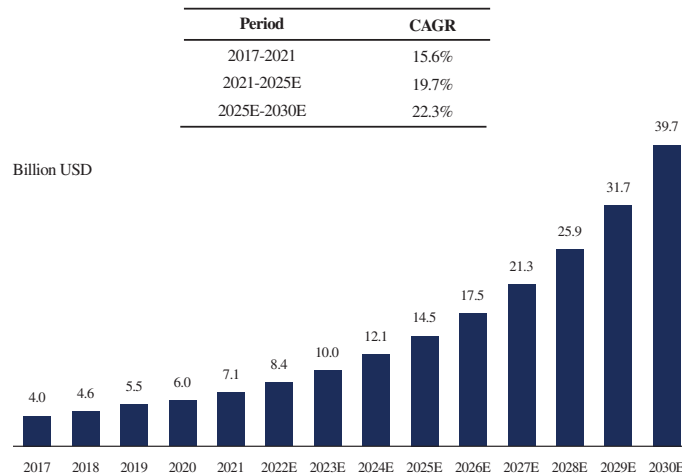
Overview

Heart valve products are medical devices implanted through interventional means, which primarily include aortic valve products and mitral valve products.

Market Size

The following chart sets forth the historical and projected sales revenue of the global valvular disease interventional device market for the periods indicated.

Global Valvular Disease Interventional Device Market, 2017-2030E

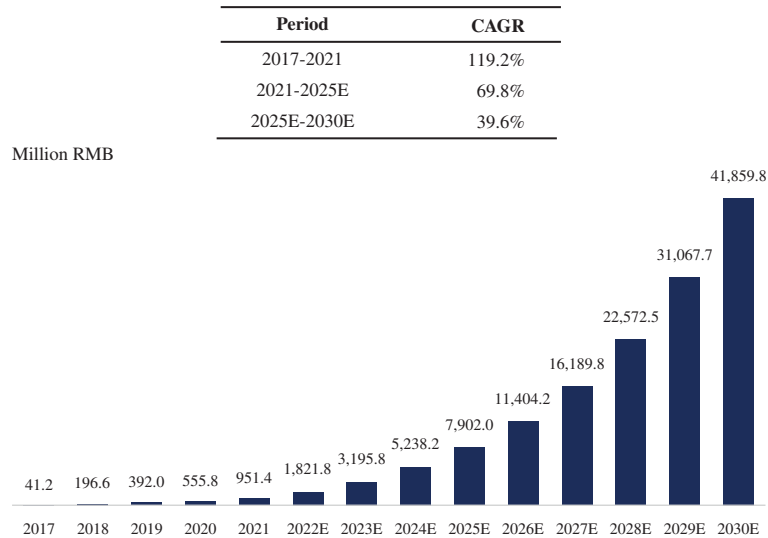


Source: F&S Report

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. The penetration rate of valvular disease interventional devices is significantly under-penetrated due to the insufficient number of qualified hospitals with experienced physicians. 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%. By 2025, the number of TMVr operations to be performed is expected to reach approximately 9,970 in China with a penetration rate of 0.08% for the TMVr operation. The following chart sets forth the historical and projected sales revenue of the China’s valvular disease interventional device market for the periods indicated.

INDUSTRY OVERVIEW

China’s Valvular Disease Interventional Device Market, 2017-2030E



Source: F&S Report

Aortic Valve Products

Overview

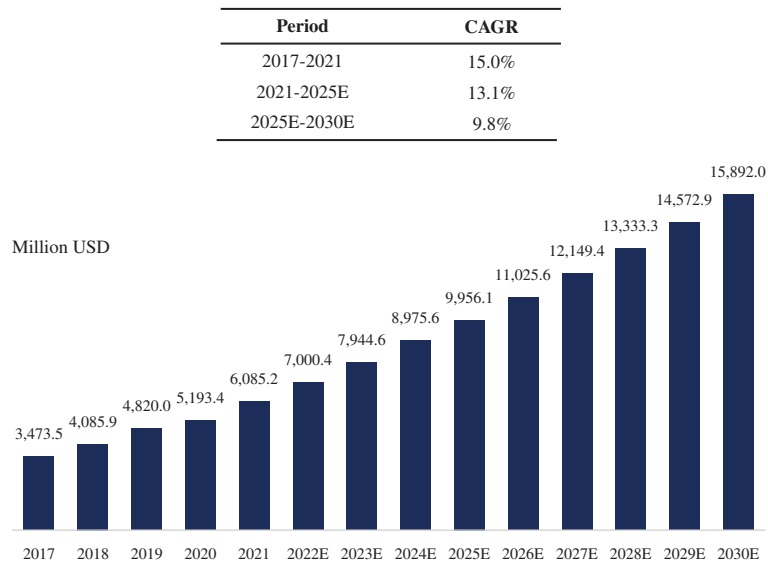
Aortic valve products primarily include TAVR system. TAVR technique implants a prosthetic valve through a vascular path to treat aortic stenosis and aortic regurgitation. TAVR technique has the advantages of small trauma and short postoperative recovery periods, which makes it suitable for patients with severe aortic stenosis or aortic regurgitation who cannot tolerate surgical aortic valve replacement.

INDUSTRY OVERVIEW

Market Size

The following chart sets forth the historical and projected sales revenue of the global TAVR market for the periods indicated.

Global TAVR Market, 2017-2030E



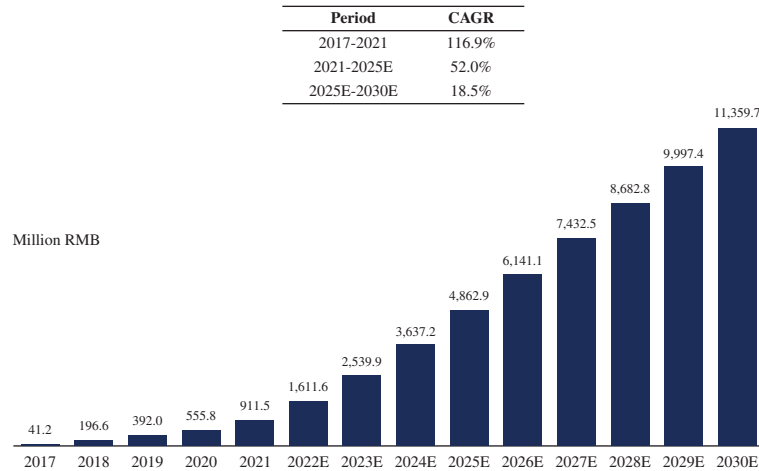
Source: F&S Report

The prevalence of aortic stenosis in China was 4.5 million in 2021 and is expected to reach 5.2 million in 2030; and the global prevalence of aortic stenosis was 20.4 million in 2021 and is expected to reach 23.9 million in 2030. The prevalence of aortic regurgitation in China was 4.0 million in 2021 and is expected to reach 4.6 million in 2030; and the global prevalence of aortic regurgitation was 27.5 million in 2021 and is expected to reach 31.6 million in 2030. Due to the insufficient number of qualified hospitals with experienced physicians, the TAVR market in China is significantly under-penetrated with only 0.8% of eligible patients treated by TAVR procedures in 2021, as compared to 4.3% globally. The number of TAVR operations to be performed in China is expected to grow from 6,600 in 2021 to 43,000 in 2025, with a CAGR of 59.6%.

INDUSTRY OVERVIEW

The following chart sets forth the historical and projected sales revenue of China’s TAVR market for the periods indicated.

China’s TAVR Market, 2017-2030E



Source: F&S Report

Competitive Landscape

TAVR market is still at an emerging stage, and there were only six major players in China’s TAVR market with only nine commercialized TAVR systems as of the Latest Practicable Date. Our TAVR system was in the clinical trial stage as of the Latest Practicable Date, and we expect to submit application to the NMPA in the fourth quarter of 2023.

INDUSTRY OVERVIEW

The following chart sets forth the existing players in China’s TAVR market with commercialized products as of the Latest Practicable Date.

Existing Players in China’s TAVR Market

Company	Product	Registration Date	Access
MicroPort CardioFlow Medtech Corporation	VitaFlow	NMPA approval in 2019	Transfemoral
	VitaFlow Liberty™	NMPA approval in 2021	Transfemoral
Venus Medtech Corporation	VenusA-Valve	NMPA approval in 2017	Transfemoral
	VenusA-Plus	NMPA approval in 2020	Transfemoral
Peijia Medical Limited	TaurusOne	NMPA approval in 2021	Transfemoral
	TaurusElite	NMPA approval in 2021	Transfemoral
Suzhou Jiecheng Medical Technology Co., Ltd.	J-Valve	NMPA approval in 2017	Transapical
Edwards Lifesciences Corporation	SAPIEN 3	NMPA approval in 2020	Transfemoral
Medtronic plc	Evolut Pro	NMPA approval in 2021	Transfemoral

Source: F&S Report

Market Drivers and Future Trends

Key growth drivers and future trends of global and China’s TAVR market include the following:

- Underserved demand.* The prevalence of aortic valve disease increases with age. Given China’s large population base, the number of high-risk aortic stenosis patients in China is enormous. For elderly patients with comorbidities, traditional surgical atrial valve replacement has a higher risk, and the post-operative recovery can be relatively slow; therefore, it is difficult to obtain effective treatment for them. The emergence of TAVR provides an alternative option for such patients with lower risk and more rapid recovery. Therefore, it is foreseeable that TAVR systems will gain market prevalence, which we believe will contribute to the market acceptance of our TAVR system upon commercialization.

INDUSTRY OVERVIEW

- *Increasing TAVR applications.* As a relatively new and refined operation, TAVR has stringent requirements for medical equipment, personnel training and technical operation. The 2020 Version of Consensus of Chinese Experts on TAVR (經導管主動脈瓣置換術中國專家共識(2020更新版)) was released on May 30, 2020 by the 14th Eastern Conference of Cardiology Forum (第十四屆東方心臟病學會議結構論壇) to promote the technical training and talent cultivation for the development of TAVR in China. In 2021, more than 170 hospitals in China carried out more than 6,000 TAVR operations, with accelerating growth rate.
- *Regulatory support.* In 2016, the State Council issued the Health and Wellness Plan in Thirteenth Five-year (“十三五”衛生與健康規劃) to promote the development of medical equipment and support the improvement of the industry-wide capacity of medical equipment and application. In 2016, NMPA, NDRC and four other ministries released the Guidelines of Plan for Development of the Pharmaceutical Industry (醫藥工業發展規劃指南) to encourage innovative medical device research and development and commercialization. These government policies will sustain the further development of the TAVR market.

Mitral Valve Products

Overview

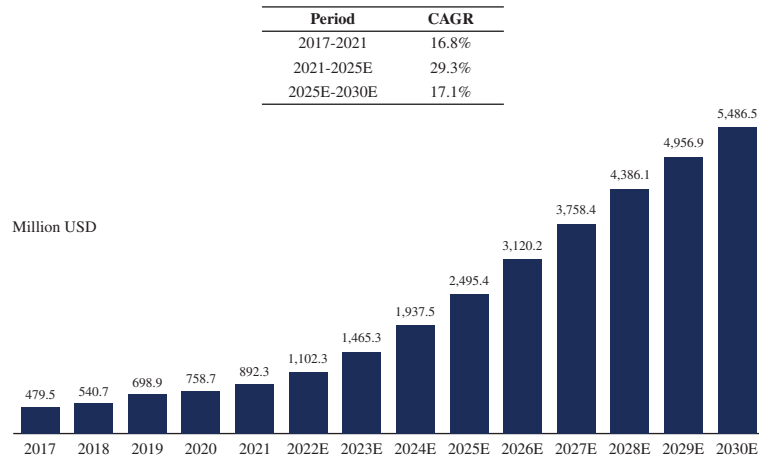
Mitral valve products primarily include the TMVCRS, the TMVr-A system, and the TMVr-F system. There are two different techniques used in mitral valve clip repair, i.e., TMVr-A and TMVr-F. TMVr market consists of (1) medical devices with application of TMVr-A technique, primarily including TMVr-A system and TMVCRS, and (2) medical devices with application of TMVr-F technique, primarily including TMVr-F system. TMVCRS is a transapical artificial chordal repair system targeting mitral regurgitation. TMVr products provide a minimally invasive option for treating the most common form of mitral regurgitation for people who cannot undergo open-chest surgery. Medical practitioners implant the product via a transcatheter technique and involve clipping together the anterior and posterior mitral valve leaflets. Compared to open-chest surgery, patients who received less invasive mitral valve products need fewer blood transfusions and ventilation days.

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Market Size

The following chart sets forth the historical and projected sales revenue of the global TMVr market for the periods indicated.

Global TMVr Market, 2017-2030E



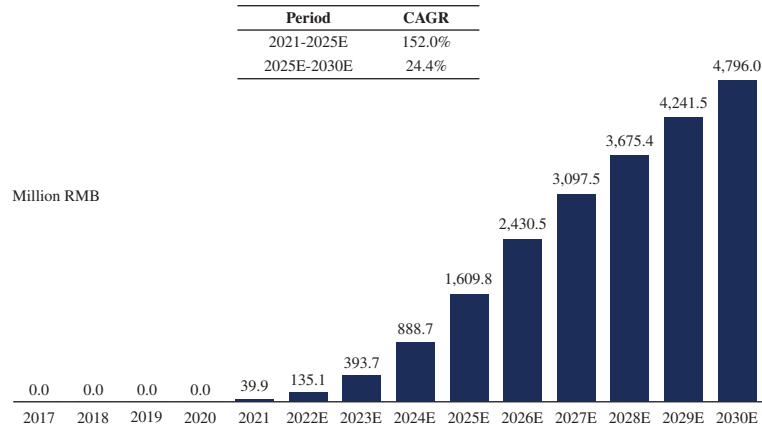
Source: F&S Report

The prevalence of mitral stenosis in China was 6.0 million in 2021 and is expected to reach 7.4 million in 2030; and the global prevalence of mitral stenosis was 16.9 million in 2021 and is expected to reach 20.2 million in 2030. The prevalence of mitral regurgitation in China was 11.1 million in 2021 and is expected to reach 13.4 million in 2030; and the global prevalence of mitral regurgitation was 99.9 million in 2021 and is expected to reach 122.0 million in 2030. The number of TMVr operations to be performed and the penetration rate of TMVr operations in China is expected to grow from approximately 190 and 0.002% in 2021 to approximately 9,970 and 0.08% by 2025, respectively.

INDUSTRY OVERVIEW

The following chart sets forth the projected sales revenue of China’s TMVr market for the periods indicated.

China’s TMVr Market, 2017-2030E



Source: F&S Report

Competitive Landscape

TMVr market is still at an emerging stage, and in 2021, there were 14 major players in China’s TMVr market, including us, with no commercialized products as of the end of 2021. Only one of such manufacturers had commercialized its TMVr device as of the Latest Practicable Date. In 2021, there were 17 major players in global TMVr market, among which only five manufacturers had commercialized their TMVr products as of the Latest Practicable Date. Our TMVCRS was at the clinical trial stage as of the Latest Practicable Date. We plan to submit registration application to the NMPA in the third quarter of 2024. As of the Latest Practicable Date, our TMVr-A system was at the clinical trial stage. We plan to submit registration application to the NMPA in the fourth quarter of 2023. Our TMVr-F system was in the type inspection stage as of the Latest Practicable Date.

INDUSTRY OVERVIEW

The following chart sets forth the existing players in China’s TMVr market with products under clinical trial stage as of the Latest Practicable Date.

Existing Players in China’s TMVr Market

Intended Use	Company	Product	Technique	Access
Repair	Hanyu Medical	ValveClamp	Edge-to-edge repair	Transapical
		ValveClasp	Edge-to-edge repair	Transfemoral
	Valgen Medtech	MitralStitch®	Mainly chordal implantation	Transapical
		DragonFly™	Edge-to-edge repair	Transfemoral
	SHSMA (LEPU ScienTech)	Memoclip	Edge-to-edge repair	Transapical
	Med-zenith	E-chord™	Chordae tendineae repair	Transapical
	Dawneo Medical	NeoNova	Edge-to-edge repair	Transfemoral
	Shenqi Medical	Qilin™ System	Edge-to-edge repair	Transfemoral
		SQ-Kyrin	Edge-to-edge repair	NA
	NewMed Medical	Valveclip-M™	Edge-to-edge repair	Transfemoral
	KOKA Lifesciences	LIFECLIP®	Edge-to-edge repair	Transapical
		KokaClip®	Edge-to-edge repair	Transfemoral
	LEPU ScienTech	TMVCRs	Chordae tendineae repair/ Edge-to-edge repair	Transapical
		TMVr-A	Edge-to-edge repair	Transapical
	Enlight Medical	NovoClasp	Edge-to-edge repair	Transfemoral & Transseptal
	HeartCare Medical	Clip2Edge®	Edge-to-edge repair	Transfemoral & Transseptal
	MVRx	ARTO	Indirect annuloplasty	Transseptal
	Neochord	NeoChord DS1000	Chordae tendineae repair	Transapical
	Valcare Medical Ltd	Amend	Chordae tendineae repair/ Edge-to-edge repair	Transapical/ Transseptal

Source: F&S Report

INDUSTRY OVERVIEW

The following chart sets forth the existing players in global TMVr market with commercialized products as of the Latest Practicable Date.

Existing Players in Global TMVr Market

Company	Product	Registration Date	Access
Abbott Laboratories	MitraClip	CE Mark in 2008	Transfemoral/Transseptal
		FDA approval in 2013	
		NMPA approval in 2020	
	Tendyne	CE Mark in 2020	Transapical
Cardiac Dimensions, Inc.	CARILLON Mitral Contour System	CE Mark in 2009	Right internal jugular vein
NeoChord, Inc.	NeoChord DS1000	CE Mark in 2013	Transapical
Edwards Lifesciences Corporation	Cardioband	CE Mark in 2015	Transfemoral/Transseptal
	PASCAL	CE Mark in 2019	Transfemoral/Transseptal
Mitralign, Inc.	MPAS Implant	CE Mark in 2016	Transfemoral

Source: F&S Report

Market Drivers and Future Trends

Key growth drivers and future trends of global and China’s TMVr market include the following:

- Underserved demand.* Mitral valve diseases have the highest prevalence in China among all valvular diseases, and the prevalence continues to rise each year due to population aging. Mitral regurgitation is the most common mitral valve disease, and approximately 40% of the patients with mitral regurgitation are not eligible for surgery due to their elder age, impaired heart function, and numerous complications. As a minimally invasive and safer option, the TMVr procedure meet the increasing demands among patients with mitral regurgitation and other mitral valve diseases, which we believe will contribute to the market acceptance of our TMVr systems upon commercialization.

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- *Advancement in disease evaluation technique.* Recent progresses have been made in echocardiography that helps to speed workflow, improve image quality, and improve valve assessments, by depicting the defective valves in structural heart diseases. Such improvement will optimize structural heart evaluations and facilitate the decision making for treating mitral valve disease, revealing more patients eligible for TMVr procedures.
- *Regulatory support.* By promoting the research and development and commercialization for innovative medical devices, government policies, such as the Health and Wellness Plan in Thirteenth Five-year (“十三五”衛生與健康規劃) and the Guidelines of Plan for Development of the Pharmaceutical Industry (醫藥工業發展規劃指南), will sustain the further development of the TMVr market.

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PRC LAWS AND REGULATIONS RELATING TO MEDICAL DEVICES

Classification of Medical Devices

Medical device industry of the PRC is subject to a large number of laws and regulations and extensive government supervision. Principal regulatory authorities of the industry are the NMPA and its local regulatory branches. In March 2018, the State Council Institutional Reform Proposal passed by the First Session of the Thirteenth National People’s Congress decided the China Food and Drug Administration (國家食品藥品監督管理總局) shall cease to exist, and the NMPA was established to undertake the duties of the former China Food and Drug Administration.

Pursuant to the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) promulgated by the State Council, which took effect on June 1, 2021, the drug administration department of the State Council shall be responsible for the supervision of medical devices of the PRC. All relevant departments of the State Council shall be responsible for the supervision of medical devices within their respective scope of duties. The drug administration departments of the local people’s governments at the county level and above are responsible for the supervision of medical devices within their own administrative jurisdictions. The relevant departments of the local people’s governments at the county level and above are responsible for the supervision of medical devices within their respective scope of duties.

Although the newly revised Regulations on Supervision and Administration of Medical Devices has come into effect, amendment of specific supporting regulations has not been completed. According to the Announcement of the NMPA on Matters Concerning the Implementation of the Regulations on Supervision and Administration of Medical Devices (《國家藥監局關於貫徹實施<醫療器械監督管理條例>有關事項的公告》) promulgated by the NMPA on May 31, 2021, the NMPA is amending the supporting regulations, normative documents and technical guidelines for the new Regulations on Supervision and Administration of Medical Devices, which will be promulgated successively as per relevant procedures. Pursuant to this announcement, among others, from June 1, 2021, applicants for registration and filing of medical devices shall continue to make the application in accordance with existing regulations until relevant supporting regulations for the new Regulations on Supervision and Administration of Medical Devices are promulgated and implemented. The registrants and filing enterprises of medical devices shall apply for production permit and conduct filing or entrusted production in accordance with the existing regulations and normative documents until relevant supporting regulations on production permit and filing are revised.

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In the PRC, medical devices are classified into three categories based on the degree of risk. Class I medical devices shall refer to those devices with low risk, and the safety and effectiveness of which can be ensured through routine administration. Class II medical devices shall refer to those devices with moderate risk, which are strictly controlled and administered to ensure their safety and effectiveness. Class III medical devices shall refer to those devices with high risk, which are strictly controlled and administered through special measures to ensure their safety and effectiveness. The classification of specific medical devices is stipulated in the Medical Device Classification Catalog (《醫療器械分類目錄》), which was latest amended on March 28, 2022.

Registration and Filings of Medical Device Products

Pursuant to the Administrative Measures for Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》) (“Medical Devices Registration Measures”) promulgated by the SAMR on August 26, 2021, which came into effect on October 1, 2021 and replaced the Regulations on Supervision and Administration of Medical Devices and the Administrative Measures for Registration of Medical Devices (《醫療器械註冊管理辦法》) which came into effect on October 1, 2014, Class I medical devices are subject to filing, and the parties undergoing the filings of medical devices shall submit the filing materials to the drug administration departments of the local people’s government at the districted city level. In case of any amendment to matters stated in the filings, such amendment shall be filed with the original filing department. Class II and Class III medical devices are subject to registration. Class II medical devices shall be examined by the drug administration departments of the people’s governments of the provinces, autonomous regions or municipality where such applicants are located. A registration certificate for such medical device shall be issued upon approval. Class III medical devices shall be examined by the NMPA. A registration certificate for such medical device shall be issued upon approval. In case of any substantial change of the product name, model, specification, designs, raw materials, production technologies, scopes of application and application methods, etc., of the registered Class II or Class III medical device, which may affect the safety and effectiveness of such medical devices, the registrants shall apply to the original registration departments for change registration.

The registration certificate for a medical device is valid for five years and the registrant shall apply to the drug administration departments for renewal six months prior to its expiration date. Except for the circumstances set forth below, the drug administration department that receives the application shall make the decision to approve the extension before the expiration of the medical device registration certificate. If the decision is not made within the time limit, it is deemed as an approval. An application for renewal registration shall not be approved under any of the following circumstances: (1) the registrant fails to apply for extending the registration within the specific time limit; (2) where the compulsory standards for medical devices have been revised, the medical devices applied for extending the registration cannot meet the new requirements; and (3) for medical devices approved with conditions, the matters stipulated in the medical device registration certificate fail to be finished within the specific time limit.

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According to the Medical Devices Registration Measures, clinical trials are not required for the filing of the Class I medical devices, but required for the application for the registration of the Class II and Class III medical devices. Medical devices may be exempt from clinical trials under any of the following circumstances: (1) the medical device has clear working mechanisms, finalized design and mature manufacturing processes, the medical devices of the same type that are available on the market have been used in clinical application for years without records of any serious adverse events, and the medical device will not change the general purposes; or (2) the safety and effectiveness of such medical device can be proved through non-clinical evaluation.

The catalog of medical devices that are exempted from clinical evaluation shall be formulated, amended and promulgated by the NMPA. On September 16, 2021, the NMPA issued the Notice on Issuing the Catalog of Medical Devices Exempted from Clinical Evaluation (《關於發佈免於臨床評價醫療器械目錄的通告》), which came into effect on October 1, 2021. Medical device products that are not included in the exemption catalog shall be analyzed and evaluated through the data obtained from the clinical trials or clinical application of the same categories of medical devices. Where the safety and effectiveness of such medical devices can be proved, applicants may specify in the course of registration application and submit relevant proof materials.

The applicants shall be an enterprise or development institution that can assume corresponding legal responsibilities, and are obliged to: (1) strengthen the quality management throughout the life cycle of medical devices, and assume liability for the safety, effectiveness and quality controllability of medical devices during the whole process of development, production, operation and use in accordance with the law; (2) establish quality management systems that are compatible with the products, and maintain their efficiency; (3) proactively carry out post-marketing research on medical devices, further confirm the safety, effectiveness and quality controllability of medical devices, and strengthen the continuous management of marketed medical device.

Medical Device Production Permit

According to the Regulations on Supervision and Administration of Medical Devices and the Administrative Measures for Supervision of the Production of Medical Devices (《醫療器械生產監督管理辦法》) promulgated by the NMPA on March 10, 2022, which became effective on May 1, 2022 and replaced the Administrative Measures for Supervision of the Production of Medical Devices issued on October 1, 2014 and amended on November 17, 2017, in addition to the required medical device registration certificates, a producer of medical devices shall file a record with or obtain a production license from drug administrative authorities at relevant level before commencing production. The medical device production license is valid for five years. Where the period of validity for the license needs to be extended upon expiry, the procedures for such extension shall be handled in accordance with the provisions of relevant laws on administrative licensing. For any changes to the contents or particulars stated in the production license, an application shall be submitted to relevant drug

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administrative authorities for such changes. For any changes to the contents or particulars stated in the certificates for production filing of Class I medical devices, the certificates shall be filed with relevant drug administration authorities for filing of changes.

According to the Administrative Measures for Supervision of the Production of Medical Devices, an enterprise engaging in the production of Class I medical devices shall complete filing with the drug administration departments under the people’s government of the city with districts where it is located and submit supporting materials evidencing its compliance with the criteria specified in the Regulations on Supervision and Administration of Medical Devices for engaging in the production of such medical devices and filing certificates of such medical devices; an enterprise engaging in the production of Class II and Class III medical devices shall apply for a production license from the drug administration departments under the people’s government of the province, autonomous region or municipality where it is located and submit supporting materials evidencing its compliance with the criteria specified in the Regulations on Supervision and Administration of Medical Devices for engaging in the production of such medical devices and the product registration certificates of such medical devices.

According to the Regulations on Supervision and Administration of Medical Devices, apart from implantable medical devices with high risks, entities that register or file the medical devices may produce such medical devices by themselves or entrust other qualified enterprises for production. The drug administration department is responsible for issuing and adjusting the specific catalogues of implantable medical devices with high risks that may not be produced by entrusted producers. Medical devices included in the Catalogue of Medical Device Prohibited from Entrusted Production (《禁止委託生產醫療器械目錄》) issued on March 11, 2022 may not be produced on an entrustment basis.

Production and Quality Management of Medical Devices

Pursuant to the Administrative Measures for Supervision of the Production of Medical Devices and the Standards on Production and Quality Management of Medical Devices (《醫療器械生產質量管理規範》) promulgated by the NMPA on December 29, 2014, which came into effect on March 1, 2015, an enterprise engaging in the production of medical devices shall establish and effectively maintain a quality control system in accordance to the requirements of the Standards on Production and Quality Management of Medical Devices. The enterprise engaging in the production of medical devices shall regularly conduct comprehensive self-inspection on the operation of quality management system in accordance with the requirements of the Standards on Production and Quality Management of Medical Devices and submit a self-inspection report to the food and drug administration departments of the local people’s governments of the provinces, autonomous regions, municipalities or at the districted city level before the end of every year. The enterprise shall establish its procurement control procedure and assess its suppliers by establishing an examination system to ensure the purchased products are in compliance with the statutory requirements. The enterprise shall record the procurement, production and inspection of raw materials. Such records shall be true, accurate, complete and traceable.

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The enterprise shall apply risk management to the whole process of design and development, production, sales and after-sale services. The measures being adopted shall be applicable to risks of the related products.

Pursuant to The Notice of Four Guidelines including On-site Inspection Guidelines for the Standards on Production and Quality Management of Medical Devices (《關於印發〈醫療器械生產質量管理規範現場檢查指導原則〉等4個指導原則的通知》) promulgated by the NMPA with effect from September 25, 2015, during the course of on-site verification of the registration of medical devices and on-site inspection of production permit, including change production permit, the inspection team will, in accordance with the guidelines, issue recommended conclusions for on-site inspections, which shall be divided into “Passed,” “Failed” and “Reassessment after rectification.” During the supervision and inspection, if it is found that the requirements of the key items or ordinary items that may have direct impact on product quality are not satisfied, the enterprise shall suspend production and go through rectification. If it is found that the requirements of the ordinary items are not satisfied, and it does not directly affect product quality, the enterprise shall rectify in a prescribed time. The regulatory authorities will examine and verify the recommended conclusions and on-site inspection materials submitted by the inspection group, and issue the final inspection results.

Good Clinical Practice for Medical Devices

On March 24, 2022, the NMPA and the National Health Commission (國家衛生健康委員會) jointly promulgated the Good Clinical Practice for Medical Devices (《醫療器械臨床試驗質量管理規範》), which became effective as of May 1, 2022. The regulation includes full procedures of clinical trial of medical devices, including, among others, the protocol design, conduction, monitoring, verification, inspection, and data collection, recording, analysis and conclusion and reporting procedure of a clinical trial. Prior to commencement of a clinical trial, the applicant must complete the pre-clinical research of the medical device, including product performance verification and confirmation, product inspection report based on the technical requirements, risk-benefit analysis, the results of which should support the clinical trial. Approval by ethics committees of the relevant clinical trial organization should also be obtained before the clinical trial, and the applicant, the clinical trial organization and the principal investigators must enter into agreements in writing to arrange their rights and obligations during the trial.

On January 4, 2018, in order to further improve the quality of registration review, encourage R&D and innovation of medical devices, the NMPA promulgated the Guidelines for the Design of Clinical Practice for Medical Devices (《醫療器械臨床試驗設計指導原則》).

In November 2018, the NMPA promulgated the Main Points of Medical Device Clinical Trial Inspection and Judgment Principles (《醫療器械臨床試驗檢查要點及判定原則》), its purpose is to strengthen the supervision and management of the clinical trial process of medical devices.

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The NMPA and the National Health and Family Planning Commission also released Medical Device Clinical Trial Institution Conditions and Filing Management Measures (《醫療器械臨床試驗機構條件和備案管理辦法》), which became effective as of January 1, 2018. According to the measures, medical device clinical trial institutions are required to submit information such as institution profile, professional technical level, organizational management capabilities, ethical review capabilities and other information to the drug administration department for archiving and reference.

Guidelines for Clinical Trials of Transcatheter Aortic Valve Implantation

In February 2019, the NMPA formally promulgated the Guidelines for Clinical Trials of Transcatheter Aortic Valve Implantation (《經導管植入式人工主動脈瓣膜臨床試驗指導原則》) (the “TAVI Clinical Trial Guidelines”). The purpose of the TAVI Clinical Trial Guidelines is to further standardize the premarketing clinical trials of transcatheter aortic valve implantation products and to guide the preparation of clinical trial data for applicants of such products when applying for the product registration.

The TAVI Clinical Trial Guidelines are the general requirements for the clinical trial of transcatheter aortic valve implantation. The applicant should enrich and refine the contents of clinical trial scheme according to the characteristics of the specific products.

Medical Device Operation Permit

According to the Regulations on Supervision and Administration of Medical Devices and the Administrative Measures for Supervision of the Operation of Medical Devices (《醫療器械經營監督管理辦法》) which was latest amended on March 10, 2022 and became effective on May 1, 2022, an enterprise engaging in the operation scale and scope, shall have quality control department or personnel suitable for the medical devices it operates. An enterprise engaging in the operations of Class I medical devices is not required to obtain approval or file a record. An enterprise engaging in the operations of Class II medical devices is required to file a record with the drug administration departments of the city with districts where it is located. An enterprise engaging in the operations of Class III medical devices shall obtain operation permit from the drug administration departments of the city with districts where it is located.

No operation permit or record filing is required for the registrant or record holder of medical devices to sell its medical devices at its domicile or production sites as long as it meets the prescribed operating conditions, while it is required for it to store and sell medical devices in other places.

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Special Procedures for Examination and Approval of Innovative Medical Devices

On October 8, 2017, the General Office of the CPC Central Committee (中共中央辦公廳) and the General Office of the State Council (國務院辦公廳) issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the “Opinions”), which aims to encourage the innovation for medical devices. Pursuant to the Opinions, the priority review and approval will be applicable to innovative medical devices supported by the National Science and Technology Major Projects (國家科技重大專項) and the National Key R&D Program of China (國家重點研發計劃支持項目), and the clinical trials of which having been conducted by the National Clinical Research Center (國家臨床醫學研究中心) and approved by the management department of the National Clinical Research Center.

Pursuant to the Special Procedures for Examination and Approval of Innovative Medical Devices (《創新醫療器械特別審查程序》) promulgated by the NMPA on November 2, 2018, which came into effect on December 1, 2018, special procedures shall be applicable to the examination and approval for medical devices in the following circumstances: (1) the applicant legally owns the invention patent of the core technology of the product through its technological innovation activities in the PRC, or legally obtained the invention patent or the right of use thereof through transfer in the PRC, and the interval between the date of application for the special examination and approval of innovative medical devices to the date of authorized publication should not exceed five years; or the patent administration department of the State Council has disclosed the application for the invention patent of the core technology and the Patent Search and Consultation Center of the National Intellectual Property Administration of the PRC (國家知識產權局專利檢索諮詢中心) has issued the patent search report setting out the novelty and innovation of the core technology solution of the product; (2) the applicant has developed the prototype product and completed the preliminary research under a true and controllable process that generated complete and traceable data; (3) the product has major working mechanism or mechanism of action which is the first of its kind in the PRC, has fundamental improvement in product performance or safety compared with similar products, is of an internationally leading standard in terms of techniques and has significant clinical value. The Center for Medical Device Evaluation of the NMPA (國家藥品監督管理局醫療器械技術審評中心) should give priority to the innovative medical devices in their technical review upon receiving the registration application, after which the NMPA will give priority to the product in their administrative approval.

Two-Invoice System

On December 26, 2016, eight government departments including the NMPA issued Notice on Opinions on the Implementation of the “Two-Invoice System” in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《印發關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)的通知》). According to the Notice, the “Two-Invoice System” refers to issuing invoice at the time from a pharmaceutical manufacturer to a circulating enterprise, and issuing invoice again at the time from a circulating enterprise to a

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medical institution. The Notice requires public medical institutions to gradually implement the “Two-Invoice System” for drug procurements and encourages other medical institutions to promote the “Two-Invoice System” so that the “Two-Invoice System” will strive to be widely promoted nationwide by 2018.

On March 5, 2018, six government departments including the National Health and Family Planning Commission issued the Notice on Consolidating the Achievements of Canceling Drug Markups and Deepening Comprehensive Reforms in Public Hospitals (《關於鞏固破除以藥補醫成果持續深化公立醫院綜合改革的通知》), which stipulates the implementation of the centralized purchase of high-value medical consumables, and that the “Two-Invoice System” in relation to high-value medical consumables shall be gradually implemented.

On July 19, 2019, the General Office of the State Council issued the Circular on Reform Plan on Managing High-Value Medical Consumables (《關於印發<治理高值醫用耗材改革方案>的通知》), which encourages local governments to adopt the “Two-Invoice System” according to actual situation in order to reduce intermediaries in the circulation of high-value medical consumables and promote the transparency of purchase and sales. This task is expected to be completed by the end of 2020.

Pursuant to the Reply of the National Healthcare Security Administration to Recommendation No. 1209 of the Second Session of the 13th National People’s Congress (《國家醫療保障局對十三屆全國人大二次會議第1209號建議的答覆》) issued by National Healthcare Security Administration on July 23, 2019, “Two-Invoice System” for high-value consumables needs to be further discussed given the huge differences between high-value consumables and pharmaceuticals and the complexity of clinical use and after-sales service.

As of the Latest Practicable Date, some provinces and municipal cities in China, had promulgated local rules to require public medical institutions in their respective administrative regions to implement the two-invoice system in the procurement process of medical consumables, such as Two-invoice System Implementation Opinions on the Procurement of Medical Consumables in Public Medical Institutions in Anhui Province (Trial) (安徽省公立醫療機構醫用耗材採購“兩票制”實施意見(試行)) promulgated on November 20, 2017, the Notice on Further Promoting the “Two Invoice System” for Medicines and Medical Consumables (關於進一步推進藥品和醫用耗材“兩票制”的通知) in Shaanxi promulgated on July 23, 2018 and the Notice from the Office of Fujian Province Medical Security Management Committee on the Province-wide Sharing of the Results of Medical Equipment (Medical Consumables) Open Procurement Implementation (福建省醫療保障管理委員會辦公室關於開展醫療器械(醫用耗材)陽光採購結果全省共享工作的通知) promulgated on July 23, 2018. According to such local rules, if the manufacturers or distributors of medical consumables fail to implement the two-invoice system, they may lose the qualification to participate in the procurement or distribution of medical consumables, and they may also be included in the bad credit record for medical consumables procurement.

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Reform Plan on High-Value Medical Consumables

According to the Notice of Ministry of Health on Further Strengthening the Administration of Centralized Procurement of Medical Devices (《衛生部關於進一步加強醫療器械集中採購管理的通知》) issued on June 21, 2007, all not-for-profit medical institutions under all levels of government and state-owned enterprises from different industries shall participate in the centralized procurement of medical devices.

Pursuant to the Notice of Opinions on Reform of Pricing System of Pharmaceuticals and Medical Services (《關於印發改革藥品和醫療服務價格形成機制的意見的通知》) issued on November 9, 2009, the management on the pricing of medical devices will be strengthened. For high-value medical devices, especially for implantable and interventional medical devices, reasonable price can be formed by measures such as limiting the price difference rate in the circulation link and publishing market price information.

According to the Administrative Norms on Centralized Procurement of High-value Medical Consumables (for Trial Implementation) (《高值醫用耗材集中採購工作規範(試行)》) issued on December 17, 2012, high-value medical consumables are defined as medical consumables directly used on human body, with strict requirement on safety and strong social response, in great demand clinically, and relatively highly-priced. The online centralized procurement works of high-value medical consumables (the “Centralized Procurement”) will be led by government and conducted by each province (region and municipality). Medical institutions and medical consumables production and operation enterprises shall make procurement through the Centralized Procurement platform established by each province (region and municipality). The administrative authorities in charge of the Centralized Procurement in each province (region and municipality) shall be responsible for formulating and preparing a Centralized Procurement list of high-value medical devices within its administrative region. High-value medical consumables listed on the Centralized Procurement list may be procured by way of public tenders, invitational tenders or by other means stipulated by PRC laws and regulations. After the procurement prices are determined, public medical institutions within relevant regions shall make procurement strictly at bidding prices.

On July 19, 2019, the General Office of the State Council issued the Circular on Reform Plan on Managing High-value Medical Consumables (《關於印發<治理高值醫用耗材改革方案>的通知》) (the “Circular”). According to the Circular, high-value medical consumables are defined as medical consumables directly used on human body, with strict requirement on safety, in great demand clinically, relatively highly-priced, and that can pose heavy burdens on patients. The Circular releases several reform initiatives aiming at managing high-value medical consumables, including: (1) the classification and codes of high-value medical consumables in the national medical insurance system will be unified gradually, and rules on unique device identification in full life cycle of the high-value medical consumables, including but not limited to registration, procurement and usage, will be implemented by the National Healthcare Security Administration, the National Medical Products Administration, and the National Health Commission of the PRC by the end of 2020; (2) The mechanism for including

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high-value medical consumables in basic medical insurance shall be built, and a list of high-value medical consumables shall be compiled, to strengthen the dynamic adjustment mechanism. The access regulations shall be promulgated by the National Health Commission and the Ministry of Finance as of the end of June 2020; (3) the price markups placed on medical consumables at public hospitals will be abolished, and all medical consumables, including high-value medical consumables will be sold at procurement price at all public hospitals as of the end of 2019; (4) the medical insurance payment policy shall be formulated and implemented by the National Healthcare Security Administration, the Ministry of Finance and the National Health Commission of the PRC. Meanwhile, the medical insurance payment standards on high-value medical consumables will be formulated and the dynamic adjustment mechanism will be established. The medical insurance funds and patients will share the cost of high-value medical consumables according to the medical insurance payment standards, and medical institutions shall further reduce procurement prices under the guidance of the Circular.

Sampling and Collecting Human Genetic Resources Filing

The Ministry of Science and Technology is responsible for the administration of human genetic resources at the national level. On July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, or Exporting Human Genetic Resources or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》), which clarified that the sampling and collection of human genetic resources through clinical trials shall be required to be filed with the China Human Genetic Resources Management Office through the online system. On October 26, 2017, the Ministry of Science and Technology promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》), which became into effect on December 1, 2017, simplifying the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

On May 28, 2019, the State Council promulgated the Administrative Regulations on Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), which came into effect on July 1, 2019, and the Standing Committee of the NPC promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) on October 17, 2020, which came into effect on April 15, 2021. According to the provisions therein, the PRC shall support the rational utilization of human genetic resources to carry out scientific research, develop the biomedical industry, improve diagnosis and treatment technologies, improve the biosafety guarantee capabilities of China, and improve people's health protection level. Foreign organizations, individuals and the institutions established or actually controlled thereby shall not collect or preserve China's human genetic resources within the territory of China, nor shall they take China's human genetic resources out of the country; while they are allowed to utilize human genetic resources of China to conduct scientific research activities through cooperation with scientific research institutions, higher education institutions, medical institutions or enterprises of China. Such international cooperative scientific research utilizing human genetic

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resources of China is subject to approval by the Ministry of Science and Technology. However, provided that human genetic resources of China are utilized in the international cooperative clinical trials for the purpose of obtaining product registration of relevant medicine and medical device in China, without providing such human genetic resources to any overseas persons, such international cooperation is subject to filing with the Ministry of Science and Technology instead of approval. Furthermore, the collection, preservation, utilization, and external provision of China's human genetic resources shall comply with the ethical principles of human genetic resources providers and be subject to ethical review in accordance with relevant regulations of the PRC.

Export Registration

Pursuant to the Rules on the Application and Issuance of Medical Device Exporting Certificate (《醫療器械產品出口證明申辦規定》) promulgated by the NMPA with effect from January 6, 1996, the NMPA represents the PRC government to conduct inspections of safety and legality of the products manufactured by domestic enterprises (including the PRC enterprises, sino-foreign equity joint ventures and foreign-owned enterprises) in accordance with the spirit of the Notice of the General Office of the State Council on Printing and Distributing the Functional Configuration, Internal Institutions and Staffing Plans of the State Administration of Medicine (《國務院辦公廳關於印發國家醫藥管理局職能配置、內設機構和人員編制方案的通知》), and to grant exporting certificate in accordance with the international conventions so as to prove that such products have obtained legitimate production permit within Chinese territory. Medical device exporting certificate granted by the NMPA must be used with the safety and quality assurance disclaimer issued by the manufacturers of such products at the same time, and such certificate shall not be used separately. Chinese version of the exporting certificate is regarded as the original copy and its English translation is deemed as a copy. Such certificate, except being specified for one time use, is valid for a term of two years.

If any of the following circumstances occurs to a production enterprise of medical device product that has obtained the exporting certificate, the NMPA will revoke such exporting certificate and inform the relevant exporting country on a timely basis: (1) the application document is found forfeited or the validity period has expired; or (2) the product received complaints from customers and such quality issue has been proved.

Advertisements of Medical Devices

Pursuant to the Regulations on Supervision and Administration of Medical Devices and the Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purpose (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) promulgated by the SAMR on December 24, 2019, which came into effect on March 1, 2020, an enterprise qualified for engaging in the production or operation of medical devices shall apply for the publication of any medical device advertisement with the market regulation, drug administration departments of the local people's governments of the provinces, autonomous regions or municipalities, and

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obtain an approval of such advertisement of medical device. The validity term of such advertisement approval shall be consistent with that of the registration certificate or record-filing certificate or the production permit of the product, whichever is the shortest. Where no validity term is set forth in the registration certificate, record-filing certificate or the production permit of the product, the advertisement approval shall be valid for two years. The content of the medical device advertisements shall be based on the registration certificate or the recordation proof. Medical device advertisement involving the name, scope of application, mechanism of action, or structure and composition of the medical device must not exceed the scope of the registration certificate or the recordation proof.

The advertisement of a medical device shall be true and lawful, and its content shall not be false, exaggerated or misleading. A publisher of a medical device advertisement shall verify approval documents and their authenticity prior to the publication. If no approval document was obtained or the authenticity of any approval document has not been verified or the content of the advertisement is inconsistent with the approval documents, such medical device advertisement shall not be published.

National Medical Insurance Program

The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the Urban Employee Basic Medical Insurance Program and the insurance premium is jointly contributed by the employers and employees. Pursuant to the Opinions on the Establishment of the New Rural Cooperative Medical System (《關於建立新型農村合作醫療制度意見的通知》) forwarded by the General Office of the State Council on January 10, 2003, China launched the New Rural Cooperative Medical System to provide medical insurance for rural residents in selected areas which has since spread to the whole nation. The State Council promulgated the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. In 2015, the General Office of the State Council announced the Outline for the Planning of the National Medical and Health Service System (2015-2020) (《全國醫療衛生服務體系規劃綱要(2015-2020年)》) which aims to establish a basic medical and health care system that covers both rural and urban residents by 2020.

On January 3, 2016, the State Council issued the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) to integrate the Urban Resident Basic Medical Insurance and the New Rural Cooperative Medical System and to establish a unified Basic Medical Insurance System for Urban and Rural Residents, which will cover all urban and rural non-working residents except for rural migrant workers and persons in flexible employment arrangements who participate in the Urban Employee Basic Medical Insurance Program.

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With regard to reimbursement for medical devices and diagnostic tests, the Notice of Opinion on the Diagnosis and Treatment Management, Scope and Payment Standards of Medical Service Facilities Covered by the Urban Employee Basic Medical Insurance Program (《關於印發城鎮職工基本醫療保險診療項目管理、醫療服務設施範圍和支付標準意見的通知》) prescribes the coverage of diagnostic and treatment devices and diagnostic tests where part of the fees is paid through the basic medical insurance program. It also includes a negative list that precludes certain devices and medical services from governmental reimbursement. Detailed reimbursement coverage and rate for medical devices and medical services (including diagnostic tests and kits) are subject to each provinces’ local policies.

Product Liability and Protection of Consumers’ Rights

Pursuant to the Product Quality Law of the PRC (《中華人民共和國產品質量法》) amended by the Standing Committee of the National People’s Congress (the “NPC”) and came into effect on December 29, 2018, producers and sellers shall have their own proper regulations for the management of product quality, rigorously implementing postoriented quality regulations, quality liabilities and relevant measures for their assessment. Producers and sellers are responsible for the product quality according to the provisions of the laws.

The product quality supervision and administration departments of the State Council are responsible for the supervision and administration of the quality of products of the whole country. All relevant departments of the State Council shall be responsible for the supervision of product quality within their own functions and duties.

Quality of products shall pass standard examinations and no substandard products shall be used as standard ones. Industrial products which may be hazardous to the health of the people and the safety of lives and property shall conform to the State and trade standards for ensuring the health of the human body and safety of lives and property. In absence of such State or trade standards, the products shall conform to the minimum requirements for ensuring the health of the human body and the safety of lives and property. It shall be prohibited to produce or sell industrial products that do not come to the requirements and demands for physical health and safety of body and property. Producers or sellers shall be responsible for any compensation arising from their unlawful acts such as production or sales of defective, eliminated or ineffective products, faking the place of origin or quality marks, mixing or adulterating products or passing off imitations as genuine, substandard products as quality ones or non-conforming products as conforming. Proceeds from the sales may be confiscated, the business license may be revoked and penalties may be imposed. If the case is serious, criminal responsibilities shall be investigated. Producers or sellers shall be liable for any damage to any person or property due to the defects of products resulting from the default of the producers or sellers.

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Pursuant to the Civil Code of the PRC (《中華人民共和國民法典》) promulgated by the Standing Committee of the NPC on May 28, 2020, which came into effect on January 1, 2021, a patient may make a claim against a medical institution or producer for any damage arising from defects of a medical device. In respect of any claim made by a patient, the medical institution is entitled to make a claim against the producer after the settlement of the compensation paid to the patient.

Medical Device Recalls

Pursuant to the Administrative Measures for Medical Device Recalls (《醫療器械召回管理辦法》) promulgated on January 25, 2017, which came into effect on May 1, 2017, in light of the severity of harm, medical device recalls are divided into: (1) Class I recall where the circumstances leading to the recall may cause or have caused serious health hazards; (2) Class II recall where the circumstances leading to the recall may cause or have caused temporary or reversible health hazards; or (3) Class III recall where the circumstances leading to the recall are not likely to cause harm.

Medical device manufacturers shall determine the recall class based on the specific situation and properly design and implement the recall plan based on the recall class and the sale and use of the medical devices. In terms of Class I recall, the recall notice shall be published on the NMPA website and major media of the central government. In terms of Class II and Class III recalls, the recall notice shall be published on the website of the food and drug administrative authority of the provinces, autonomous regions or municipalities.

PRC LAWS AND REGULATIONS RELATING TO COMPANY ESTABLISHMENT AND FOREIGN INVESTMENT

The establishment, operation and management of corporate entities in the PRC is governed by the Company Law of PRC (《中華人民共和國公司法》) (the “Company Law”), which was issued by the Standing Committee of the NPC on December 29, 1993, latest revised and became effective on October 26, 2018. Limited liability companies and stock limited companies established in the PRC shall be subject to the Company Law. A foreign-invested company is also subject to the Company Law unless otherwise provided by the foreign investment laws.

On March 15, 2019, the NPC approved the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “Foreign Investment Law”), which became effective on January 1, 2020, replaced the Sino-Foreign Equity Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合資經營企業法》), the Sino-Foreign Cooperative Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合作經營企業法》) and the Wholly Foreign-Invested Enterprise Law of the PRC (《中華人民共和國外資企業法》), and becomes the legal foundation for foreign investment in the PRC. On December 26, 2019, the State Council issued the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), which came into effect on January 1, 2020 and replaced

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the Regulations on Implementing the Sino-Foreign Equity Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合資經營企業法實施條例》), Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture Enterprise Law of the PRC (《中外合資經營企業合營期限暫行規定》), the Regulations on Implementing the Wholly Foreign-Invested Enterprise Law of the PRC (《中華人民共和國外資企業法實施細則》) and the Regulations on Implementing the Sino-foreign Cooperative Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合作經營企業法實施細則》).

The Foreign Investment Law sets out the basic regulatory framework for foreign investments and proposes to implement a management system of pre-establishment national treatment with a negative list for foreign investments, pursuant to which (1) foreign natural persons, enterprises or other organizations (collectively the “Foreign Investors”) shall not invest in any sector forbidden by the negative list for access of foreign investment, (2) for any sector restricted by the negative list, Foreign Investors shall conform to the investment conditions provided in the negative list, and (3) sectors not included in the negative list shall be managed under the principle that domestic investment and foreign investment shall be treated equally. The Foreign Investment Law also sets forth necessary mechanisms to facilitate, protect and manage foreign investments and proposes to establish a foreign investment information report system in which Foreign Investors or foreign-invested enterprises shall submit the investment information to competent departments of commerce through the enterprise registration system and the enterprise credit information publicity system. The organization form and structure and operating rules of foreign-invested enterprises are subject to the provisions of the Company Law, the Partnership Enterprise Law of the PRC (《中華人民共和國合夥企業法》) and other applicable laws, if applicable.

On December 30, 2019, the Ministry of Commerce (the “MOFCOM”) and the State Administration for Market Regulation issued the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect on January 1, 2020 and replaced the Interim Administrative Measures for the Record-filing of the Incorporation and Change of Foreign-invested Enterprises (《外商投資企業設立及變更備案管理暫行辦法》). Since January 1, 2020, for carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce administrative authorities through the Enterprise Registration System and the National Enterprise Credit Information Publicity System pursuant to these measures.

The Catalog for the Guidance of Foreign Investment Industries

Investment activities in the PRC by foreign investors and foreign-invested enterprises shall comply with the Special Administrative Measures (Negative List) for Foreign Investment Access (2021 version) (《外商投資准入特別管理措施(負面清單)(2021年版)》) (the “Negative List 2021”) and the Catalog of Industries for Encouraging Foreign Investment (2020 Version) (《鼓勵外商投資產業目錄(2020年版)》) (the “Encouraging Catalog 2020”) which were promulgated by the National Development and Reform Commission and the MOFCOM.

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Pursuant to the Encouraging Catalog 2020 and the Negative List 2021, foreign-invested projects are categorized as encouraged, restricted and prohibited. Foreign-invested projects that are not listed in the Negative List 2021 are permitted foreign invested projects.

According to the Encouraging Catalog 2020 and the Negative List 2021, the industry in which we are primarily engaged does not fall into the category of restricted or prohibited industries.

PRC LAWS AND REGULATIONS RELATING TO INTELLECTUAL PROPERTY

The Trademark Law

Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and latest amended on April 23, 2019 as well as the Implementation Regulation of the PRC Trademark Law (《中華人民共和國商標法實施條例》) adopted by the State Council on August 3, 2002 and amended on April 29, 2014. In China, registered trademarks include commodity trademarks, service trademarks, collective marks and certification marks.

The Trademark Office under the CNIPA, handles trademark registrations and grants a term of 10 years to registered trademarks. Trademarks are renewable every 10 years where a registered trademark needs to be used after the expiration of its validity term. A registration renewal application shall be filed within 12 months prior to the expiration of the term. A trademark registrant may license its registered trademark to another party by entering into a trademark license contract. Trademark license agreements must be filed with the Trademark Office for record. The licensor shall supervise the quality of the commodities on which the trademark is used, and the licensee shall guarantee the quality of such commodities. As with trademarks, the PRC Trademark Law has adopted a “first come, first file” principle with respect to trademark registration. Where trademark for which a registration application has been made is identical or similar to another trademark which has already been registered or been subject to a preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right first obtained by others, nor may any person register in advance a trademark that has already been used by another party and has already gained a “sufficient degree of reputation” through such party’s use.

The Patent Law

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》) which was amended by the Standing Committee of the NPC on October 17, 2020 and came into effect on June 1, 2021 and the Implementation Rules of The Patent Law of the PRC (《中華人民共和國專利法實施細則》) which was amended by the State Council on January 9, 2010 and came into effect on February 1, 2010, patents in China are divided into invention patent, utility patent and

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design patent. Invention patent refers to new technical solutions for a product, method or its improvement; utility patent refers to new technical solutions for the shape, structure or the combination of both shape and structure of a product, which is applicable for practical use; design patent refers to new designs of the shape, pattern or the combination of shape and pattern, or the combination of the color, the shape and pattern of a product with esthetic feeling and industrial application value. Any design for which patent right may be granted shall not be an existing design, nor has any entity or individual filed before the date of filing with the patent administration department under the State Council an application relating to the identical design disclosed in patent documents announced after the date of filing. The protection period is 20 years for an invention patent, 10 years for a utility patent and 15 years for design patent, commencing from their respective application dates. The patent right entitled to its owner shall be protected by the laws. Any person shall be licensed or authorized by the patent owner before using such patent. Otherwise, the use constitutes an infringement of the patent right.

The Copyright Law

Pursuant to the Copyright Law of the PRC (《中華人民共和國著作權法》) which was amended by the Standing Committee of the NPC on November 11, 2020 and came into effect on June 1, 2021, Chinese citizens, legal persons or other organizations shall, whether published or not, enjoy copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology and computer software created in writing or oral or other forms. A copyright holder shall enjoy a number of rights, including the right of publication, the right of authorship and the right of reproduction.

Pursuant to the Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》) promulgated by the National Copyright Administration (國家版權局) on February 20, 2002 and the Regulations on Computers Software Protection (《計算機軟件保護條例》) amended by the State Council on January 30, 2013 with effect from March 1, 2013, the National Copyright Administration is mainly responsible for the registration and management of software copyright in China and recognizes the China Copyright Protection Center as the software registration organization. The China Copyright Protection Center shall grant certificates of registration to computer software copyright applicants in compliance with the regulations of the Measures for the Registration of Computer Software Copyright and the Regulations on Computers Software Protection.

Domain Names

Pursuant to the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》) which was promulgated by the Ministry of Industry and Information Technology (工業和信息化部) on August 24, 2017 and came into effect on November 1, 2017, the establishment of any domain name root server and institution for operating domain name root servers, managing the registration of domain name and providing registration services in relation to domain name within the territory of China shall be subject to the approval of the Ministry of Industry and Information Technology or provincial, autonomous regional and municipal communications administration. The registration of domain name shall follow the

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principle of “first apply first register.” The Notice of the Ministry of Industry and Information Technology on Regulating the Use of Domain Names in Internet Information Services (《工業和信息化部關於規範互聯網信息服務使用域名的通知》) promulgated by the Ministry of Industry and Information Technology on November 27, 2017 with effect from January 1, 2018 specifies the obligation of anti-terrorism and maintaining network security of internet information service providers.

PRC LAWS AND REGULATIONS RELATING TO LABOR

Pursuant to the PRC Labour Law (《中華人民共和國勞動法》) promulgated on July 5, 1994 with effect from January 1, 1995, and latest revised on December 29, 2018, as well as the PRC Labour Contract Law (《中華人民共和國勞動合同法》) promulgated on June 29, 2007, revised on December 28, 2012 with effect from July 1, 2013, if an employment relationship is established between an entity and its employees, written labour contracts shall be executed between them. The relevant laws stipulate the maximum number of working hours per day and per week, respectively. Furthermore, the relevant laws also set forth the minimum wage. The entities shall establish and develop systems for occupational safety and sanitation, implement the rules and standards of the PRC government on occupational safety and sanitation, educate employees on occupational safety and sanitation, prevent accidents at work and reduce occupational hazards.

Pursuant to the Interim Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) promulgated on January 22, 1999, and last revised on March 24, 2019, Decisions of the State Council on Modifying the Basic Endowment Insurance System for Enterprise Employees (《國務院關於完善企業職工基本養老保險制度的決定》) promulgated on December 3, 2005, Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program, the Regulations on Unemployment Insurance (《失業保險條例》) effective from January 22, 1999, Regulations on Work-Related Injury Insurance (《工傷保險條例》) promulgated on April 27, 2003 with effect from January 1, 2004, and latest amended on December 20, 2010, and the Interim Measures concerning the Maternity Insurance for Enterprise Employees (《企業職工生育保險試行辦法》) promulgated on December 14, 1994 with effect from January 1, 1995, employers are required to register with the competent social insurance authorities and provide their employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and medical insurance.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), which was promulgated on October 28, 2010 and latest amended with effect from December 29, 2018, all employees are required to participate in basic pension insurance, basic medical insurance schemes and unemployment insurance, which must be contributed by both the employers and the employees. All employees are required to participate in work-related injury insurance and maternity insurance schemes, which must be contributed by the employers. Employers are required to complete registrations with local social insurance authorities.

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Moreover, the employers must timely make all social insurance contributions. Except for mandatory exceptions such as force majeure, social insurance premiums may not be paid late, reduced or be exempted. Where an employer fails to make social insurance contributions in full and on time, the social insurance contribution collection agencies shall order it to make all or outstanding contributions within a specified period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

Pursuant to the Administrative Regulations on Housing Provident Fund (《住房公積金管理條例》) effective from April 3, 1999, and latest amended on March 24, 2019, enterprises are required to register with the competent administrative centers of housing provident fund and open bank accounts for housing provident funds for their employees. Employers are also required to timely pay all housing fund contributions for their employees. Where an employer fails to submit and deposit registration of housing provident fund or fails to go through the formalities of opening housing provident fund accounts for its employees, the housing provident fund management center shall order it to go through the formalities within a prescribed time limit. Failing to do so at the expiration of the time limit will subject the employer to a fine of not less than RMB10,000 and up to RMB50,000. When an employer fails to pay housing provident fund due in full and in time, housing provident fund center is entitled to order it to rectify, failing to do so would result in enforcement exerted by the court.

Furthermore, according to the Notice of the General Office of the SAT on Conducting the Relevant Work Concerning the Collection and Administration of Social Insurance Premiums in a Steady, Orderly and Effective Manner (《國家稅務總局辦公廳關於穩妥有序做好社會保險費徵管有關工作的通知》) issued on September 13, 2018 and the Urgent Notice of the General Office of the Ministry of Human Resources and Social Security on Implementing the Spirit of the Executive Meeting of the State Council in Stabilizing the Collection of Social Insurance Contributions (《人力資源社會保障部辦公廳關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知》) issued on September 21, 2018, all the local authorities responsible for the collection of social insurance are strictly forbidden to conduct self-collection of historical unpaid social insurance contributions from enterprises. The Notice of the SAT on Implementing Measures to Further Support and Serve the Development of Private Economy (《國家稅務總局關於實施進一步支持和服務民營經濟發展若干措施的通知》) issued on November 16, 2018 further underlines that tax authorities at all levels may not organize self-collection of arrears of taxpayers including private enterprises in the previous years. The Notice of the General Office of the State Council on Promulgating the Comprehensive Plan for the Reduction of Social Insurance Premium Rate (《國務院辦公廳關於印發降低社會保險費率綜合方案的通知》) issued on April 1, 2019 generally reduces the social insurance contribution burden of enterprises, and re-emphasizes that local authorities shall not conduct self-collection of historical unpaid social insurance contributions from enterprises.

REGULATORY OVERVIEW

PRC LAWS AND REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) which was latest amended on April 24, 2014 and became effective on January 1, 2015; the Law of the PRC on Environment Impact Assessment (《中華人民共和國環境影響評價法》) which was revised and became effective on December 29, 2018; the Rules on the Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) which was revised on July 16, 2017 and became effective on October 1, 2017; the Interim Measures on the Environmental Protection Acceptance Check on Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) promulgated with effect from November 20, 2017, for a construction project for which an environmental impact report or environmental impact statement shall be prepared, the construction unit shall submit the environmental impact report or environmental impact statement to the competent administrative department of the environmental protection for approval before starting construction. For a construction project for which an environmental impact registration form shall be filled in according to the law, the construction unit shall submit the environmental impact registration form to the competent administrative department of the environmental protection for record. For a construction project for which an environmental impact report or environmental impact statement shall be prepared, before starting to operate, the construction unit shall organize the inspection and acceptance, after passing the acceptance check, the project can go into production or be delivered for use.

PRC LAWS AND REGULATIONS RELATING TO FIRE SECURITY

Pursuant to the Fire Protection Law of the PRC (《中華人民共和國消防法》) which was latest revised on April 29, 2021, and the Measure for Supervision on and Inspection of Fire Protection (《消防監督檢查規定》) amended in 2012, enterprises shall implement a fire safety accountability system, install firefighting facilities and equipment, conduct a yearly comprehensive inspection of firefighting facilities and keep the inspection records for future reference, and perform other fire safety measures as well as other fire safety and protection responsibilities. Pursuant to Interim Provisions on the Administration of Fire Protection Design Review and Final Inspection of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) ("Interim Provisions Regarding Fire Protection") effective on June 1, 2020, a special construction project as stipulated in the Interim Provisions Regarding Fire Protection shall be subject to fire protection design review before such project was commenced construction and shall be subject to fire protection inspection before such project was put into used. Other construction projects other than a special construction project shall be subject to fire protection inspection recordation, and the competent department of housing and urban-rural development shall conduct a random fire protection inspection thereof. If the project fails to pass the random fire protection inspection, such project shall be ceased to use.

REGULATORY OVERVIEW

PRC LAWS AND REGULATIONS RELATING TO PRODUCTION SAFETY

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》) amended by the Standing Committee of the NPC on August 31, 2014 and coming into effect on December 1, 2014, an enterprise shall (1) provide production safety conditions as stipulated in this law and other relevant laws, administrative regulations, national and industry standards, (2) establish a comprehensive production safety accountability system and production safety rules, and (3) develop production safety standards to ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities. The person-in-charge of an enterprise shall be fully responsible for the safety of production of the enterprise. An enterprise having more than 100 employees shall establish a department or engage in personnel managing production safety specifically. Personnel who is responsible for managing production safety shall inspect the safety of production regularly based on the characteristics of production of the enterprise and shall deal with any safety issue identified during the inspection in a timely manner. Any unsolved issue shall be reported to the person-in-charge in a timely manner and the person-in-charge shall solve such issue immediately. The inspection and measures taken shall be duly recorded. Enterprises and institutions shall provide their employees with training on production safety and shall truthfully inform their employees of any potential risks in relation to the workplace and duties, preventive measures and emergency measures. In addition, an enterprise shall provide its employees with protective equipment that meet the national or industry standards and supervise and train them to use such equipment.

On June 10, 2021, the Standing Committee of the NPC amended the Production Safety Law of the PRC, which will come into effect on September 1, 2021. Pursuant to the latest amended Production Safety Law of the PRC, an enterprise shall implement the production safety responsibility system with full participation of all staff, and establish a dual prevention mechanism consisting of graded management and control of risks and investigation and handling of hidden dangers. The latest amended law also imposes heavier penalties for illegal acts by raising the upper and lower limits of fines and continuously calculating fines on a daily basis.

PRC LAWS AND REGULATIONS RELATING TO TAXATION

Enterprises Income Tax

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) promulgated by the NPC on March 16, 2007, which took effect on January 1, 2008 and was latest amended on December 29, 2018, and its implementing rules, a unified enterprise income tax rate of 25% is applied equally to both domestic enterprises and foreign invested enterprises excluding non-resident enterprises.

REGULATORY OVERVIEW

Value-added Tax

The Circular on Comprehensively Promoting the Pilot Program of the Collection of Value-added Tax in Lieu of Business Tax (《關於全面推開營業稅改徵增值稅試點的通知》) was promulgated by SAT and Ministry of Finance on March 23, 2016 and effective from May 1, 2016, the pilot program of the collection of value-added tax in lieu of business tax shall be promoted nationwide in a comprehensive manner as of May 1, 2016.

Pursuant to the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例》) promulgated by the State Council on December 13, 1993 and latest amended on November 19, 2017 and its implementing rules promulgated on December 25, 1993 and latest amended by Ministry of Finance on November 28, 2011, tax payers engaging in selling goods, labor services, or tangible movable property leasing services or importing goods within the territory of the PRC shall pay value-added tax (the “VAT”) at the tax rate of 6%, 11% or 17%. Taxpayers engaged in selling services or intangible assets shall pay VAT at the tax rate of 6%. Unless otherwise provided by the State Council, the tax rate of VAT shall be zero on goods exported by taxpayers.

According to the Interim Regulations of the PRC on Business Tax (《中華人民共和國營業稅暫行條例》) (the “BT Regulations”) promulgated by the State Council on December 13, 1993 and amended on November 10, 2008, all units and individuals providing taxable services as prescribed in the BT Regulations, transferring intangible assets or selling immovable properties within the territory of the PRC shall be taxpayers of business tax, and shall pay business tax in accordance with these regulations. For taxpayers providing services, transferring intangible assets or selling immovable properties under different tax items, the turnover, transfer and sales volume under different tax items shall be accounted for respectively. Where the turnover has not been accounted for respectively, a higher tax rate shall apply. The BT Regulations has been abolished by the State Council on November 19, 2017.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on the Adjustment to VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) which was promulgated by Ministry of Finance and SAT on April 4, 2018 and came into effect on May 1, 2018, the VAT rates of 17% and 11% applicable to the general VAT payers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively. According to the Announcement on Policies for Deepening the VAT Reform (《關於深化增值稅改革有關政策的公告》) jointly which was promulgated by Ministry of Finance, SAT and General Administration of Customs on March 20, 2019, which became effective on April 1, 2019, for general VAT payers’ sales activities or imports that are subject to VAT at an existing applicable rate of 16% or 10%, the applicable VAT rate is adjusted to 13% or 9% respectively.

REGULATORY OVERVIEW

Dividend Withholding Tax

Pursuant to the Enterprise Income Tax Law of the PRC and its implementation rules, if a non-resident enterprise has not set up an organization or establishment in the PRC, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. Pursuant to the Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), the withholding tax rate in respect to the payment of dividends by a PRC enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise is the beneficial owner of the dividends and directly holds at least 25% of the PRC enterprise.

Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》), if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment. Furthermore, the Administrative Measures for Non-Resident Taxpayer to Enjoy Treatments under Tax Treaties (《非居民納稅人享受稅收協定待遇管理辦法》) (the “SAT Circular 60”), which became effective in November 2015, require that non-resident enterprises which satisfy the criteria for entitlement to tax treaty benefits may, at the time of tax declaration or withholding declaration through a withholding agent, enjoy the tax treaty benefits, and be subject to ongoing administration by the tax authorities. In the case where the non-resident enterprises do not apply to the withholding agent to claim the tax treaty benefits, or the materials and the information stated in the relevant reports and statements provided to the withholding agent do not satisfy the criteria for entitlement to tax treaty benefits, the withholding agent should withhold tax pursuant to the provisions of the PRC tax laws. The SAT issued the Announcement of State Taxation Administration on Promulgation of the Administrative Measures on Non-resident Taxpayers Enjoying Treaty Benefits (《國家稅務總局關於發佈〈非居民納稅人享受協定待遇管理辦法〉的公告》) (the “SAT Circular 35”) on October 14, 2019, which became effective on January 1, 2020. The SAT Circular 35 further simplified the procedures for enjoying treaty benefits and replaced the SAT Circular 60. According to the SAT Circular 35, no approvals from the tax authorities are required for a non-resident taxpayer to enjoy treaty benefits, where a non-resident taxpayer self-assesses and concludes that it satisfies the criteria for claiming treaty benefits, it may enjoy treaty benefits at the time of tax declaration or at the time of withholding through the withholding agent, but it shall gather and retain the relevant materials as required for future inspection, and accept follow-up administration by the tax authorities. There are also other conditions for enjoying the reduced withholding tax rate according to other relevant tax rules and regulations. According to the Circular of the State Administration of Taxation on Several Issues regarding the “Beneficial Owner” in Tax Treaties (《國家稅務總局關於稅收協定中“受益所有人”有關問題的公告》), which was issued on February 3, 2018 by the SAT, effective as of April 1, 2018, when determining the applicant’s status of the “beneficial owner” regarding tax treatments in

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connection with dividends, interests or royalties in the tax treaties, several factors, including without limitation, whether the applicant is obligated to pay more than 50% of its income in 12 months to residents in third country or region, whether the business operated by the applicant constitutes the actual business activities, and whether the counterparty country or region to the tax treaties does not levy any tax or grant tax exemption on relevant incomes or levy tax at an extremely low rate, will be taken into account, and it will be analyzed according to the actual circumstances of the specific cases. This circular further provides that applicants who intend to prove his or her status of the “beneficial owner” shall submit the relevant documents to the relevant tax bureau according to the Administrative Measures for Non-Resident Taxpayers to Enjoy Treatments under Tax Treaties.

PRC LAWS AND REGULATIONS RELATING TO FOREIGN EXCHANGE

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》) which was promulgated by the State Council on January 29, 1996 and latest amended on August 5, 2008. Pursuant to these regulations and other PRC rules and regulations on currency conversion, Renminbi is freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of the SAFE or its local counterpart is obtained.

On February 13, 2015, SAFE promulgated the Notice on Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies (《關於進一步簡化和改進直接投資外匯管理政策的通知》), according to which, entities and individuals may apply for such foreign exchange registrations from qualified banks. The qualified banks, under the supervision of SAFE, may directly review the applications and conduct the registration. On March 30, 2015, SAFE promulgated the Circular on Reforming the Management Approach regarding the Settlement of Foreign Capital of Foreign-invested Enterprise (《關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the “SAFE Circular 19”). According to the SAFE Circular 19, the foreign exchange capital of foreign-invested enterprises shall be subject to the Discretionary Foreign Exchange Settlement, which means that the foreign exchange capital in the capital account of a foreign-invested enterprise for which the rights and interests of monetary contribution have been confirmed by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operational needs of the foreign-invested enterprise, and if a foreign-invested enterprise needs to make further payment from such account, it still needs to provide supporting documents and proceed with the review process with the banks. Furthermore, the SAFE Circular 19 stipulates that the use of capital by foreign-invested enterprises shall follow the principles of authenticity and self-use within the business scope of enterprises. The capital of a foreign-invested enterprise and capital in Renminbi obtained by the foreign-invested enterprise from foreign exchange settlement shall not be used for the following purposes: (1) directly or indirectly used for payments beyond the business scope of the enterprises or payments as prohibited by relevant laws and regulations;

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(2) directly or indirectly used for investment in securities unless otherwise provided by the relevant laws and regulations; (3) directly or indirectly used for granting entrust loans in Renminbi (unless permitted by the scope of business), repaying inter enterprise borrowings (including advances by the third-party) or repaying the bank loans in Renminbi that have been sub-lent to third parties; or (4) directly or indirectly used for expenses related to the purchase of real estate that is not for self-use (except for the foreign-invested real estate enterprises).

The Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《關於進一步改進和調整直接投資外匯管理政策的通知》) (the “SAFE Circular 59”) which became effective on December 17, 2012 and was amended on December 30, 2019, cancels the administrative approvals of foreign exchange registration of direct domestic investment and direct overseas investment and simplifies the procedure of foreign exchange-related registration. Pursuant to SAFE Circular 59, investors should register with banks for direct domestic investment and direct overseas investment.

The Circular on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《關於改革和規範資本項目結匯管理政策的通知》) (the “SAFE Circular 16”), was promulgated by SAFE on June 9, 2016. Pursuant to SAFE Circular 16, enterprises registered in the PRC may also convert their foreign debts from foreign currency to Renminbi on a self-discretionary basis. The SAFE Circular 16 reiterates the principle that Renminbi converted from foreign currency-denominated capital of a company may not be directly or indirectly used for purposes beyond its business scope or prohibited by PRC Laws, while such converted Renminbi shall not be provided as loans to its non-affiliated entities.

On January 26, 2017, SAFE promulgated the Circular on Further Improving Reform of Foreign Exchange Administration and Optimizing Genuineness and Compliance Verification (《關於進一步推進外匯管理改革完善真實合規性審核的通知》), which stipulates several capital control measures with respect to the outbound remittance of profit from domestic entities to offshore entities, including: (1) banks should check board resolutions regarding profit distribution, the original version of tax filing records, and audited financial statements pursuant to the principle of genuine transactions; and (2) domestic entities should hold income to account for previous years’ losses before remitting the profits. Moreover, pursuant to this circular, domestic entities should make detailed explanations of the sources of capital and utilization arrangements, and provide board resolutions, contracts, and other proof when completing the registration procedures in connection with an outbound investment.

On October 23, 2019, the SAFE promulgated the Notice for Further Advancing the Facilitation of Cross-border Trade and Investment (《關於進一步促進跨境貿易投資便利化的通知》), which, among other things, allows all FIEs to use Renminbi converted from foreign currency denominated capital for equity investments in China, as long as the equity investment is genuine, does not violate applicable laws, and complies with the negative list on foreign investment. However, since this circular is newly promulgated, it is unclear how the SAFE and competent banks will carry it out in practice.

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According to the Circular of the State Administration for Foreign Exchange on Optimizing Foreign Exchange Administration to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) (the “SAFE Circular 8”) promulgated with effect from April 10, 2020 by the SAFE, the reform of facilitating the payments of incomes under the capital accounts shall be promoted nationwide. Under the prerequisite of ensuring true and compliant use of funds and compliance and complying with the prevailing administrative provisions on use of income from capital projects, enterprises which satisfy the criteria are allowed to use income under the capital account, such as capital funds, foreign debt and overseas listing, etc., for domestic payment, without the need to provide proof materials for veracity to the bank beforehand for each transaction.

On December 30, 2020, the SAFE promulgated the Circular on Further Optimizing Cross-border Renminbi Policies to Support the Stabilization of Foreign Trade and Foreign Investment(《關於進一步優化跨境人民幣政策支持穩外貿穩外資的通知》), effective as of February 4, 2021, which promotes the facilitation of Renminbi settlement for trade and investment based on the needs of the real economy, further simplifies the cross-border Renminbi settlement process, optimizes the administration of cross-border Renminbi investment and financing, facilitates the cross-border Renminbi receipt and payment under individual current accounts and the use of Renminbi bank settlement accounts by overseas institutions.

SANCTIONS LAWS AND REGULATIONS

Hogan Lovells, our International Sanctions Legal Advisors, have provided the following summary of the sanctions regimes imposed by their respective jurisdictions. This summary does not intend to set out the laws and regulations relating to the United States, the United Nations and the European Union sanctions in their entirety.

United States

Treasury Regulations

OFAC is the primary agency responsible for administering U.S. sanctions programmes against targeted countries, entities, and individuals. “Primary” U.S. sanctions apply to “U.S. persons” or activities involving a U.S. nexus (e.g., funds transfers in U.S. currency or activities involving U.S.-origin goods, software, technology or services even if performed by non-U.S. persons), and “secondary” U.S. sanctions apply extraterritorially to the activities of non-U.S. persons even when the transaction has no U.S. nexus. Generally, U.S. persons are defined as entities organized under U.S. law (such as companies and their U.S. subsidiaries); any U.S. entity’s domestic and foreign branches (sanctions against Iran and Cuba also apply to U.S. companies’ foreign subsidiaries or other non-U.S. entities owned or controlled by U.S. persons); U.S. citizens or permanent resident aliens (“green card” holders), regardless of their location in the world; individuals physically present in the United States; and U.S. branches or U.S. subsidiaries of non-U.S. companies.

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Depending on the sanctions program and/or parties involved, U.S. law also may require a U.S. company or a U.S. person to “block” (freeze) any assets/property interests owned, controlled or held for the benefit of a sanctioned country, entity, or individual when such assets/property interests are in the United States or within the possession or control of a U.S. person. Upon such blocking, no transaction may be undertaken or effected with respect to the asset/property interest — no payments, benefits, provision of services or other dealings or other type of performance (in case of contracts/agreements) — except pursuant to an authorization or license from OFAC.

OFAC’s comprehensive sanctions programmes currently apply to Cuba, Iran, North Korea, Syria, the Crimea region of Russia/Ukraine and the self-proclaimed Luhansk People’s Republic and self-proclaimed Donetsk People’s Republic regions (the comprehensive OFAC sanctions programme against Sudan was terminated on October 12, 2017). OFAC also prohibits virtually all business dealings with persons and entities identified in the SDN List. Entities that a party on the SDN List owns (defined as a direct or indirect ownership interest of 50% or more, individually or in the aggregate) are also blocked, regardless of whether that entity is expressly named on the SDN List. Additionally, U.S. persons, wherever located, are prohibited from approving, financing, facilitating, or guaranteeing any transaction by a non-U.S. person where the transaction by that non-U.S. person would be prohibited if performed by a U.S. person or within the United States.

United Nations

The United Nations Security Council (the “UNSC”) can take action to maintain or restore international peace and security under Chapter VII of the United Nations Charter. Sanctions measures encompass a broad range of enforcement options that do not involve the use of armed force. Since 1966, the UNSC has established 30 sanctions regimes.

The UNSC sanctions have taken a number of different forms, in pursuit of a variety of goals. The measures have ranged from comprehensive economic and trade sanctions to more targeted measures such as arms embargoes, travel bans, and financial or commodity restrictions. The UNSC has applied sanctions to support peaceful transitions, deter non-constitutional changes, constrain terrorism, protect human rights and promote non-proliferation.

There are 14 ongoing sanctions regimes which focus on supporting political settlement of conflicts, nuclear non-proliferation, and counter-terrorism. Each regime is administered by a sanctions committee chaired by a non-permanent member of the UNSC. There are 10 monitoring groups, teams and panels that support the work of the sanctions committees.

United Nations sanctions are imposed by the UNSC, usually acting under Chapter VII of the United Nations Charter. Decisions of the UNSC bind members of the United Nations and override other obligations of United Nations member states.

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European Union

Under European Union sanction measures, there is no “blanket” ban on doing business in or with a jurisdiction targeted by sanctions measures. It is not generally prohibited or otherwise restricted for a person or entity to do business (involving non-controlled or unrestricted items) with a counterparty in a country subject to European Union sanctions where that counterparty is not a Sanctioned Person or not engaged in prohibited activities, such as exporting, selling, transferring or making certain controlled or restricted products available (either directly or indirectly) to, or for use in a jurisdiction subject to sanctions measures.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OVERVIEW

Our history dates back to May 1994 when Shanghai Shiliupu Material (Group) Company (上海十六鋪物資(集團)公司, “Shiliupu”), an independent third party, established Shanghai Shape Memory Alloy, our sole operating subsidiary as at the Latest Practicable Date, to carry out the development and application of shape memory alloy.

Considering its assessment of Shanghai Shape Memory Alloy’s techniques and with a view to optimizing its principal business by expanding its product line to capture more market opportunities, Lepu Medical acquired Shanghai Shape Memory Alloy in October 2008 to be its subsidiary to focus on the development of occluders. Leveraging Shanghai Shape Memory Alloy’s techniques and the sales network of the Lepu Medical Group, Shanghai Shape Memory Alloy has been focusing on the research, development, manufacture and commercialization of interventional medical device primarily targeting structural heart diseases. We have also cultivated the most comprehensive product portfolio of heart valve product candidates in China, according to the F&S Report, with 21 major product candidates as of the Latest Practicable Date, to access the enormous market potential treating valvular diseases.

In preparation for the [REDACTED], Lepu Medical and Target Medical established the Company in the PRC on January 29, 2021 as the holding company of Shanghai Shape Memory Alloy. Immediately upon establishment, the Company’s entire equity interest was wholly owned by Lepu Medical, comprising 99% direct equity interest held by Lepu Medical itself and 1% indirect equity interest held by it through its wholly-owned subsidiary, Target Medical.

BUSINESS MILESTONES

The following table sets forth the key business development milestones of our Group:

Year	Milestones
1994	<ul style="list-style-type: none">Shanghai Shape Memory Alloy was established by its then shareholder which is an independent third party in Shanghai in May.
2001	<ul style="list-style-type: none">Utilizing Shanghai Shape Memory Alloy’s occluders, the first “VSD occluder implantation (VSD介入治療)” surgery was successfully operated in China in December.
2003	<ul style="list-style-type: none">The China Food and Drug Administration (now known as the NMPA) granted approvals to Shanghai Shape Memory Alloy in connection with its PDA occluder and ASD occluder for commercial use in April, and VSD occluder for commercial use in December.
2008	<ul style="list-style-type: none">Lepu Medical acquired the entire equity interest of Shanghai Shape Memory Alloy in October.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Year	Milestones
2009	<ul style="list-style-type: none">Interventional treatment series occluder for defective congenital heart disease (缺損性先天性心臟病介入治療系列封堵器), the then key product of Shanghai Shape Memory Alloy, was awarded “Second Prize of National Science and Technology Progress Award (國家科學技術進步二等獎).”
2012	<ul style="list-style-type: none">The occluder under the trademark of MemoPart™, the then key product of Shanghai Shape Memory Alloy, received CE Mark in August.
2018	<ul style="list-style-type: none">Utilizing Shanghai Shape Memory Alloy’s occluders, the first “fully biodegradable occluder implantation (完全生物可降解封堵器植入術)” surgery in the world was conducted successfully in February.
2020	<ul style="list-style-type: none">Shanghai Shape Memory Alloy’s product “MemoCarna® ASD Occluder III (Oxide Coating) (MemoCarna® 房間隔缺損封堵器III代(氧化膜))” was approved by the NMPA for commercial use in May.Shanghai Shape Memory Alloy’s product “MemoLefort® LAA Closure Occluder I (MemoLefort® 左心耳封堵器I代)” was approved by the NMPA for commercial use in June, extending the targeted diseases of our products to structural heart diseases.Animal tests of transapical mitral valve repair system (經心尖二尖瓣修復系統) were completed in August.
2021	<ul style="list-style-type: none">The Company was established in January.The first implantation at the clinical research stage in the world of the transcatheter implantable aortic valve system (經導管植入式主動脈瓣膜系統) was successfully completed in April, upon which we embarked on the clinical trial stage of our TAVR system.The [REDACTED] were completed in June.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OUR CORPORATE DEVELOPMENT

Establishment and development of Shanghai Shape Memory Alloy

Shanghai Shape Memory Alloy was initially incorporated under the name of Shanghai Shape Memory Alloy Development Company (上海形狀記憶合金材料發展公司) in the PRC on May 5, 1994 with a registered capital of RMB0.3 million, which was contributed solely by Shiliupu. In April 2000, Shanghai Shape Memory Alloy changed its name to Shanghai Shape Memory Alloy Co., Ltd.* (上海形狀記憶合金材料有限公司).

After a series of capital injections and changes in its shareholding interests, in October 2008, Shanghai Shape Memory Alloy was held by Mr. Xu Jialong (許嘉龍) (“Mr. Xu”), Mr. Gong Shanshi (龔善石) (“Mr. Gong”) and Ms. Zou Mengyun (鄒孟雲) (“Ms. Zou”) as to 34%, 33% and 33%, respectively, with a registered capital of RMB1 million. Each of Mr. Xu, Mr. Gong and Ms. Zou is an independent third party. Shanghai Shape Memory Alloy was principally engaged in the research, development, production and sales of occluders and occluder-related medical devices. Mr. Xu, Mr. Gong and Ms. Zou were also the shareholders of Shanghai Xingji Technology, Industry and Trade Company Limited* (上海形記科工貿有限公司) (“Shanghai Xingji”) holding 37%, 33% and 30% of its shareholding interests, respectively, since the inception of Shanghai Xingji on October 13, 2005. Shanghai Xingji was mainly engaged in trading of the products and medical devices then manufactured by Shanghai Shape Memory Alloy.

On October 22, 2008, with a view to optimizing its principal business by expanding its product line to capture more market opportunities, Lepu Medical acquired the entire equity interest of Shanghai Shape Memory Alloy and Shanghai Xingji from Mr. Xu, Mr. Gong and Ms. Zou at an aggregate consideration of approximately RMB36.83 million and RMB26.17 million, respectively and became their respective sole shareholder. The consideration was determined based on the valuation of the equity interests of Shanghai Shape Memory Alloy and Shanghai Xingji at the time of the transaction according to a valuation report issued by an independent valuer. Lepu Medical acquired Shanghai Shape Memory Alloy and Shanghai Xingji to devote its R&D and production efforts on occluders, which further enriched Lepu Medical’s medical device business segment. With a view to streamlining the group structure, Lepu Medical procured Shanghai Shape Memory Alloy to merge Shanghai Xingji by absorption in May 2011 upon which Shanghai Xingji was deregistered.

In December 2011, December 2012 and December 2013, respectively, Shanghai Shape Memory Alloy obtained further capital injections from Lepu Medical, upon which the registered capital of Shanghai Shape Memory Alloy was eventually increased to RMB100 million.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Disposal of Ningbo Bingkun

Ningbo Bingkun (through its subsidiaries) is principally engaged in the research, development, production and sales of surgical matching device and minimally invasive surgical-related products for use in open surgeries and laparoscopic surgeries. It was initially acquired by Shanghai Shape Memory Alloy, which served as a shareholding entity designated by Lepu Medical, to be an operating entity of the surgical products segment of Lepu Medical.

Shanghai Shape Memory Alloy disposed of all of its equity interest in Ningbo Bingkun to Lepu Medical in December 2020 (the “Disposal”) at a consideration of RMB1,098 million, which was determined at after arms’ length negotiation with reference to the valuation of Ningbo Bingkun’s equity shares at the time of the Disposal according to a valuation report prepared by an independent professional valuer engaged by Lepu Medical. The valuation was conducted with income approach (收益法) (for the valuation of Ningbo Bingkun’s subsidiaries) and asset-based approach (資產基礎法) (for the valuation of Ningbo Bingkun) on various assumptions, among others, that (1) the assets involved were freely tradeable in a fully competitive market, (2) the operations of the entities involved were sustainable, (3) the assets involved would be utilized in the same way it was used, and (4) there would not be material adverse change in the legal and economic environment that would affect the valuation. Such consideration was settled in January 2021. Shanghai Shape Memory Alloy was historically designated by Lepu Medical to act as a mere holding company of Ningbo Bingkun in September 2015 mainly due to its geographical proximity. Notwithstanding the fact that Shanghai Shape Memory Alloy held 98.05% equity interest in Ningbo Bingkun, the Directors are of the view that there had been a clear delineation between Shanghai Shape Memory Alloy and Ningbo Bingkun historically based on the fact that there was no overlap between the management teams of, or business certificates held by Ningbo Bingkun and Shanghai Shape Memory Alloy. Since it was acquired by Lepu Medical (through Shanghai Shape Memory Alloy) and up till the Disposal, Ningbo Bingkun had been managed directly by Lepu Medical with its business conducted independently from Shanghai Shape Memory Alloy. The Disposal was a step to rationalize the ownership of Ningbo Bingkun by Lepu Medical. More importantly, Ningbo Bingkun, together with several other subsidiaries of Lepu Medical, forms a standalone business subsegment, namely, surgical-related products, which is not in line with our Group’s business.

- In August 2018, Jiangsu Bolangsensi Medical Equipment Co., Ltd. (江蘇博朗森思醫療器械有限公司) (“Bolang”), a subsidiary of Ningbo Bingkun, was ordered to suspend the business operation for rectification of certain aspects of its quality control system. Such rectification was completed shortly after the said order after which Bolang recommenced operation in September of the same year. Bolang had not received any other administrative penalties, nor had it been involved in any litigation, arbitration or other legal proceedings that had a material adverse effect, due to this incident.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

- In April 2018 and July 2018, respectively, Bolang and Changzhou Yiwote Medical Instrument Co., Ltd. (常州伊沃特醫療器械有限公司) (“Yiwote”), a subsidiary of Ningbo Bingkun, were subject to fines of RMB382,600 and RMB375,000, respectively, for producing medical devices which did not fully comply with the relevant requirements. All products involved were recalled by Bolang and Yiwote, as applicable, and there was no alleged incident of adverse effects relating to such products.

Neither Bolang nor Yiwote had received any other administrative penalties, nor had they been involved in any litigation, arbitration or other legal proceedings that had a material adverse effect, due to these incidents.

Save for the immaterial non-compliance incidents above, Ningbo Bingkun and its subsidiaries had not received other administrative penalties due to any violation of PRC laws or regulations, nor had they been involved in any litigation, arbitration or other legal proceedings that had a material adverse effect during the Track Record Period or afterwards prior to the Disposal. Our Directors believe that had the Disposal not taken place, our Group would still be suitable for [REDACTED] under Rule 8.04 of the Listing Rules.

Even though Ningbo Bingkun had never formed a part of our business historically, we are of the view that we have an appropriate internal control system in place to prevent the non-compliance incidents associated with the manufacturing process of the subsidiaries of Ningbo Bingkun from happening in our Group. In particular, we have been rigorously abiding by our practice protocols, which serve to ensure the precision, efficiency and safety of our manufacturing processes. We have established a three-tier quality control system based on (1) domestic medical device laws and regulations, (2) EU medical device laws and regulations as well as (3) the relevant international quality authentication standard to monitor all aspects throughout the product lifecycle. See “Business — Quality Control.”

The net profit of Ningbo Bingkun in each year of 2019, 2020, 2021 and the six months ended June 30, 2022 was above RMB30 million according to its management accounts. Historically, Shanghai Shape Memory Alloy and a subsidiary of Ningbo Bingkun had a series of sale and purchase transactions during the Track Record Period which will continue and constitute continuing connected transactions under Chapter 14A of the Listing Rules upon [REDACTED]. Such potential continuing connected transactions will be entered into in compliance with the requirements under the Listing Rules. See “Connected Transactions — Summary of Our Continuing Connected Transactions — Fully Exempt Continuing Connected Transactions — 1. Purchase of Parts Framework Agreement.”

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Business injection

As further elaborated in “Industry Overview”, the interventional medical device market targeting structural heart diseases consists primarily of three major fields of application, including (1) CHD, (2) cardioembolic stroke and (3) valvular diseases, according to the F&S Report. Prior to the injection of the interventional heart valve business as illustrated below, our occluder product portfolio had covered the first two major fields of application (i.e., CHD and cardioembolic stroke). As part of the Reorganization and with a view to solidifying the Group’s position as the sole platform under the Lepu Medical Group focusing on interventional medical devices primarily targeting structural heart diseases, the interventional heart valve business was injected into Shanghai Shape Memory Alloy, including the products of which primarily target the third major field of application (i.e., valvular diseases), from Lepu Medical pursuant to an asset transfer agreement (including an intellectual property transfer agreement as attached thereto) in January 2021. The aggregate consideration of this transaction was approximately RMB72 million, which was determined after arms’ length negotiation with reference to the net book value of the interventional heart valves related assets and relevant research and development costs. The transaction was closed on April 14, 2021, which was when the transfer of assets involved was all completed and the business injection was therefore considered completed pursuant to the asset transfer agreement. The consideration of the transaction was settled on March 5, 2021.

Among the product candidates under the injected interventional heart valve business, the key research and development work including type inspections and animal tests of certain heart valve product candidates (i.e., the Entrusted Products) had been conducted under the name of Lepu Medical prior to the business injection. See “Business — Our Products — Heart Valve Product Candidates — Entrusted Products” for a summary of the regulatory restrictions under the prevailing PRC laws and regulations pertaining to the Entrusted Products and relevant implications.

As of the Latest Practicable Date, the pre-clinical R&D work for each of the Entrusted Products had been substantially completed and each of the Entrusted Products has entered into clinical trial stage. See “Business — Overview — Our Product Portfolio.”

Our Directors are of the view that the injection of the interventional heart valve business into our Group is beneficial to our Group and the Shareholders as a whole, on the basis that (1) such injection was in line with our focus on interventional medical devices primarily targeting structural heart diseases, and (2) such injection strategically complemented our then existing product portfolio and enabled us to have a product portfolio covering all three major fields of application in the interventional medical device market targeting structural heart diseases.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Incorporation of our Company

Our Company was incorporated as a joint stock limited liability company in the PRC on January 29, 2021 with a registered capital of RMB0.28 billion contributed by Lepu Medical and Target Medical. Immediately upon establishment, the Company’s entire equity interest was wholly owned by Lepu Medical, comprising 99% direct equity interest held by Lepu Medical itself and 1% indirect equity interest held by it through its wholly-owned subsidiary, Target Medical. Lepu Medical paid up its subscribed registered share capital by injection of the 100% equity interests of Shanghai Shape Memory Alloy held by it to the Company, upon which Shanghai Shape Memory Alloy became our wholly-owned subsidiary.

Establishment of Ningbo Jiadu and Ningbo Jiacheng as the shareholding platforms

Both of Ningbo Jiadu and Ningbo Jiacheng were established in February 2021. The general partner of both Ningbo Jiadu and Ningbo Jiacheng is Lepu Growth. As at the Latest Practicable Date, the limited partners of Ningbo Jiadu were 49 employees of our Group, among which 9.67%, 8.38%, 3.55%, 3.55%, 1.93% and 1.93% of the partnership interest were held by Ms. Chen Juan (陳娟), Ms. Zhang Yuxin (張昱昕), Mr. Qin Xue (秦學), Ms. Zhang Xiani (張夏妮), Mr. He Yufeng (何玉鳳) and Qian Weidong (錢衛東), respectively, each of who is an executive Director, senior management of our Company or Supervisor; while the limited partners of Ningbo Jiacheng were 49 employees of the Retained Lepu Medical Group, among which [REDACTED]% of the partnership interest were held by Mr. Zheng Guorui (鄭國銳), who is a non-executive Director (collectively, the “LP Employees”). Lepu Growth will purely execute the daily administrative matters of Ningbo Jiadu and Ningbo Jiacheng pursuant to their respective partnership agreements, in order to carry out the function of Ningbo Jiadu and Ningbo Jiacheng as shareholding platforms. Lepu Growth will vote on behalf of each of Ningbo Jiadu and Ningbo Jiacheng on the Shareholders’ general meetings by following the instruction reached at by its partners holding more than 50% of its paid-up capital by way of a poll.

As provided in the limited partnership agreements of Ningbo Jiadu and Ningbo Jiacheng, the LP Employees are restricted from selling, transferring or disposing of their respective partnership interest for the first 12 months from the [REDACTED]. On the first [REDACTED] after each of the first and second anniversary of the [REDACTED], 15% of the interest owned by each of them will be released. On the first [REDACTED] after the third anniversary of the [REDACTED], the remaining 70% of the interest owned by each of them will be released.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

[REDACTED]

On May 28, 2021, the [REDACTED] and the Company entered into a capital increase agreement, pursuant to which each of the [REDACTED] agreed to [REDACTED] in our Company by subscription of the increased registered capital of our Company. Details are set forth below:

Name of [REDACTED]	Consideration	Number of Domestic Shares or Unlisted Foreign Shares subscribed for	Date on which consideration was fully settled
Vivo Capital Fund IX	US\$50,000,000	15,527,950 Unlisted Foreign Shares	June 15, 2021
Sequoia Capital China Growth	US\$20,000,000	6,211,180 Unlisted Foreign Shares	June 15, 2021
CDH Supermatrix	US\$10,000,000	3,105,590 Unlisted Foreign Shares	June 15, 2021
Total	US\$80,000,000	24,844,720 Unlisted Foreign Shares	June 15, 2021
Huaihua Haozhi	RMB32,180,000	1,560,798 Domestic Shares	June 15, 2021
SHC	RMB65,000,000	3,152,637 Domestic Shares	June 16, 2021
Total	RMB97,180,000	4,713,435 Domestic Shares	

The below table summarizes the other principal terms of the [REDACTED]:

Date of the share subscription agreements	May 28, 2021
Approximate post-money valuation of our Company	US\$1,045.18 million
Basis of consideration	The valuation of the Company immediately prior to the [REDACTED]
Cost per Share	US\$3.22
[REDACTED] to the [REDACTED] ⁽¹⁾	6.26%

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

[REDACTED] period

Pursuant to the applicable PRC law, within the 12 months following the [REDACTED], Shares [REDACTED] by the Company prior to the [REDACTED] (including those held by the [REDACTED] at the time of the [REDACTED]) are restricted from [REDACTED].

[REDACTED] from the [REDACTED]

Since the completion of the [REDACTED] in June 2021 and as of the Latest Practicable Date, approximately RMB[REDACTED] million (representing approximately [REDACTED]%) of the [REDACTED] received from the [REDACTED] has been utilized by the Group for purposes including research and development activities, payment of salary of staff, purchase of raw materials consumed in our ordinary course of business, facilities upgrading for research and manufacturing activities. In addition to being continuously used towards such purposes, the remaining [REDACTED] will also be used to support our domestic and overseas sales and marketing activities and as our supplementary working capital.

Strategic benefits of the [REDACTED] brought to our Company

At the time of the [REDACTED], our Directors were of the view that (1) our Company could benefit from (i) the additional capital derived from the [REDACTED], and (ii) the knowledge and experience in the healthcare and medical devices sectors (in the cases of Vivo Capital Fund IX, SHC, CDH Supermatrix and Sequoia Capital China Growth); (2) the [REDACTED] demonstrated the [REDACTED] confidence in the operation and development of our Group; and (3) Mr. Fu Shan, one of our non-executive Directors and a representative of Vivo Capital Fund IX, complements our executive Directors to support good corporate governance.

(1) Based on exchange rate of RMB0.9056 to HKD1.00 and RMB7.1086 to US\$1.00, the median rate set by PBOC for foreign exchange transactions prevailing on the settlement date of the [REDACTED], and assuming the [REDACTED] is fixed at HK\$[REDACTED], being the mid-point of the indicative [REDACTED].

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Rights of the [REDACTED]

All the shareholders (including the [REDACTED]) of our Company are bound by the [REDACTED] Shareholders Agreement dated May 28, 2021 which superseded all previous agreements among the contracting parties in respect of the shareholders’ rights in our Company. Pursuant to the [REDACTED] Shareholders Agreement, no special right is expected to be granted to the [REDACTED] or become effective if the [REDACTED] is consummated prior to December 31, 2022.

Information about the [REDACTED]

Vivo Capital Fund IX is an investment fund organized under the laws of Delaware, the United States. The general partner of Vivo Capital Fund IX is Vivo Capital IX, LLC, which is under the management of Vivo Capital LLC. Founded in 1996, Vivo Capital LLC is a global investment firm focused on healthcare with approximately US\$6.4 billion in assets under management as of December 31, 2021, and provides a multi-fund investment platform, covering private equity including buyout, venture capital, and public equity. Funds managed by Vivo Capital LLC invest broadly in healthcare across all fund strategies, including biotechnology, pharmaceuticals, medical devices, and healthcare services, with a focus on the largest healthcare markets. The ultimate beneficial owners of Vivo Capital Fund IX are independent third parties.

Sequoia Capital China Growth is an exempted company with limited liability incorporated under the laws of the Cayman Islands and is a wholly-owned subsidiary of Sequoia Capital China Growth Fund VI, L.P. (“Sequoia Capital China GVI Fund”), which is an investment fund focusing on making equity investments in private companies. The general partner of Sequoia Capital China GVI Fund is SC China Growth VI Management, L.P., whose general partner is SC China Holding Limited, a wholly-owned subsidiary of SNP China Enterprises Limited. Mr. Neil Nanpeng Shen (沈南鵬) is the sole shareholder of SNP China Enterprises Limited. Each of Sequoia Capital China Growth, the abovementioned entities and Mr. Neil Nanpeng Shen is an independent third party.

SHC is principally engaged in equity investment in the pharmaceutical industry in the PRC and is a limited partnership established in the PRC. The general partner of SHC is Shanghai Healthcare Capital Management Co., Ltd. (上海生物醫藥產業股權投資基金管理有限公司), an independent third party. All of the limited partners of SHC are independent third parties and none of them holds more than one-third of the partnership interest in SHC.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

CDH Supermatrix is a company limited by shares incorporated under the laws of Hong Kong and is a wholly-owned subsidiary of Aries Rosemary, L.P., the general partner of which is CDH China HF Holdings Company Limited, which is wholly owned by CDH Wealth Management Company Limited (“CDH Wealth Management”). CDH Wealth Management is owned as to 75% by CDH Investment Management Company Limited (“CDH Investment Management”), a member of the CDH Investments group (鼎暉投資), and as to 25% by Advance Faith Investing Limited, a company wholly-owned by Mr. Ying Wei (應偉). The ultimate beneficial owner of CDH Investment Management is Mr. Wu Shangzhi (吳尚志), the chairman of CDH Investments. Each of CDH Supermatrix, the abovementioned entities, Mr. Wu Shangzhi and Mr. Ying Wei is an independent third party.

Huaihua Haozhi is a limited partnership incorporated in PRC and is principally engaged in enterprise management consultation services, financial consultation services, business information consultation services, advertisement design services, culture and art event planning services, entity marketing planning services, conference organization services, market analysis and research services and exhibition organizing services. The general partner of Huaihua Haozhi is Zhangjiajie Ruicheng Enterprise Management Partnership (Limited Partnership)* (張家界睿成企業管理合夥企業(有限合夥)) (“Zhangjiajie Ruicheng”), which is in turn controlled by Mr. Li Qing (李青) through his capacity as the general partner of Zhangjiajie Ruicheng. Each of Huaihua Haozhi, Zhangjiajie Ruicheng and Mr. Li Qing is an independent third party.

Confirmation from the Sole Sponsor

After reviewing the terms of the [REDACTED] and the [REDACTED] Shareholders Agreement and given that (1) our Directors confirmed that the terms of the [REDACTED] (including the consideration) were determined on arm’s length basis, and (2) there will be more than 120 clear days before the [REDACTED] since the settlement of the considerations for the [REDACTED], the Sole Sponsor has confirmed that the investment by the [REDACTED] is in compliance with the applicable requirements under the Guidance Letter HKEX-GL29-12 issued on January 2012 and updated in March 2017, the Guidance Letter HKEX-GL43-12 issued by the Stock Exchange in October 2012 and updated in March 2017 and the Guidance Letter HKEX-GL44-12 issued by the Stock Exchange in October 2012 and updated in March 2017.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

PUBLIC FLOAT

Upon completion of the [REDACTED] and the [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares, the Shares held by certain of our Shareholders who are our core connected persons, namely each of Lepu Medical, Target Medical, Ningbo Jiadu and Ningbo Jiacheng, representing an aggregate of approximately [REDACTED]% of our issued Shares (assuming the [REDACTED] is not exercised) will not count towards part of the public float pursuant to Rule 8.24 of the Listing Rules.

Save as provided above, upon completion of the [REDACTED] and the [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares, each of Vivo Capital Fund IX, Sequoia Capital China Growth, SHC, Huaihua Haozhi, and CDH Supermatrix shall not be considered as a core connected person of our Company and accordingly in aggregate approximately [REDACTED]% of our issued Shares (assuming the [REDACTED] is not exercised), being all the Shares held by our [REDACTED], will count towards part of our public float pursuant to Rule 8.24 of the Listing Rules.

SHAREHOLDING STRUCTURE OF OUR COMPANY AS AT THE [REDACTED]

Insofar as our Directors are aware, immediately following the completion of the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares (assuming the [REDACTED] is not exercised), the following table sets forth the details of the Shares to be held by our Shareholders as at the [REDACTED]:

<u>Name of Shareholder</u>	<u>Class of Shares</u>	<u>Number</u>	<u>Percentage in our total issued share capital</u>
<i>Controlling Shareholders</i>			
Lepu Medical ⁽¹⁾	H Shares [REDACTED] from Domestic Shares	277,200,000	[REDACTED]%
Target Medical ⁽¹⁾	H Shares [REDACTED] from Domestic Shares	2,800,000	[REDACTED]%
<i>Shareholding platforms of employees of our Group and the Retained Lepu Medical Group</i>			
Ningbo Jiadu	H Shares [REDACTED] from Domestic Shares	9,136,842	[REDACTED]%
Ningbo Jiacheng	H Shares [REDACTED] from Domestic Shares	5,600,000	[REDACTED]%

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

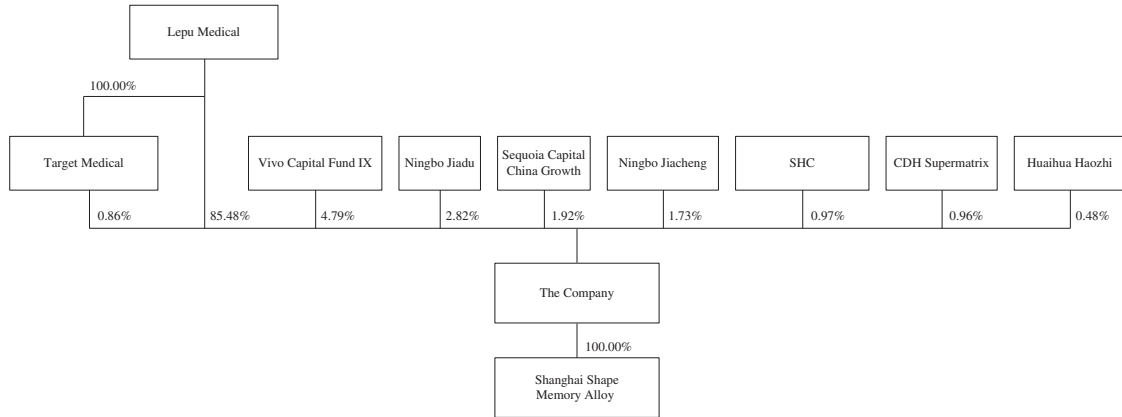
Name of Shareholder	Class of Shares	Number	Percentage in our total issued share capital
[REDACTED] Vivo Capital Fund IX	H Shares [REDACTED] from Unlisted Foreign Shares	15,527,950	[REDACTED]%
Sequoia Capital China Growth	H Shares [REDACTED] from Unlisted Foreign Shares	6,211,180	[REDACTED]%
SHC	H Shares [REDACTED] from Domestic Shares	3,152,637	[REDACTED]%
CDH Supermatrix	H Shares [REDACTED] from Unlisted Foreign Shares	3,105,590	[REDACTED]%
Huaihua Haozhi	H Shares [REDACTED] from Domestic Shares	1,560,798	[REDACTED]%
<i>Others</i>			
[REDACTED]	H Shares [REDACTED] pursuant to the [REDACTED]	[REDACTED]	[REDACTED]%
Total	H Shares	[REDACTED]	100.00%

- (1) Immediately following the completion of the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares (assuming the [REDACTED] is not exercised), Lepu Medical held approximately [REDACTED]% of the shareholding interest of our Company, including approximately [REDACTED]% indirect shareholding interest through Target Medical and approximately [REDACTED]% direct shareholding interest. Lepu Medical held the entire share interest in Target Medical and was therefore deemed to be interested in the Shares held by Target Medical under the SFO. According to the Listing Rules of the ChiNext Board of the Shenzhen Stock Exchange (《深圳證券交易所創業板股票上市規則》) where Lepu Medical, our Controlling Shareholder, is listed, an actual controller refers to an individual or entity that can control a company by way of investment relationship, contracts or other arrangements. As Dr. Pu is able to control Lepu medical and exert substantial influence over it, we regard Dr. Pu as our Controlling Shareholder. Lepu Medical, Dr. Pu and Target Medical are considered as a group of Controlling Shareholders of our Company and he was therefore deemed to be interested in the Shares held by Lepu Medical under the SFO.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

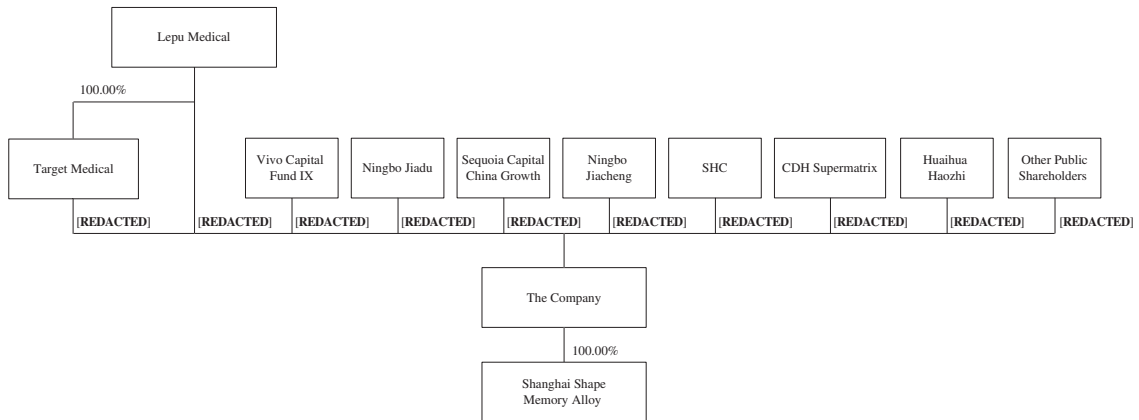
OUR STRUCTURE IMMEDIATELY PRIOR TO THE [REDACTED]

The following diagram illustrates the corporate and shareholding structure of our Company immediately prior to the completion of the [REDACTED]:



OUR STRUCTURE IMMEDIATELY FOLLOWING THE [REDACTED]

The following diagram illustrates the corporate and shareholding structure of our Company immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised):



BUSINESS

OVERVIEW

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

As of the Latest Practicable Date, we had a comprehensive product portfolio of 20 marketed occluder products and nine occluder product candidates as well as 21 major heart valve product candidates**. All of our products are developed in-house. As of the same date, we also had an expansive collection of intellectual property rights including 232 registered patents and 51 pending patent applications in China as well as 14 patents under application in the United States and the European Union.

Our Adoption of Biodegradable Technology

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

* 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.

BUSINESS

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

Our Product Portfolio

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

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

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Cardioembolic stroke. We have commercially launched our first generation LAA occluder product in June 2020 and first generation PFO occluder product in August 2012. China’s cardioembolic stroke occluder products market has significant growth potential. According to the F&S Report, the market size of China’s cardioembolic stroke occluder products market is expected to increase from RMB0.7 billion in 2021 to RMB1.9 billion in 2025 at a CAGR of 28.1%; 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\$2.3 billion in 2025 at a CAGR of 20.8%. As of the Latest Practicable Date, we had obtained one NMPA registration certificate for Class III medical devices for our first generation LAA occluder product and one CE Mark for our first generation PFO occluder product. Our first generation LAA occluder product, launched in June 2020, had demonstrated therapeutic effects in clinical trials with a 100% operation success rate and reached an LAA closure rate of 97.6% after 12 months following the operation, with no probability of post-operative ischemic stroke. Specifically, operation success rate refers to the probability of successful implantation of the LAA occluder without death, which indicates safety, and LAA closure rate refers to the probability of successful implantation of the LAA occluder without dislodging, which indicates efficacy, according to the F&S Report. We expect our biodegradable PFO occluder product candidate to be among the first PFO biodegradable occluder products to be registered in China, according to the F&S Report. As of the Latest Practicable Date, our biodegradable PFO occluder product candidate was in the registration preparation process with the NMPA, and our biodegradable LAA occluder product candidate was in the stage of clinical trial preparation in China.

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

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

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	Product ⁽¹⁾	Pre-clinical	Clinical Trial ⁽²⁾	Registration ⁽³⁾	Next Milestone/ Actual Launch Time ⁽⁴⁾
Left atrial appendage occluder	MemoLefort® LAA Closure Occluder I	●		Launched	NMPA Approval in 2020Q2
	LAA Closure Occluder II (Biodegradable)	○	Clinical trial preparation		Clinical Trial in PRC in 2022Q4E
Interatrial shunt device	Interatrial shunt device I		Clinical trial		NMPA Application in 2023Q4E
	Interatrial shunt device II (Biodegradable)		Design stage		Clinical Trial in PRC in 2023Q3E
	Interatrial shunt device III (Radiofrequency ablation shunt device)		Type inspection		Clinical Trial in PRC in 2023Q4E
	Radiofrequency ablation device (Device)		Type inspection		Clinical Trial in PRC in 2023Q4E
Vascular plug	MemoPart® Plug I (Double-rivet)			Launched	CE Mark in 2012 ⁽⁶⁾
	MemoPart® Plug II (Single-rivet)			Launched	CE Mark in 2012 ⁽⁶⁾
	MemoFlex® Plug III (Double-waist)		Clinical trial		NMPA Application in 2023Q4E
Occluder Products ⁽⁵⁾	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)	▲		Registration in progress	NMPA Approval in 2023Q3E
Procedural accessories					

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	Product⁽¹⁾	Pre-clinical	Clinical Trial⁽²⁾	Registration⁽³⁾	Next Milestone/ Actual Launch Time⁽⁴⁾
Heart Valve Products	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
			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
Mitral valve products	○	Type inspection		Clinical Trial in PRC in 2023Q4E	
		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 ⁽¹⁾	Pre-clinical	Clinical Trial ⁽²⁾	Registration ⁽³⁾	Next Milestone/ Actual Launch Time ⁽⁴⁾
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
Heart Valve Products	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, PFO occluder products and LAA occluder products, are designed to treat the respective heart defects. Our interatrial shunt device (“IASD”) product candidates are designed to reduce left atrial hypertension. Our vascular plugs are designed for rapid vessel occlusion. Our heart valve product candidates, including aortic valve product candidates, mitral valve product candidates, tricuspid valve product candidates and pulmonary valve product candidate, are designed to treat the respective valvular diseases. Our portfolio of products and product candidates also includes occluder related procedural accessories and heart valve related procedural accessories.

(2) We plan to commence overseas clinical trial process for various product candidates. Specifically, we plan to commence clinical trial for the following product candidates: MemoSorb® ASD Occluder IV in the European Union and the United States in the fourth quarter of 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 232 registered patents and 51 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 (上海市科學技術獎一等獎) and the first prize of the Shanghai Medical Technology Award (上海市醫學科技獎一等獎). We maintain continuous collaboration with hospitals, research institutions and KOLs to ensure that our research and development progress is capable of addressing the evolving needs of patients and physicians. During such collaboration, we lead the research and development process of our products. Specifically, we completed the world’s first fully biodegradable VSD occluder implantation in February 2018 during its clinical trial, which marked a breakthrough in the field of fully biodegradable occluders globally, according to the F&S Report. We have also collaborated with a prominent medical institution in China in the research and development of our TAVR system which is expected to be 100% deployable, retrievable and repositionable

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

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

Commercialization. We have a proven track record of commercializing 14 products in China and 11 products overseas as of the Latest Practicable Date both by ourselves and through historical collaboration with the Retained Lepu Medical Group. Consistent with industry practice, we sell our products both directly to hospitals and through distributors covering all provinces, municipalities and autonomous regions in China. As of June 30, 2022, we had established a nationwide network of 288 distributors covering 878 hospitals. In China, we generally operate a single-layer distribution system which allows us to understand and manage the market demand. We historically collaborated with the Retained Lepu Medical Group to sell our products overseas. See “Connected Transactions — Non-Exempt Continuing Connected Transactions” and “— Sales, Distribution and Marketing — Sales Arrangements.” We believe direct distribution arrangement with such distributors allows for more control over our overseas distributor networks and better understanding of overseas market demands. We have also built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution.

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Our business grew rapidly during the Track Record Period. Our revenue increased by 27.3% from RMB116.5 million in 2019 to RMB148.2 million in 2020, and further increased by 50.1% to RMB222.6 million in 2021. Our revenue increased by 12.5% from RMB111.0 million in the six months ended June 30, 2021 to RMB124.8 million in the six months ended June 30, 2022. Our net profit increased by 32.5% from RMB51.9 million in 2019 to RMB68.8 million in 2020. Our net profit decreased by 14.6% to RMB58.7 million in 2021. Our net profit decreased by 41.9% from RMB41.8 million in the six months ended June 30, 2021 to RMB24.3 million in the six months ended June 30, 2022. Our net profit margin was 44.6%, 46.4%, 26.4%, 37.6% and 19.4% in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively.

COMPETITIVE STRENGTHS

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

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

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

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

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We have marketed PFO and LAA occluder products, which prevent cardioembolic stroke and related symptoms, including migraine, peripheral arterial embolism, and decompression sickness. According to the F&S Report, as the major interventional medical devices targeting cardioembolic stroke, PFO and LAA occluder therapies are still at an emerging stage with their first adoption in China in 2014, much later than drug treatment. As of the Latest Practicable Date, there were only eight players in China that had marketed PFO and/or LAA occluder products, according to the same source. As a result of the growing number of patients and a relatively low penetration rate of such therapies in China, being approximately 42.4% for PFO occluder products and approximately 5.9% for LAA occluder products in 2021, the market size of China’s PFO occluder products market is expected to increase from RMB187.1 million in 2021 to RMB370.0 million in 2025 at a CAGR of 18.6%, and the market size of China’s LAA occluder products market is expected to increase from RMB0.5 billion in 2021 to RMB1.6 billion in 2025 at a CAGR of 31.0%, according to the same source. In addition, the market size of the global PFO occluder products market is expected to increase from US\$189.2 million in 2021 to US\$432.2 million in 2025 at a CAGR of 22.9%, and the market size of the global LAA occluder products market is expected to increase from US\$0.9 billion in 2021 to US\$1.9 billion in 2025 at a CAGR of 20.3%, according to the same source. As of the Latest Practicable Date, we had launched our first-generation PFO occluder product with one CE Mark and first-generation LAA occluder product with one NMPA registration certificate for Class III medical devices. Our newly launched LAA occluder product has demonstrated therapeutic effects in clinical trials with a 100% operation success rate and reached an LAA closure rate of 97.6% after 12 months following the operation, with no probability of post-operative ischemic stroke. As of the Latest Practicable Date, our biodegradable LAA occluder product candidate was in the stage of clinical trial preparation, designed to degrade over time into carbon dioxide and water upon the completion of endothelial repair. We believe we are well-positioned to capitalize on the significant growth potential in these fast-growing and under-penetrated markets, leveraging our early-mover advantages, advanced product features (such as the ease of use, effective closure and safety record), and established sales channels for CHD occluder products.

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

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

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Compared with traditional metal occluders, biodegradable occluders are designed to degrade over time into carbon dioxide and water upon completion of endothelial repair, according to the F&S Report. Our design for biodegradable occluder product and product candidates not only ensures effective autologous tissue closure but also minimizes potential compression and wear on surrounding tissues caused by metal implants, which lowers the risk of long-term complications. In addition, we believe it leaves available for patients additional future treatment options, especially transseptal procedures, as the biodegradable occluders would not be a permanent implant in the human body, benefiting all patients receiving occluder implants, and in particular, to children who constitute the majority of patients suffering from CHD and also expect a significantly longer remaining life span and better life quality, according to the F&S Report.

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

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

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

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

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

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

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

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

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Platform backed by strong research and development and manufacturing capabilities

Strong product research and development capability is the cornerstone of our industry-leading platform. As of the Latest Practicable Date, we had obtained a total of 14 NMPA registration certificates for Class III medical devices and valid CE Marks for nine of our products. Our research and development capability also enables us to build an expansive and evolving product pipeline. As of the Latest Practicable Date, we had 30 major product candidates in our pipeline, of which one was in the clinical trial preparation stage, two in the registration process with the NMPA, two in the registration preparation process with the NMPA, seven in clinical trials, eight in the type inspection stage, and 10 in the product design stage.

We have built our research and development team with technological expertise in various areas, primarily including nitinol shape memory cutting and braiding techniques, animal source material processing techniques, biodegradable material controlled release techniques, suturing techniques, and structure design and processing techniques. As of the Latest Practicable Date, our research and development team had a total of 79 members, with approximately 38.0% holding a master’s or higher degree in relevant fields. We have developed a significant portfolio of intellectual property rights in relation to our technologies and products. As of the Latest Practicable Date, we had 232 registered patents and 51 pending patent applications in China. We have received numerous awards and accolades, including the second prize of the National Science and Technology Progress Award (國家科學技術進步獎二等獎), the first prize of the Shanghai Science and Technology Award (上海市科學技術獎一等獎), and the first prize of the Shanghai Medical Technology Award (上海市醫學科技獎一等獎). Our in-house team closely monitors technological advancements and industry trends globally, to actively facilitate the iterative innovations and value exploration of our existing technologies and products.

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

We have solid manufacturing capabilities supported by our experienced production team, advanced manufacturing facilities, and strict quality control standards. We have applied our core technologies, such as nitinol braiding and heat processing, to optimize the blocking effect of our occluder products. For our heart valve product candidates, we have independently implemented a valve leaflet processing procedure using our animal source material processing platform and a valve frame processing procedure using our nickel-titanium alloy platform, both

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of which were developed in-house. We also conduct substantially all the key manufacturing procedures in-house except for sterilization. We believe our manufacturing capabilities have served to maintain effective quality control and cost control. We strictly adhere to industry norms for our medical device production quality management and strive to maintain stable production and quality control teams and supply chains to ensure stable production of consistently high-quality products. Our quality control team participates in our daily operations, such as product design and development, raw material supply and procurement, product manufacturing and delivery, and after-sales follow-ups, to ensure the quality management of our products. We have also established a three-tier quality control system based on (1) domestic medical device laws and regulations, (2) EU medical device laws and regulations as well as (3) the relevant international quality authentication standard to monitor all aspects throughout the product lifecycle.

Extensive distributor network and effective academic promotion and marketing capability

We have a proven track record of commercializing 14 products in China and 11 products overseas as of the Latest Practicable Date both by ourselves and through historical collaboration with the Retained Lepu Medical Group. Leveraging our extensive network of distributors and effective academic promotion and marketing capability, our products reached 878 hospitals in China as of June 30, 2022, including 503 Class III Grade A hospitals. We believe we can leverage our established sales network to market our product candidates, as we have established our reputation among cardiologists, distributors, and most importantly, patients over the years. We believe our industry-leading sales channels and growing penetration in hospitals serve to solidify our competitive edge in the market, which will allow us to cross-sell existing products and rapidly ramp up the future sales of our product candidates. With these considerable early-mover advantages, we believe we are well-positioned to capture the upside potential when commercializing our product candidates for cardioembolic stroke and valvular diseases. Consistent with industry practice, we sell products both directly to hospitals and through our extensive network of distributors covering all provinces, municipalities and autonomous regions in China.

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

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

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

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

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

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GROWTH STRATEGIES

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

Promote the development and clinical trial progress of our product candidates

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

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

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

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quarter of 2024. For our LAA occluder product candidate, we expect to initiate overseas clinical trial for our first generation LAA occluder product candidate in the European Union in the fourth quarter of 2022; and we expect to initiate the clinical trial for our biodegradable LAA occluder product candidate in the fourth quarter of 2022 in China, and overseas clinical trial in both the European Union and the United States thereafter.

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

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

Continue to enhance research and development capabilities

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

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

Expand brand exposure and market share in China

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

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

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

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

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

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

Selectively pursue strategic investments and acquisitions

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

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

Expand our production capabilities to support future growth

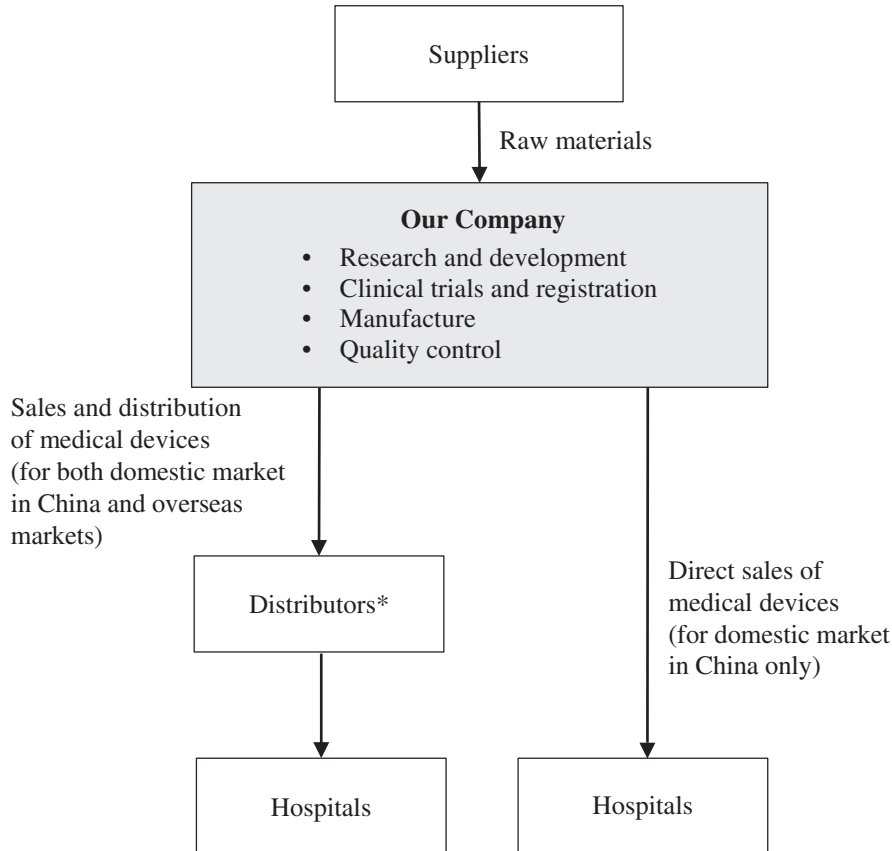
In response to our increasingly rich product portfolio and growing demand for our products, we will continue to expand our production capacity by purchasing more machinery and equipment and installing new product lines. We plan to enhance the production capacity for our marketed products by purchasing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

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

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OUR BUSINESS MODEL

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



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

OUR PRODUCTS

As of the Latest Practicable Date, we had a comprehensive portfolio of 50 products and major product candidates covering three key market segments in the interventional medical device industry targeting structural heart diseases, including primarily CHD, cardioembolic stroke and valvular diseases. We categorize our product portfolio into two major segments, i.e., occluder products and heart valve products. As of the Latest Practicable Date, we had developed a comprehensive product portfolio of occluder products and product candidates, including primarily (1) various CHD occluder products and (2) PFO occluder products and

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

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

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

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

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

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

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Sales volume	Average selling price ⁽¹⁾	Sales volume	Average selling price ⁽¹⁾	Sales volume	Average selling price ⁽¹⁾	Sales volume	Average selling price ⁽¹⁾	Sales volume	Average selling price ⁽¹⁾
		<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[®] ASD Occluder III in May 2020, which started to generate revenue in the second half of 2020 with relatively higher pricing per unit compared to CHD occluder products of older generations due to its upgrade in product design and manufacturing process. Specifically, as a percentage of the total revenue generated from sales of CHD occluder products, sales of our MemoCarna[®] ASD Occluder III accounted for 3.1% and 24.3% in 2020 and 2021, respectively; and (2) the increase in pricing per unit for our CHD occluder products sold overseas through the Retained Lepu Medical Group from 2019 to 2020. See “Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement.” See “Financial Information — Period to Period Comparison of Results of Operations.” The average selling price for our CHD occluder products increased from RMB4,560 per unit in the six months ended June 30, 2021 to RMB4,624 per unit in the six months ended June 30, 2022, primarily due to the increased sales volume of our MemoCarna[®] ASD Occluder III and the launch of our MemoCarna[®] PDA Occluder III and MemoCarna[®] VSD Occluder III in mid-2021, all of which have relatively higher pricing per unit compared to CHD occluder products of older generations as a result of the upgrade in product design and manufacturing process.

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The average selling price for our PFO and LAA occluder products increased from RMB460 per unit in 2019 to RMB11,152 per unit in 2020 and further to RMB15,784 per unit in 2021, primarily due to (1) the launch of our LAA occluder product in June 2020, which started to generate revenue in the second half of 2020 with relatively higher pricing per unit due to the relatively more complex structure and sophisticated manufacturing process used in producing LAA occluder products; specifically, as a percentage of the total revenue generated from sales of PFO and LAA occluder products, sales of our LAA occluder product accounted for 87.4% and 91.1% in 2020 and 2021, respectively; and (2) the increase in pricing per unit for our PFO occluder products sold overseas through the Retained Lepu Medical Group from 2019 to 2020. See “Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement.” See “Financial Information — Period to Period Comparison of Results of Operations.” The average selling price for our PFO and LAA occluder products decreased from RMB19,336 per unit in the six months ended June 30, 2021 to RMB6,679 per unit in the six months ended June 30, 2022, primarily due to the decreased sales volume of our relatively higher pricing LAA occluder products as a result of our limited technical training and surgical assistance capabilities amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022, which were critical for the execution of the implantation of and therefore the related sales. The sales volume of our LAA occluder products was relatively high in the six months ended June 30, 2021 as our first generation LAA occluder product launched in June 2020 quickly captured the market potential with its compelling therapeutic effects, backed by our continued investments in the related academic promotion activities and market fairs. Specifically, as a percentage of the total revenue generated from sales of PFO and LAA occluder products, sales of our LAA occluder product accounted for 95.9% and 53.9% in the six months ended June 30, 2021 and 2022, respectively.

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

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

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin
	<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	313	89.7	84	76.4	21	25.8	24	66.7	24	36.1
Total	<u>102,832</u>	88.3	<u>133,113</u>	89.8	<u>197,545</u>	88.8	<u>99,084</u>	89.3	<u>109,482</u>	87.7

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

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Biodegradable technology in Occluder Products

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

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

- *Material selection.* We have a comprehensive understanding of the properties of a variety of biodegradable materials to select appropriate biodegradable materials, including polylactic acid and polydioxanone, to meet the performance requirements of different product candidates.
- *Structural design.* With our understanding of the properties of biodegradable materials, we complement the mechanical performance of our biodegradable product candidates with unique structural design, including suturing, parachute-shaped lock and double-disk concave configuration, to ensure secure and firm clamping.
- *Controlled biodegradation.* We use rate-controlling technology to reconcile biodegradation process with tissue repair process, achieving a safe and controllable biodegradation performance for our product candidates.
- *Product processing.* We have developed a range of technologies for processing biodegradable occluder product and product candidates to ensure their performance and validity, including biodegradable wire mesh technology, heat molding technology, vacuum drying and sterilization control technology, and water-proof packaging technology.

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

BUSINESS

Occluder Products

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

We believe our occluder products have the following key advantages.

- *Effective closure rates.* Our devices have consistently been shown to be highly effective in closing structural heart defects. For example, clinical study reports in relation to our MemoCarna[®] ASD Occluder III have reported a closure rate of 98.1% after six months following the operation, and clinical study reports in relation to our MemoCarna[®] VSD Occluder III, MemoSorb[®] VSD Occluder IV, and MemoCarna[®] PDA Occluder III have reported 100.0% closure rates after six months following the operation.
- *Safe and precise delivery.* Our occluder products are delivered through our tailor-made delivery systems to ensure safe and precise delivery and release at the site of the defect to be closed. See “— Our Products — Occluder Products — Other Products — Procedural Accessories — Delivery System.”
- *Minimally invasive.* Our occluder products are designed to be implanted through transapical or transfemoral procedures, serving to reduce surgical complications associated with invasive open-chest surgeries.

CHD Occluder Products

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

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

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

ASD Occluder Products

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

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


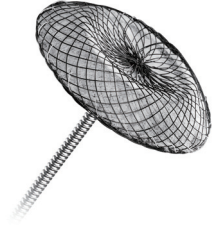
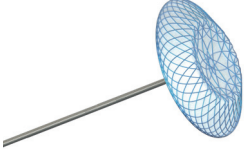
As of the Latest Practicable Date, we had launched three generations of ASD occluder products. MemoPart[®] ASD Occluder I, our first generation ASD occluder product, was approved by the NMPA in April 2003 and was granted the initial CE Mark in August 2012. MemoPart[®] ASD Occluder II, our second generation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

As of the Latest Practicable Date, we were developing our fourth generation ASD occluder product, MemoSorb[®] ASD Occluder IV, which is biodegradable. According to the F&S Report, occluders for septal defect treatment are usually made of non-degradable metallic and synthetic fabric materials. Compared with traditional metal occluders, biodegradable ASD occluders are designed to degrade over time into carbon dioxide and water upon completion of endothelial repair, according to the same source. Our design for biodegradable occluder product and product candidates not only ensures effective autologous tissue closure but also minimizes potential compression and wear on surrounding tissues caused by metal implants,

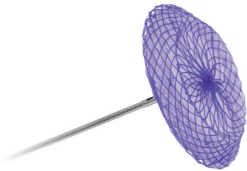
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which lowers the risk of long-term complications. In addition, we believe it leaves available for patients additional future treatment options, especially transseptal procedures, as the biodegradable occluders would not be a permanent implant in the human body, benefiting all patients receiving occluder implants, and in particular, to children who constitute the majority of patients suffering from CHD and also expect a significantly longer remaining life span and better life quality, according to the F&S Report. As of the Latest Practicable Date, our MemoSorb® ASD Occluder IV was in the clinical trial process, and we expect to submit application to the NMPA in the second quarter of 2023 and receive approval in the second quarter of 2024. We plan to commence clinical trial for MemoSorb® ASD Occluder IV in the European Union and the United States in the fourth quarter of 2024.

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

<u>Product Name</u>	<u>Key Features and Benefits</u>	<u>Product Structure</u>
MemoPart® ASD Occluder I (Double-rivet)	<ul style="list-style-type: none"> Nitinol material with biocompatibility and elastic deformation and recovery capability for secure and firm clamping Double-rivet design 	
MemoPart® ASD Occluder II (Single-rivet)	<ul style="list-style-type: none"> Nitinol material Single-rivet design to reduce metal implants and load to the heart More flattened discs than the first generation product to improve endothelialization 	
MemoCarna® ASD Occluder III (Oxide Coating)	<ul style="list-style-type: none"> Nitinol material Single-rivet design: Datura-shaped braided mesh allowing more flattened discs to facilitate endothelialization while preserving a pathway for future transseptal treatments Uniform and dense oxide coating produced under plasma treatment process to minimize the precipitation of nickel ions 	

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<u>Product Name</u>	<u>Key Features and Benefits</u>	<u>Product Structure</u>
MemoSorb [®] ASD Occluder IV (Biodegradable) (product candidate)	<ul style="list-style-type: none"> • Biodegradable material • Single-rivet design • Patented mold locking structure to ensure secure and firm clamping • Platinum marker bands outside the biodegradable wire to enable precise positioning during the procedure 	

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

VSD Occluder Products

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

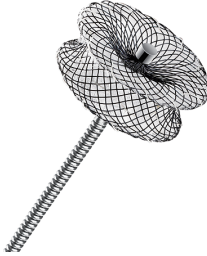
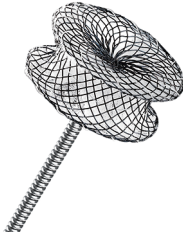

VSD occluder is a percutaneous transcatheter occlusion device intended for the closure of VSD. The first three generations of our VSD occluder products are self-expandable occlusion devices constructed with two discs made of braided nitinol wire mesh and a connecting waist. We utilize our physical kneading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

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

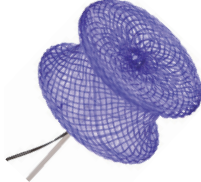
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MemoSorb[®] VSD Occluder IV, which is fully biodegradable, is the latest addition to our VSD occluder product family. Compared with traditional metal occluders, biodegradable VSD occluders are designed to degrade over time into carbon dioxide and water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

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

Product Name	Key Features and Benefits	Product Structure
MemoPart [®] VSD Occluder I (Double-rivet)	<ul style="list-style-type: none"> • Nitinol material with biocompatibility and elastic deformation and recovery capability for secure and firm clamping • Double-rivet design 	
MemoPart [®] VSD Occluder II (Single-rivet)	<ul style="list-style-type: none"> • Nitinol material • Single-rivet design to reduce metal implants and load to the heart 	
MemoCarna [®] VSD Occluder III (Oxide Coating)	<ul style="list-style-type: none"> • Nitinol material • Single-rivet design: Datura-shaped braided mesh allowing more flattened discs to facilitate endothelialization • Uniform and dense oxide coating produced under plasma treatment process to minimize the precipitation of nickel ions 	

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<u>Product Name</u>	<u>Key Features and Benefits</u>	<u>Product Structure</u>
MemoSorb [®] VSD Occluder IV (Biodegradable)	<ul style="list-style-type: none">• Fully biodegradable material• Single-rivet design• Patented mold locking structure to ensure secure and firm clamping	

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

PDA Occluder Products






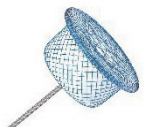
PDA is one of the most common congenital heart diseases. As a normal fetal artery connecting the aorta and the pulmonary artery, ductus arteriosus allows blood to detour away from the lungs before birth. The ductus arteriosus usually narrows and closes within the first two to three weeks after birth,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

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

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

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

Product Name	Key Features and Benefits	Product Structure	
MemoPart® PDA Occluder I (Double-rivet)	<ul style="list-style-type: none"> Nitinol material with biocompatibility and elastic deformation capability for secure clamping Unique cylinder or cone shape to ensure a close and stable fit to the wall of ductus arteriosus Double-rivet design 	 <p>Cylinder-shaped</p>	 <p>Cone-shaped</p>
MemoPart® PDA Occluder II (Single-rivet)	<ul style="list-style-type: none"> Nitinol material Unique cylinder or cone shape Single-rivet design to reduce metal implants and load to the heart 	 <p>Cylinder-shaped</p>	 <p>Cone-shaped</p>
MemoCarna® PDA Occluder III (Oxide Coating)	<ul style="list-style-type: none"> Nitinol material Unique cylinder or cone shape Single-rivet design: Datura-shaped braided mesh allowing more flattened discs to facilitate endothelialization and lighter weight to relieve load to the heart Oxide coating produced under plasma treatment process to minimize the precipitation of nickel ions 	 <p>Cylinder-shaped</p>	 <p>Cone-shaped</p>

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

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Occluder Products for Prevention of Cardioembolic Stroke

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

According to the F&S Report, the market size of the global cardioembolic stroke occluder products market is expected to increase from US\$1.1 billion in 2021 to US\$2.3 billion in 2025 at a CAGR of 20.8%, and further to US\$4.2 billion in 2030 at a CAGR of 12.7% from 2025 to 2030. The market size of China’s cardioembolic stroke occluder products market is expected to increase from RMB0.7 billion in 2021 to RMB1.9 billion in 2025 at a CAGR of 28.1%, and further to RMB7.8 billion in 2030 at a CAGR of 32.1% from 2025 to 2030, according to the same source.

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

PFO Occluder Products

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



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

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

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

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

<u>Product Name</u>	<u>Key Features and Benefits</u>	<u>Product Structure</u>
MemoPart [®] PFO Occluder I	<ul style="list-style-type: none"> • Nitinol material with biocompatibility and elastic deformation capability for secure and firm clamping • Single-rivet design to reduce metal implants and load to the heart, or double-rivet design 	
MemoSorb [®] PFO Occluder II (Biodegradable) (product candidate)	<ul style="list-style-type: none"> • Biodegradable material • Single-rivet design • Patented mold locking structure to ensure secure and firm clamping • Platinum marker bands outside the biodegradable wire to enable precise positioning during the procedure 	

LAA Occluder Products

The LAA is a long, narrow, curved and blind-ended structure extending forward and downward the anterior wall of the left atrium, which forms during the fourth week of embryonic development. Blood tends to stagnate in the LAA as a result of its shape and the pectinate muscles within it, and in patients with cardioembolic stroke, a vast majority of the clots are formed in the LAA. Our transcatheter LAA occluder products offer a safe and effective method to prevent clots by occluding the LAA. Unlike traditional procedures, LAA

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occluders can be used as a preventative treatment for patients with the tendency to form cardiogenic embolism and is also suitable for patients with high risks for surgeries. LAA occluders generally have a better result than traditional procedures because it is less likely to cause clots after implementation.

The market size of China’s LAA occluder products market is expected to increase from RMB0.5 billion in 2021 to RMB1.6 billion in 2025 at a CAGR of 31.0%, and further to RMB7.1 billion in 2030 at a CAGR of 35.0% from 2025 to 2030, according to the F&S Report. The market size of the global LAA occluder products market is expected to increase from US\$0.9 billion in 2021 to US\$1.9 billion in 2025 at a CAGR of 20.3%, and further to US\$3.4 billion in 2030 at a CAGR of 12.7% from 2025 to 2030, according to the same source.

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



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

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

Other Products

IASD Product Candidates

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

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

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symptoms and improve the life quality for patients. Our IASD III is designed to be used together with our radiofrequency ablation device. We plan to initiate the clinical trial for IASD III in China in the fourth quarter of 2023. The following diagrams illustrate the structures of our IASD product candidates.



IASD I



IASD II



IASD III

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

Vascular Plug Products

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

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

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Procedural Accessories

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

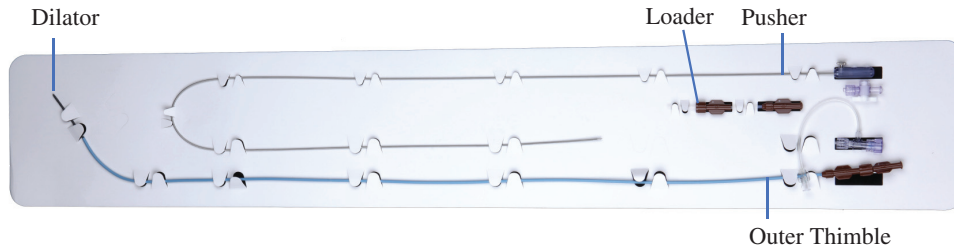
Delivery Systems

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

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

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



MemoPart[®] Interventional Delivery System I



Interventional delivery System II (Integrated)

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

Snares

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

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

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Heart Valve Product Candidates

Entrusted Products

As of the Latest Practicable Date, we also conducted research and development for heart valve products targeting valvular diseases. All of our initial heart valve product candidates were acquired from Lepu Medical during the business injection as further elaborated in “History, Reorganization and Corporate Structure — Our Corporate Development — Business Injection”, which include, but not limited to, the Entrusted Products, while we have also independently initiated R&D for six heart valve product candidates in the product pipeline by ourselves since then. Set forth below is a summary of the regulatory restrictions under the prevailing PRC laws and regulations pertaining to the Entrusted Products (the “Entrusted Products Regulatory Restrictions”), which are applicable to the medical devices industry, and relevant implications:

Entrusted Products Regulatory Restrictions ^(Note)	Relevance to Lepu Medical and us	Corresponding Implications
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Stage one: R&D

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

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

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Entrusted Products Regulatory Restrictions ^(Note)	Relevance to Lepu Medical and us	Corresponding Implications
<p>ii. In terms of sample production prior to the registration of medical devices, an applicant for registration of medical devices is generally prohibited from engaging any other enterprise to produce the product samples for registration purpose, unless such medical devices enjoy certain exemptions for falling within a specifically designated category (a category which none of the Entrusted Products falls within).</p>	<p>Lepu Medical is prohibited from engaging us to produce any samples of the Entrusted Products for registration purpose.</p>	<p>Please refer to the table headed “Entrustment Arrangements” below and the framework agreement with Lepu Medical as detailed in “Connected Transactions — Non-exempt Continuing Connected Transactions — 2. Entrusted Products Related Framework Agreement” for arrangements relating to Relevant Activities.</p> <p>Same as above.</p>
<p><i>Stage two: Upon registration</i></p>		
<p>iii. The registration certificates or the related registration application rights and interests for medical devices are generally not allowed to be directly transferred.</p>	<p>Lepu Medical is not allowed to directly transfer the registration certificates or the related registration application rights for any of the Entrusted Products to us.</p>	<p>Same as above.</p>
<p><i>Stage three: Upon commercialization</i></p>		
<p>iv. In terms of commercial manufacturing, a registrant of medical devices is only allowed to engage a third-party enterprise to manufacture the registered medical devices provided that the registrant remains capable of manufacturing the medical device and the third-party enterprise obtains the manufacture permit for such medical device, except that registrants of medical devices falling within the Prohibited Catalogue are prohibited from engaging any third-party enterprise to manufacture the medical devices listed therein.</p>	<p>Two of the Entrusted Products, <i>i.e.</i>, TAVR system and TMVCRS, fall within the Prohibited Catalogue.</p> <p>The other Entrusted Product, <i>i.e.</i>, balloon dilatation catheter for aortic valve, does not fall within the Prohibited Catalogue.</p>	<p>As a result of this item iv of the Entrusted Products Regulatory Restrictions, at the post-registration stage:</p> <ul style="list-style-type: none"> • Lepu Medical is prohibited from engaging us for commercial manufacturing of the TAVR system and TMVCRS unless there are regulatory changes lifting such restriction; and • as for balloon dilatation catheter for aortic valve, Lepu Medical is allowed to engage us for commercial manufacturing, provided that Lepu Medical remains capable of manufacturing the product and we obtain the manufacture permit for such product. <p>As such, we will take initiative to apply for the relevant manufacturing permits as and when the balloon dilatation catheter approaches registration stage.</p> <p>Please refer to the table headed “Entrustment Arrangements” below for the arrangements relating to commercial manufacturing for each of the Entrusted Products.</p>

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

Entrustment Arrangements

Business Rationale: Considering the Entrusted Products Regulatory Restrictions and for the purpose of maintaining a clear business delineation between our Group and the Retained Lepu Medical Group in the interventional heart valve business subsequent to the business injection, the Entrustment Arrangements were devised for our Group to gain control of the Entrusted Products to the greatest extent possible under the prevailing regulatory framework and restrictions, with Lepu Medical carrying out the remaining necessary activities for the Entrusted Products according to our instructions and for our benefit.

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Entrustment Arrangements

- Specific Arrangements:
- (i) ***Control over properties and personnel.*** In line with the business rationale as stated above, we have acquired all intellectual properties and key equipment and assets, materials and personnel pertaining to the interventional heart valve business (including the Entrusted Products) from Lepu Medical, except that:
 - (a) Lepu Medical maintains the minimum level of personnel for the Entrusted Products led by Ms. Zhang Yuxin, our executive Director, deputy general manager and chief technology officer, who will continue to oversee the clinical-related R&D work for the Entrusted Products undertaken by Lepu Medical in accordance with our instructions and with technical support and training from us; and
 - (b) Lepu Medical maintains necessary production capabilities relating to the Entrusted Products to support the need of product samples for clinical trial purposes.

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

- (ii) ***Control over activities pertaining to the Entrusted Products and relevant costs.***
 - (a) ***Control over Relevant Activities.*** As part of the Entrustment Arrangements, Lepu Medical shall only carry out the research and development, registration and manufacturing activities for the Entrusted Products (to the extent that the then applicable PRC laws and regulations prohibit us from carrying out such activities) (the “Relevant Activities”) legally in accordance with our instructions and for our benefit, with the actual costs of the Relevant Activities incurred by Lepu Medical to be reimbursed by us. Our consent is required for any material matters pertaining to the R&D, registration and manufacturing process of the Entrusted Products, including but not limited to key milestones, funding budgets, selection of clinical trial research institutions, investigators, suppliers and other business partners, amending, terminating or entering into any material agreements and business relationships, and any changes in internal protocols, policies or strategies in connection with the Relevant Activities. In particular, with respect to commercial manufacturing,
 - Lepu Medical has exclusively and irrevocably authorized us to manufacture the Entrusted Product which does not fall within the Prohibited Catalog (*i.e.*, balloon dilatation catheter for aortic valve) after its registration; and

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Entrustment Arrangements

- Lepu Medical will be responsible for the manufacturing activities (as part of the Relevant Activities) for the TAVR system and TMVCRS after their registration due to restrictions in item iv of the Entrusted Products Regulatory Restrictions as illustrated above. Lepu Medical is in the process of constructing a dedicated facility with commercialization-ready manufacturing capabilities for the TAVR system and TMVCRS, which will be put into operation as and when the TAVR system and TMVCRS approach large-scale manufacturing stage.
- (b) *Control over commercialization and sales activities.* Lepu Medical has irrevocably and exclusively authorized us to carry out commercialization and sales activities for each of the Entrusted Products, and our Group has the rights to determine and adjust the prices for each of the Entrusted Products.
- (c) *Cost Control.* Lepu Medical and we have formed a joint committee (the “Entrusted Products Committee”) pursuant to the terms of the asset transfer agreement in January 2021. The Entrusted Products Committee is responsible for, among others, overseeing the implementation of the Relevant Activities, evaluation and confirmation of milestones achieved, formulating funding budgets, and approving costs incurred pertaining to the Entrusted Products. We have the final confirmatory and decisive power for matters handled by the Entrusted Products Committee according to the asset transfer agreement. As such, the costs relating to Relevant Activities incurred by Lepu Medical had been and will continue to be properly reviewed and approved by us and reflected in our books of account. See “Relationship with Our Controlling Shareholders — Independence from Controlling Shareholders — Financial Independence” for the responsibilities of our financial department which is independent of Lepu Medical. Please also see paragraph (iii)(a) below in this table for Lepu Medical’s further covenants with respect to, among others, maintaining/increasing the value of the Entrusted Products, obtaining/maintaining all regulatory documents pursuant to financially and commercially sound standards, and refraining from charging us any additional fees other than the actual costs incurred by it in carrying out the Relevant Activities.

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Entrustment Arrangements

(iii) *Further covenants by Lepu Medical.*

- (a) *Covenants by Lepu Medical under the current regulatory framework.* Lepu Medical irrevocably covenanted that it shall, among others, (1) carry out the Relevant Activities in line with its usual business practices, use its best endeavours to maintain and increase the value of the Entrusted Products and refrain from any action or inaction that may negatively impact the status or value of the Entrusted Products; (2) obtain and maintain all licenses, permits, registration certificates and filings that are necessary for the Entrusted Products in accordance with financially and commercially sound standards and management principles; (3) refrain from charging us any additional fees other than the actual costs incurred by it in carrying out the Relevant Activities; and (4) refrain from entering into any material contracts relating to the Entrusted Products or amending any material internal policies or strategies without our prior written consent.
- (b) *Covenants by Lepu Medical in case of favorable regulatory changes.* Lepu Medical further irrevocably covenanted that, if and when, and to the extent permissible under the then applicable PRC laws and regulations, it shall (1) unconditionally transfer all remaining rights (namely, all rights excluding the intellectual property rights which have already been transferred to the Group) relating to the application or registration of the Entrusted Products to us, which include rights relating to R&D, manufacturing and marketing; and (2) cease to carry out any activities (including research and development, manufacturing and commercialization) in connection with the Entrusted Products subsequent to such transfer and/or authorization.

(iv) *Responsibilities for potential product liabilities*

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

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

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

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

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

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

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

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

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

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

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

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

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Valvular Disease and Our Heart Valve Product Candidates

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

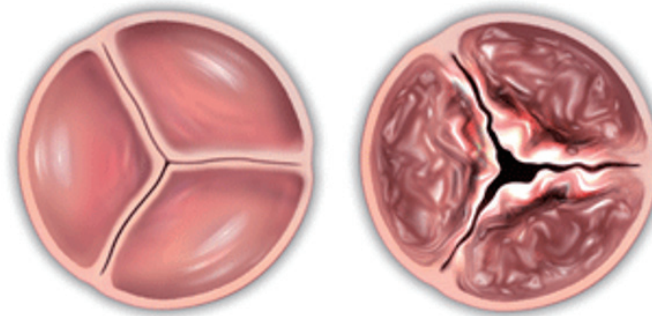
Our transcatheter heart valve product candidates are delivered into patient's diseased heart through a minimally invasive heart procedure using a catheter-based delivery system. Our transcatheter heart valve product candidates provide a beneficial alternative treatment for patients who are inoperable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

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

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Aortic Valve Product Candidates

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



Normal aortic valve

Aortic stenosis

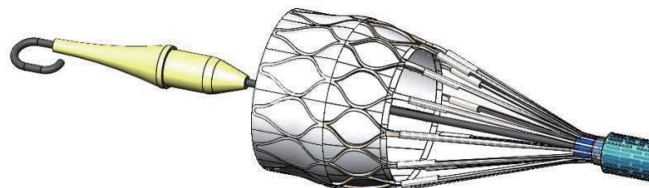
Our aortic valve product candidates are designed to treat aortic stenosis, and mainly include TAVR system and various non-implantation therapeutic auxiliary devices. According to the F&S Report, due to the insufficient number of qualified hospitals with experienced physicians, the TAVR market in China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

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TAVR System

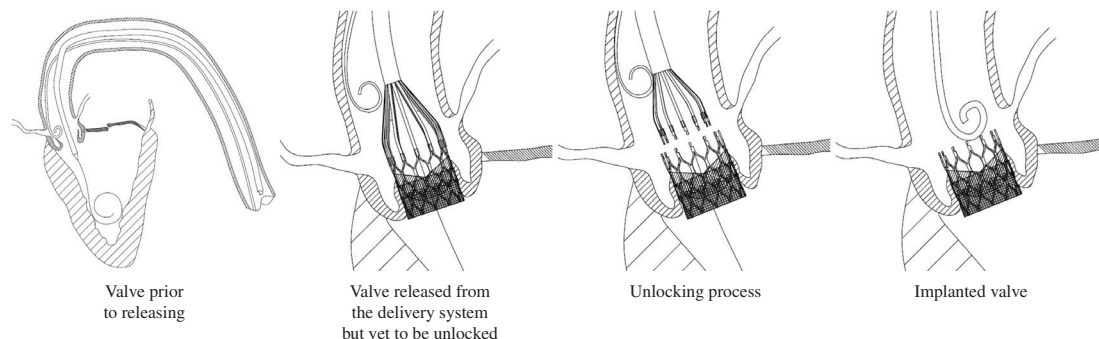
Our TAVR system is a bio-prosthesis aortic valve that primarily consists of a self-expanding nitinol stent sutured with bovine pericardial valve leaflets and PET skirt. Our TAVR system adopts bovine pericardium as the valve leaflet material to provide excellent durability and hemodynamic performance.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

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



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



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

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

Transcatheter Aortic Valve Stenosis Therapy System

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

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

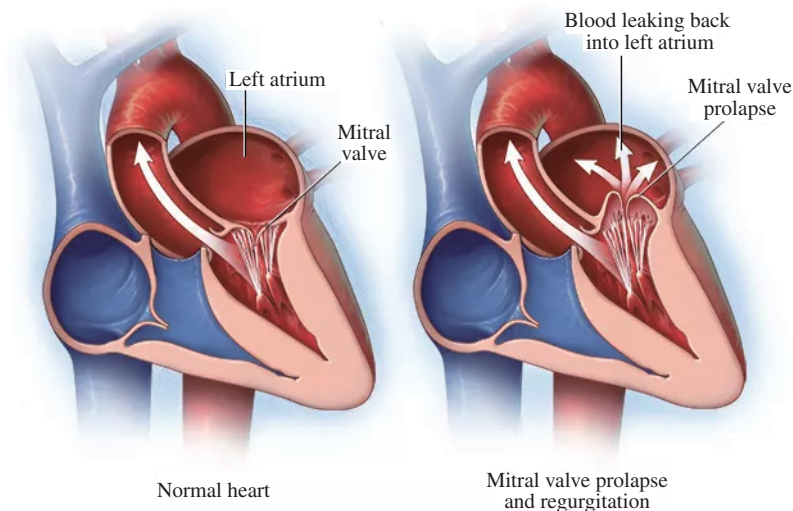
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As of the Latest Practicable Date, our transcatheter aortic valve system (balloon dilation) designed for patients with aortic stenosis was in the type inspection stage, and artificial heart valve with polymer leaflets for transcatheter implantation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

Mitral Valve Product Candidates

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

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



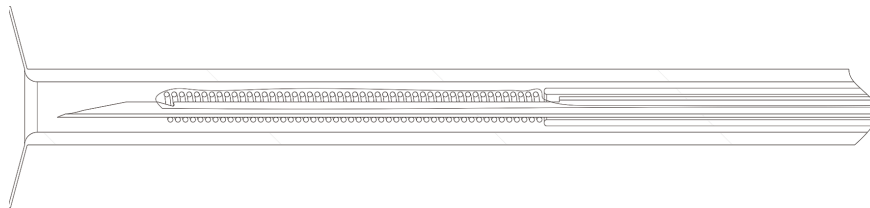
Our mitral valve product candidates mainly include TMVCRS, TMVr systems, and TMVR system.

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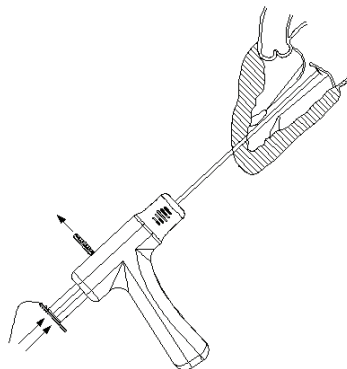
TMVCRS

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

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



The following graph illustrates the operation of our TMVCRS.



TMVCRS

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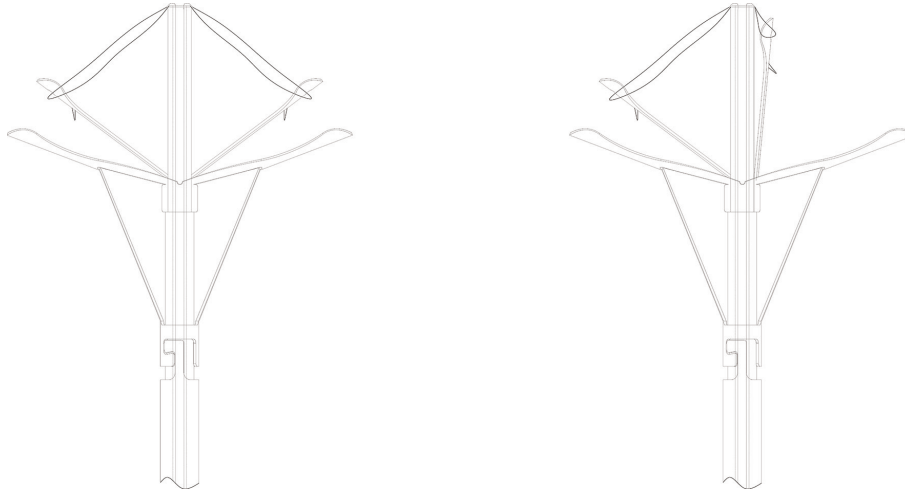
TMVr-A and TMVr-F systems

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

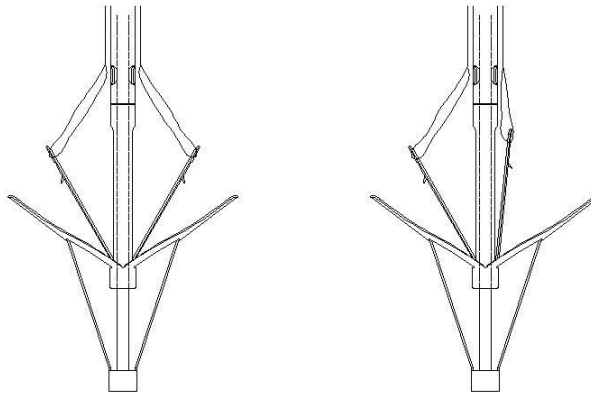
Our TMVr systems, or TMVr-A and TMVr-F systems, are interventional medical devices designed for the edge-to-edge repair of mitral valve to treat patients with mitral regurgitation, including both functional mitral regurgitation and degenerative mitral regurgitation. The TMVr-A system can be delivered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

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

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TMVr-A system



TMVr-F system

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

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

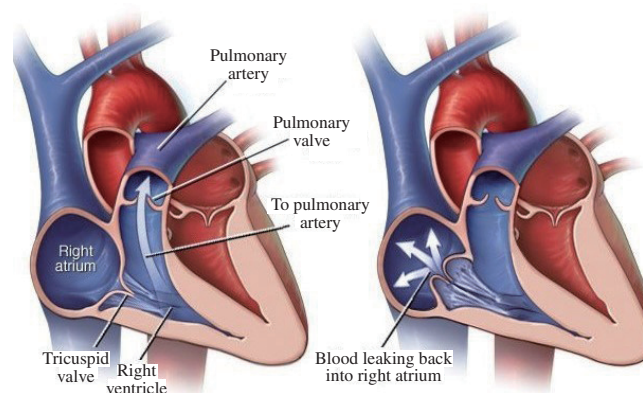
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We began to develop our TMVCRS, TMVr-A system, and TMVr-F system in 2018, aiming to provide innovative medical solutions for mitral valve patients. As of the Latest Practicable Date, we had successfully commenced the clinical trial for TMVCRS enabling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

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

Tricuspid Valve Product Candidates

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



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

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Pulmonary Valve Product Candidate

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

Procedural Accessories for Heart Valve Product Candidates

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

Balloon Dilatation Catheter for Aortic Valve

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

Thrombus Protection Device

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

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

Vascular Closure Device System

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

Disposable Introducing Sheath

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

Disposable Delivery Sheath

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

Disposable Atrial Septal Puncture System

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

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Product Candidates in Design Stage

As of the Latest Practicable Date, we had 10 major product candidates in the design stage covering different product categories of interventional medical devices for structural heart diseases. The following table summarizes information on our product candidates in the design stage.

Category and Name	Classification of Medical Devices in terms of NMPA	Design Features and Applications
<i>Heart Valve Product Candidates</i>		
Artificial heart valve with polymer leaflets for transcatheter implantation	Class III	Novel polymer material as the valve leaflet material with improved durability; larger orifice area and smaller profile; suitable for transcatheter heart valve products
Aortic valve perfusion system	Class III	Targeted drug delivery for aortic valve calcification
Transcatheter annulus repair system	Class III	Anchored and sized on the mitral valve annulus under real-time ultrasound guidance to reduce regurgitation; pre-formed shape with barbs, providing stable positioning
TMVR system	Class III	Suitable for treating patients with severe mitral regurgitation or unsuitable for open-chest surgery or TMVr; D-shaped stent design to avoid left ventricular outflow tract obstruction
Transcatheter papillary muscle repair system	Class III	Real-time adjustment of papillary muscle under ultrasound guidance
Transcatheter tricuspid valve repair system	Class III	Each clip arm being independently adjustable to capture one leaflet
Transcatheter tricuspid valve replacement system	Class III	Suitable for treating tricuspid valve regurgitation
Transcatheter pulmonary valve replacement system	Class III	Suitable for treating pulmonic regurgitation
Vascular closure device system	Class III	Procedural accessories
<i>Occluder Product Candidates</i>		
IASD II (Biodegradable)	Class III	Relieving left atrium overload; biodegradable

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Our Global Distribution Footprint

We generated revenue from the Retained Lepu Medical Group for products sold overseas of RMB7.8 million, RMB28.0 million, RMB10.2 million, RMB8.5 million and RMB0.6 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, accounting for 6.7%, 18.9%, 4.6%, 7.7% and 0.5% of our total revenue in the same periods, respectively. Through gradual termination of our cooperation with the Retained Lepu Medical Group for the distribution of our products overseas, as of September 30, 2021, we had entered into distribution agreements with overseas distributors directly, except for India. See “Connected Transactions — Non-Exempt Continuing Connected Transactions” and “— Sales, Distribution and Marketing — Sales Arrangements.” We believe direct distribution arrangement with such distributors allows for more control over our overseas distributor networks and better understanding of overseas market demands. Prior to the change in the distribution model for overseas markets in 2021, the Retained Lepu Medical Group was our sole distributor for overseas markets. As of the Latest Practicable Date, we had accumulated considerable experience in product registration and launch in the European Union and attained valid CE Marks for nine of our products. Depending on the market demand and conditions, we plan to commence necessary overseas clinical trial process for select product candidates and gradually complete overseas registration for our product candidates in key target markets. We plan to purchase materials and equipment, conduct animal studies, clinical trials, inspections and registration, and engage local agencies and consultants for clinical trials and registration matters. We also intend to accelerate the commercialization of our future biodegradable occluder product candidates and heart valve product candidates in overseas markets such as the European Union, Southeast Asia and the United States.

OUR PLATFORM

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

Research and Development

Our Research and Development Team

We have built our research and development team with technological expertise in various areas, primarily including nitinol shape memory material cutting and braiding techniques, animal source material processing techniques, biodegradable material controlled release techniques, suturing techniques, and structure design and processing techniques. We have developed a comprehensive portfolio of 50 marketed products and major product candidates,

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and maintained an expansive collection of intellectual property rights including 232 registered patents and 51 pending patent applications in China as of the Latest Practicable Date. As of the same date, we also had 14 patents under application in the United States and the European Union.

As of the Latest Practicable Date, our research and development team had 79 members based in Beijing and Shanghai, approximately 38.0% of whom possess a master’s or higher degree in relevant fields. Our research and development team is led by Ms. ZHANG Yuxin, our executive Director and chief technology officer, who has over 10 years of experience in medical device research and development and is the co-inventor of more than 30 patents. Our research and development team is further divided into the occluder team and the heart valve team, each with specialized tasks, to facilitate the product development process. We have entered into legally-binding confidentiality and non-compete agreements with our key employees and employees involved in our research and development activities. We have also entered into service invention agreements with such employees, pursuant to which any intellectual property conceived and developed during their employment belongs to us and they waive all relevant rights or claims to such intellectual property.

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

Collaboration with Research Institutions, Hospitals, KOLs and Physicians

Our research and development teams collaborate closely with research institutions and hospitals, who provide invaluable insights, guidance and recommendations. We lead the research and development process of our products. We collect market information from physicians and hospitals as well as professional advice from KOLs at the project proposal stage to optimize product design. After we have a preliminary design, we seek suggestions from partnered research institutions and KOLs to evaluate feasibility and further refine product features. Specifically, we collaborate with the National Engineering Research Center for Biomaterials (國家生物醫學材料工程技術研究中心) to study the properties of biodegradable polymer materials in order to facilitate our research and development of biodegradable occluder products. Specifically, Dr. Yunbing Wang, who serves as the director of the National Engineering Research Center for Biomaterials, the academic dean of the College of Biomedical Engineering of Sichuan University (四川大學生物醫學工程學院), and the vice chairman of the Chinese Society for Biomaterials (中國生物材料學會), has agreed to serve as our external consultant. We have also collaborated with Fuwai Yunnan Cardiovascular Hospital (雲南省阜外心血管病醫院) in completing the world’s first fully biodegradable VSD Occluder implantation in February 2018 during its clinical trial, which marks a breakthrough in the field

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of fully biodegradable occluders globally, according to the F&S Report. We have also collaborated with a prominent medical institution in China in the research and development of our TAVR system which is expected to be 100% deployable, retrievable and repositionable before being detached from the delivery system. We are generally responsible for the research and development activities at our own cost, and the collaborating institutions are responsible for providing premises, equipment, research advice and technical instructions to us. We are entitled to the ownership of substantially all of the technologies developed from such collaborations, including patented and unpatented technologies. We also maintain continuous communications with research institutions, KOLs, physicians and hospitals, who are informed of our latest research and development progress. In addition, we actively participate in medical conferences and industry exhibitions and host meetings and seminars to foster collaborative relationship with industry participants.

Product Design and Pre-clinical Development

Product Design

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

- *Project proposal.* Our sales and marketing staff collect market information and coordinate with KOLs and physicians to keep our research and development team well informed of market demands of physicians and patients. Our research and development staff conduct economic and feasibility analysis, with costs, product functions, market potential, existing products and regulatory requirements taken into consideration. After the analysis, our research and development staff formulate a preliminary product protocol.
- *Project approval.* After a project has passed all internal assessments, representatives from our research and development, clinical management, supply chain and manufacturing and quality control and management teams collectively review the project proposal and determine whether the project should proceed and also set a detailed project timetable. The research and development team shares their studies on project feasibility. The supply chain team assists with determining raw material requirements. The quality control and clinical management team helps ensure that the product design complies with all applicable laws and regulations. The manufacturing team then produces and modifies product samples. Based on feedback from functional teams, the senior management will then determine whether a project should proceed.
- *Design and development.* Our new medical device product design and development is guided by our internal control protocol. See “— Quality Control” for more details.

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Pre-clinical Animal Studies

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

Clinical Trials

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

We conduct clinical trials of our new products in order to obtain the requisite regulatory approvals and collect post-procedure data that can improve and enhance the design and features of our products. In addition, robust clinical data are an important marketing tool for increasing the credibility of our brand and products. The goal of a clinical trial is to verify the clinical efficacy and safety of a device. Within our research and development team, we have assembled a regulatory affairs team, which is independent from our clinical management team, in charge of regulatory approval to submit our clinical report together with other materials to the relevant government agencies. As of the Latest Practicable Date, we were in the process of seven clinical trials in China, and our current clinical data and practices are designed to meet the standards of the Norms on the Quality Management for the Clinical Trials of Medical Devices (《醫療器械臨床試驗質量管理規範》) as promulgated by the China Food and Drug Administration (currently known as the NMPA) and National Health and Family Planning Commission of the PRC. Our occluder products, such as ASD, VSD, PDA and PFO occluder products, typically go through non-inferiority clinical trials designed to evaluate efficacy and safety by comparing the safety and efficacy endpoints among patients undergoing procedures using our occluder product candidate to be launched and our marketed occluder product of older generations or marketed occluder product of other reputable medical device providers. According to the F&S Report, it is an industry norm in China for medical device providers to adopt single-arm clinical trials for product candidates in emerging markets with very limited

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marketed products. In line with industry standard, our heart valve product candidates typically go through single-arm clinical trials, where a sample of individuals with the targeted medical condition is given the experimental therapy and then followed up over time to observe their response and prognosis to collect efficacy and safety data. We also plan to commence overseas clinical process for MemoSorb[®] VSD Occluder IV, and as soon as practicable when suitable market conditions arise after we obtain the NMPA approval for certain product candidates, such as MemoSorb[®] ASD Occluder IV, MemoSorb[®] PFO Occluder II, MemoLefort[®] LAA Occluder I, LAA Occluder II, TAVR system, TMVr-A, and TMVr-F.

In line with industry practice, during the Track Record Period, we engaged industry-leading CROs to provide certain supporting services in the clinical trials for our products. Such CROs, including Beijing Tailian BioPharma Co., Ltd. (北京太鏈生物醫藥科技有限公司) and Beijing Excellence Angel Medicinal Technological Progress Co., Ltd. (北京卓越天使醫藥科技發展有限公司), are private companies in China primarily engaged in providing clinical support to the pharmaceutical, biotechnology and medical device industries on a contract basis. We select our CROs based on various factors, including service quality, capability, reputation, cost-effectiveness and research experience in treating heart disease. We typically enter into master service agreements with our CROs with a detailed scope of work for each study or trial, establishing specific and detailed metrics on working methods, procedures, standards and timelines to further ensure the quality of the outcomes. We monitor the CROs to ensure they perform their duties with a standard in line with our protocols and industry benchmark to safeguard the integrity of the data collected from the trials and studies. Since 2018, all the clinical trial results, none of which contains any personally identifiable information, are stored in and managed through an online electronic data capture system, which is only accessed by our responsible employees, the employees of the CRO that are in charge of the clinical trial and personnel of other professional parties that we cooperate with during the clinical trial process. We recorded service fees paid to the same CRO of RMB0.2 million in 2019, representing the last installment for our LAA occluder product. We recorded service fees paid to our CROs of RMB2.8 million in 2020 in connection with the clinical trials for our fully biodegradable VSD occluder product, biodegradable ASD occluder product candidate and biodegradable PFO occluder product candidate. We recorded service fees paid to our CROs of RMB12.3 million in 2021 in connection with the clinical trials for our fully biodegradable VSD occluder product, biodegradable PFO occluder product candidate, biodegradable ASD occluder product candidate and TMVr-A system. We recorded service fees paid to our CROs of RMB2.1 million in the six months ended June 30, 2022 in connection with the clinical trials for our IASD I and biodegradable ASD occluder product candidate. We did not record any service fee payable to our CROs as of December 31, 2019 and 2020. We recorded service fee payable to our CROs of RMB1.3 million as of December 31, 2021. We did not record any service fee payable to our CROs as of June 30, 2022. Such service fees were typically determined by the nature of the services provided, manpower involved, amount of time and resources devoted, as well as other operational costs of the CROs. We became acquainted with one of our CROs through referral by Lepu Medical, to whom the CRO had provided clinical trial management services. We became acquainted with another one of our CROs through its parent company, which had

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provided site management services for us. We became acquainted with the remainder of our CROs during the Track Record Period through public tender processes. To the best of our Directors' knowledge, save as disclosed above, none of our CROs (including their respective shareholders, directors or senior management, or any of their respective associates) had any past or present relationships (including, without limitation, business, employment, family, trust, financing, shareholding or otherwise) with our Group, our shareholders, Directors, senior management or any of their respective associates.

Collaboration with Clinical Trial Institutions

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

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

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Manufacturing

Production Facilities

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

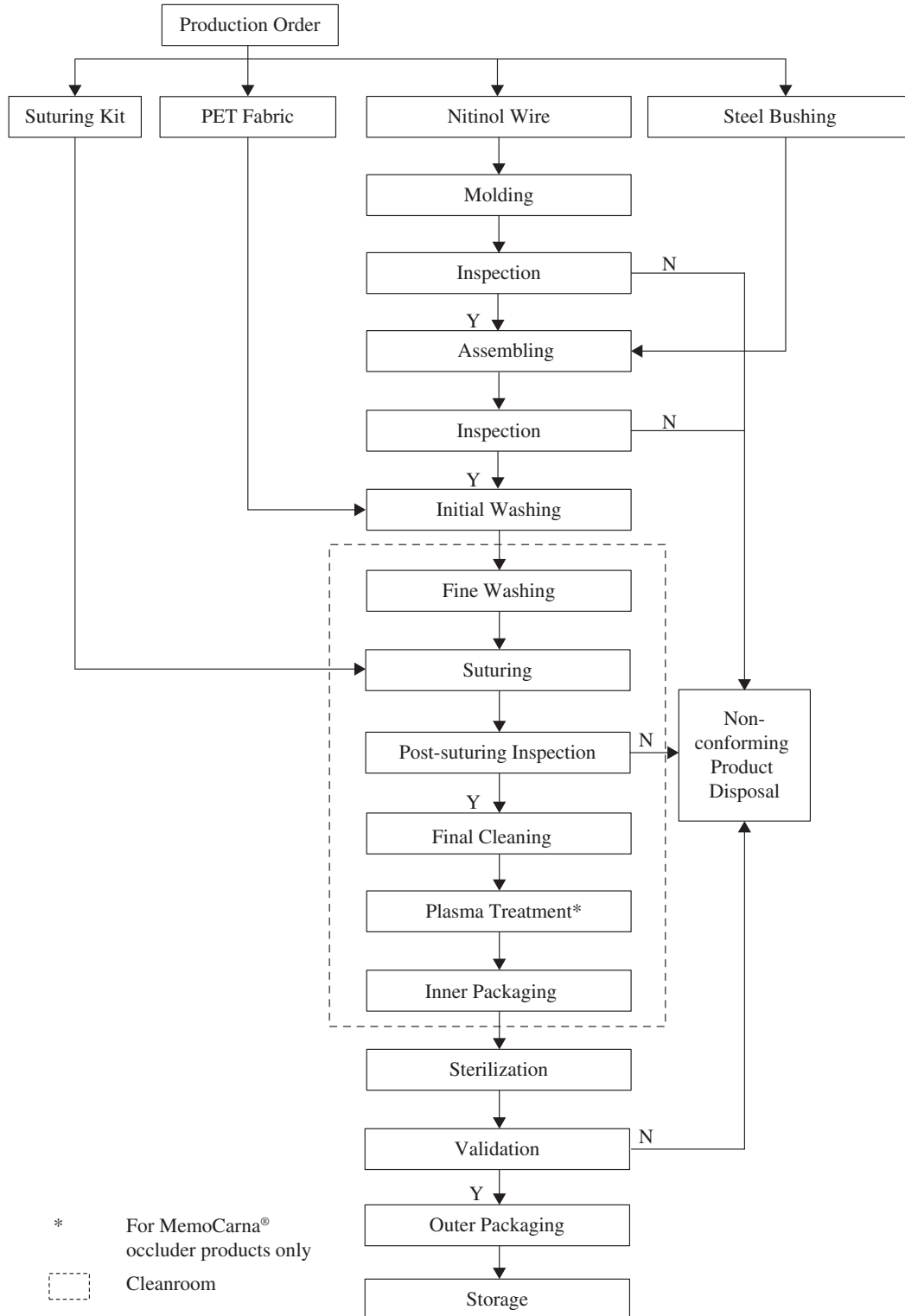
We typically require our employees to undergo health checks before they start producing medical devices, and we require new employees to undergo training before they commence work on our production lines. The on-board training typically covers equipment operation protocols, cleanroom hygiene, product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

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

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Production Process

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



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

- *Raw material quality inspection.* We examine the quality of the raw materials purchased in accordance with the internally-established technical requirements and procurement specifications.
- *Molding.* We shape raw materials into semi-finished components and parts through specifically designed procedures such as laser cutting, physical kneading and heat processing. We inspect the dimensions of the semi-finished products and assess the molding results to ensure that they conform to our production specifics and quality control requirements.
- *Washing.* We carry out the initial washing on the semi-finished products before moving them into the cleanroom. Within the cleanroom, we wash the semi-finished products for a second time with ultrasonic cleaner and then dry them.
- *Suturing and assembling.* Suturing must be done through our specifically designed process by experienced technicians as it requires significant technical know-how in assessing the appearance and tightness. We then conduct a comprehensive quality inspection on the products.
- *Cleaning.* We clean the products to remove any potential particles from the manufacturing process. For our MemoCarna[®] occluder products, we also have the products go through a plasma treatment process to produce a uniform and dense oxide coating on the surfaces.
- *Packaging.* We pre-package the finished products.
- *Sterilization.* We transport the packaged products to a third-party sterilization service provider for professional sterilization.
- *Finished product validation.* We proceed with the outer packaging process and conduct a comprehensive quality inspection on sterilized products. We then deliver the finished products to our warehouse for proper storage.

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All the steps in our production process are conducted in compliance with the Good Manufacturing Practice for Medical Devices (《醫療器械生產質量管理規範》) as promulgated by China Food and Drug Administration (currently known as NMPA). The procedures within the dotted line above are conducted within a controlled cleanroom environment in accordance with the Good Manufacturing Practice for Bacteria-free Medical Devices, and the procedures outside the dotted line are conducted in regular environments. To maintain the controlled environment in our cleanrooms, in addition to regular internal inspections, we also engage qualified third parties to perform thorough inspections on an annual basis, with inspection reports issued. We have implemented quality management systems as part of our manufacturing processes. Our major quality control inspection including (1) raw material inspection in accordance with technical requirements and procurement specifications on appearance, dimension, physical properties, chemical properties and microbial properties; (2) in-process inspection in accordance with manufacturing process inspection procedures on the appearance, dimension and physical properties of semi-finished products; (3) finished product validation in accordance with technical requirements and inspection procedures on appearance, dimension, physical properties, chemical properties, microbial properties and sterilization results. We conduct substantially all the key manufacturing procedures in-house except for sterilization. In line with industry practice, we collaborate with contract sterilization facilities to utilize their industry-conformed equipment, well-trained personnel and thorough understanding of recognized sterilization standards, in addition to saving cost. Moreover, the ethylene oxide sterilization involved in our manufacturing process is required to be conducted by qualified sterilization facilities in accordance with local environmental impact assessment planning. To ensure a consistent standard of sterilization, we generally delegate the work to one primary entity. We are able to monitor and control the standard and quality of the delegated sterilization work through our agreements with the third party. The delegated party is obligated to perform sterilization in accordance with confirmed parameters and validate sterilization results under the Requirements for the Development, Validation and Routine Control of the Sterilization Process of Medical Devices, Part I of the Sterilization of Healthcare Products with Ethylene Oxide (《醫療保健產品滅菌環氧乙烷第1部分：醫療器械滅菌過程的開發、確認和常規控制的要求》). We retain the right to inspect the delegated party's facility and equipment, evaluate whether it adheres to the required standards and request the delegated party to improve accordingly. Also, the delegated party's work product is subject to our examination. To further ensure that the sterilization process can be effectively conducted, we have established cooperative relationships with two qualified sterilization partners to safeguard against any contingencies of one of them.

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Production Capacity, Actual Production Volume and Utilization Rates

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

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

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

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

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SALES, DISTRIBUTION AND MARKETING

Sales and Marketing Team

As of the Latest Practicable Date, our sales and marketing team had 63 members. Our sales and marketing team was led by Ms. ZHANG Xiani, our deputy general manager, who had over 10 years of extensive sales and marketing experience in the medical device industry. See “Directors, Supervisors and Senior Management.” We primarily recruit sales and marketing staff with education background and work experience in the medical device industry. We offer regular training sessions to our newly recruited sales and marketing staff to develop their knowledge of our products, industry knowledge and sales skills. We have also built a specialized sales and marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas, and implemented regional management strategy to further promote overseas distribution.

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

Sales and Marketing Strategy

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

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

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

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

Marketing Model

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

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

- *Duration.* The agreements with our consultants generally provide a fixed term of less than one year.
- *Rights and obligations.* Our consultants shall provide services in accordance with our specific requirements under the agreements in a designated geographic area, which generally include, among others, (1) carrying out market research and analysis including field studies on the market conditions and competitive landscape for our designated products, (2) delivering comprehensive research results supported by solid market data, and (3) tracking the sales performance of the designated products and making targeted marketing suggestions. We shall have the right to understand and monitor the research progress.
- *Pricing.* The agreements generally stipulate a fixed price covering all expenses incurred.
- *Payment method.* We generally make one-time payments to our consultants.
- *Exclusivity.* We generally engage the consultants to carry out market research and analysis in a designated geographic area. Under certain agreements, the consultants shall not directly or indirectly provide market research services for our competitors within the designated geographic area. We will retain all legal means to defend our rights and interests if the consultants were found to violate the exclusivity clause.
- *Confidentiality.* The consultants shall not disclose to any third party our confidential information or the data and information covered by the research results they provided to us, which clause shall survive the term of the agreements.
- *Termination.* The agreements can generally be terminated upon mutual consents or a party's failure to perform its principal obligations under the agreements.

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

Sales Arrangements

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

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

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

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

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

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total	Amount	% of Total
	<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 ⁽¹⁾	9,603	8.2	10,988	7.4	13,576	6.1	5,733	5.2	3,785	3.0
Total	116,451	100.0	148,247	100.0	222,583	100.0	110,968	100.0	124,804	100.0

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

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Sales to Distributors

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

Selection and Management of Distributors

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

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

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

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

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

Prevention of Cannibalization

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

- *Geographic restrictions.* We generally only authorize one distributor to sell our products to each hospital.
- *Product type restrictions.* We specify the types of products that distributors are authorized to sell in the written authorization letters. Our distributors can only sell certain types of our products to their designated hospitals as provided under the authorization.
- *End customer monitoring.* Our sales and marketing staff visit hospitals where our products are sold to confirm details of the distributors they work with and any potential instances of non-compliance with our distribution agreements or policies. Furthermore, hospitals generally have internal policies which require them to only conduct business with distributors who have appropriate authorization from medical device manufacturers. We also communicate with physicians and hospitals that use our products through our academic activities, medical conferences and industry exhibitions that we attend in order to monitor the actual usage of our products and to collect feedback on our products.

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- *Mutual supervision policy.* We encourage our distributors to supervise each other and report to us unauthorized sales by other distributors. In the event of any report or identification of such potential non-compliance, we conduct independent verification of such reported behavior, and may penalize the relevant distributors according to the distribution agreements and our internal policies, for example, by imposing monetary penalties or termination of business relationships.
- *Accountability.* Any sales outside of the designated hospitals will be deemed as cannibalization. If we discover any cannibalization activity by our distributors, we are entitled to pursue liabilities against such distributors and to terminate our authorization and/or business relationships.

Distribution Agreements

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

- *Duration.* Our standard distribution agreement has a term of one year and will be automatically renewed for three months.
- *Exclusivity and prevention of cannibalization.* The distributors are authorized to sell our products only within the designated hospitals and are prohibited from selling outside the designated hospitals. Any sales outside of the designated hospitals will typically be deemed as cannibalization. If we discover any cannibalization activity by our distributors, we are entitled to request such distributors to return all the products that were sold outside of the designated hospitals, and reimburse us an agreed-upon percentage of its annual sales amount. Our distributors, including their affiliates, are also prohibited from selling competing products without our prior written confirmation.
- *Sub-distributors.* We operated a single-layer of distributors during the Track Record Period and do not intend to allow any distributor to procure sub-distributors in the domestic market. According to the F&S Report, hospitals in China require medical device distributors to obtain authorization letters granted by manufacturers as a prerequisite for selling the relevant products to hospitals. We grant such authorization letters only to distributors selected by our sales and marketing

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

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

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- *Credit term.* We generally do not grant credit period to our distributors. Under limited circumstances, we may grant distributors who have a good track record with us a temporary credit period.
- *Delivery.* We are responsible for transporting our products to the distributor and bearing the costs of transportation.
- *Product return and customers’ rights to claim additional units.* We generally are not responsible for product sale, return or exchange once our products are sold to the distributors. We may allow for an exchange only if the product is proved to be defective, and the exchanged product will be subject to inspections by our quality control team. According to the F&S Report, in line with industry practice, distributors generally have the right to claim additional units when the original units are discarded during the process of implantation upon our confirmation based on evidence provided by them, such as product serial number.
- *Confidentiality.* Distributors are required to keep confidential any information relating to our business and shall not disclose the confidential information to any third parties within the term of the agreement and three years after its termination.
- *Termination.* Each party has the right to terminate the agreement if the other party breaches the terms and conditions therein.

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

As of September 30, 2021, we had terminated our cooperation with the Retained Lepu Medical Group for the distribution of our products overseas and entered into distribution agreements with overseas distributors directly, except for India. See “Connected Transactions — Non-Exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement” and “— Sales Arrangements.” The new distribution agreements we enter into directly with the overseas distributors are in substantially identical terms with that with the Retained Lepu Medical Group. As a result of the change in the distribution model for overseas markets, we have taken over the roles and responsibilities of the Retained Lepu Medical Group, such as distributor communications and management as well as other overseas sales and marketing activities. We believe direct distribution arrangement with such distributors allows for more control over our overseas distributor networks and better understanding of overseas market demands. We have also hired the key sales and marketing personnel from Lepu Medical who used to be responsible for our overseas distribution and built a specialized sales and

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marketing team well-versed in foreign trade involving medical devices to lead our product distribution overseas. See “— Sales Arrangements.” We will continue to expand our sales and marketing team and recruit approximately 30 to 50 sales and marketing personnel for overseas distribution in the European Union, Southeast Asia and the United States. In addition, we plan to establish overseas sales offices and recruit sales and marketing personnel located in key overseas markets in the future to facilitate our overseas distribution. Also, we plan to conduct market conferences and academic promotion activities in overseas markets. See “Future Plans and [REDACTED] — [REDACTED].”

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

- *Duration.* Our standard overseas distribution agreement generally has an initial term of one year. Upon the expiration of the initial term, the agreement may be renewed for six months if the distributors meet certain minimum purchase and sales requirements during the initial term.
- *Exclusivity.* Our overseas distributors are authorized to sell our products only within designated geographic area. In addition, the distributors may not directly or indirectly resell to buyers residing outside the designated area.

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- *Sub-distributors.* Our overseas distributors generally have the right to recruit on their own behalf sub-distributors in the designated area and grant authorization for the sub-distribution of our products in the designated area upon our prior written consent. The distributors shall be liable for the actions of the sub-distributors in the designated area. There is no specific requirement on single-layer distributors in overseas markets.
- *Minimum purchase volume.* We typically set a minimum purchase volume with our overseas distributors depending upon various conditions at the target market such as patient number as well as the brand awareness and market acceptance of our products. We will review the minimum purchase volume at the end of the contract term and adjust if necessary. The minimum purchase volume serves as an annual sales goal instead of strict purchase requirements. If a distributor fails to meet its sales goal, we generally will consider factors such as the distributor's distribution capability and general market conditions to adjust the sales goal for the next contract term or determine whether to terminate our agreement with it. During the Track Record Period, our overseas distributors and sub-distributors have generally been able to achieve the sales goals, except for having been negatively affected during the COVID-19 outbreak.
- *Obligations.* Our overseas distributors are obligated to, among other things, (1) act as an independent contractor, purchasing our products, seeking sales and customers as well reselling our products on their own; (2) undertake that it has not used our brand or name or has not received any material advance or financial assistance from us; (3) comply with relevant laws and regulations; (4) provide a report on marketing and sales information for the designated area on a monthly basis; and (5) devote their best efforts to the adequate promotion, exploitation and development of sales of our products within the designated area.
- *Pricing and payment.* We generally set out the current prices in the overseas distribution agreement, which may be amended by us from time to time at our sole discretion provided that we so advise the distributor at least three months in advance in writing specifying the changes and the effective date of the changes.
- *Credit term.* The overseas distributors generally shall make full payment within seven calendar days after the order acceptance is confirmed by us.
- *Delivery.* Our overseas distributors bear costs for importing, storing and selling our products in the designated area.

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- *Product return and exchange.* In line with the industry practice, we generally do not allow our overseas distributors to exchange or return products, unless under limited circumstances such as product quality issues and incorrect products manufactured or shipped because of our mistakes.
- *Confidentiality.* Each party agrees not to divulge to any third party and not to use, except for the purpose of the distribution agreement, any information of the other party, which is of confidential nature to the other party. In addition, upon expiration or termination of the agreement, each party shall return to the other party all confidential material which they have received during the term of this agreement from the other party.
- *Termination.* Each party has the right to terminate the agreement if the other party breaches or violates an essential obligation and fails to remedy the breach or violation within 30 calendar days after it is requested by the other party in writing to do so. In the event of termination, our overseas distributors shall refrain from further usage of our trademarks, secure that any sub-distributor shall immediately refrain from using our trademarks, and transfer any permissions and licenses required for selling our products in the designated area to us.

Number of Distributors and Sub-distributors

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

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

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

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

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

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

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

(1) Represent number of sub-distributors.

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

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

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Domestic Direct Sales to Hospitals

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

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

Pricing

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

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

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

For our products sold overseas through the Retained Lepu Medical Group during the Track Record Period, the Retained Lepu Medical Group determined prices through commercial negotiations with sub-distributors based on a number of factors, primarily including the specific market conditions of each overseas market, product specifications, the scale and potential of overseas customers, their purchase amounts and the pricing of multinational competitors in the same market. With its long-standing experience and reputation in the overseas market and established sales network, the Retained Lepu Medical Group had been actively assisting us in the overseas sales since 2012. As a result, prior to 2020, for our products for onsale to overseas markets, we sold such products to the Retained Lepu Medical Group at prices calculated by adding a prevailing margin to our cost of production. As we had gradually built up our own brand recognition and sales capabilities, by the beginning of 2020, the contribution from the Retained Lepu Medical Group to the overseas distribution of our products had been reduced to such an extent that its involvement and functions became similar to our distributors in China. We and the Retained Lepu Medical Group have agreed to adjust the pricing model for our sales to the Retained Lepu Medical Group accordingly so that the consideration paid by the Retained Lepu Medical Group since the beginning of 2020 has been calculated based on an agreed discount, at prevailing market rates, to the price paid by the overseas sub-distributors, which has resulted in a substantial increase in our selling prices to the Retained Lepu Medical Group. The gross profit margin that we generated from our sales to the Retained Lepu Medical Group in 2020 was at the comparable rate with that generated from the sales to our other distributors that are independent third parties. Furthermore, we have

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gradually established direct business relationships with overseas distributors since in 2021 and now sell our products to such distributors directly at prevailing market rates. See “Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement.”

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

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

Medical insurance reimbursement coverage for medical devices in China is determined at the provincial level. See “Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices — National Medical Insurance Program” for more details. As the national medical insurance reimbursement system in China covers the treatment of CHD, all the occluder products and the related procedural accessories for the treatment of CHD are eligible for the medical insurance reimbursement. Accordingly, as of the Latest Practicable Date, our MemoPart[®] ASD Occluder I, MemoPart[®] VSD Occluder I, MemoPart[®] PDA Occluder I, MemoPart[®] interventional delivery system I, MemoPart[®] Snare I and interventional delivery system II were eligible for medical insurance reimbursement in all the provinces, autonomous regions and municipal cities in China. As of the same date, our MemoCarna[®] ASD Occluder III, MemoCarna[®] PDA Occluder III, MemoLefort[®] LAA Closure Occluder I, MemoCarna[®] VSD Occluder III, integrated interventional delivery system for Plug III, delivery system and interventional delivery system (biodegradable) were eligible for medical insurance reimbursement in certain provinces in China, such as Shanghai, Tianjin, Jiangsu province, Anhui province, Guangdong province, Guangxi Zhuang autonomous region, Fujian province, Yunnan province, Guizhou province, Liaoning province, Henan province, Shandong province, Gansu province, Shaanxi province, Xinjiang Uygur autonomous region, Inner Mongolia autonomous region, Zhejiang province, Tibet autonomous region, Shanxi province, Beijing, Hebei province, Heilongjiang province, Sichuan province, Chongqing, Qinghai province, Jiangxi province, Hainan province, Hunan province, Hubei province and Ningxia Hui autonomous region. We strategically develop and position our products taking into consideration these insurance reimbursement schemes. Whether a product is included in the medical insurance reimbursement coverage may impact the prices our end customer pay for our products. However, medical insurance reimbursement coverage has no direct impact on the pricing of our products to our customers, including primarily distributors and hospitals. Such pricing is generally determined by the public prices, which are determined through the public tender processes organized by the procurement platforms.

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Anti-bribery Measures

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

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

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

BUSINESS

CUSTOMERS

Our customers are distributors who on-sell our products to hospitals and, to a lesser extent, hospitals to which we sell our products directly. During the Track Record Period, we derived substantially all of our revenue from the sale of CHD occluder products and related procedural accessories. Sales to our five largest customers in each year/period of the Track Record Period amounted to RMB32.2 million, RMB56.0 million, RMB47.2 million and RMB18.9 million, respectively, accounting for 27.6%, 37.8%, 21.2% and 15.1% of our total revenue for the same periods, respectively. Sales to our largest customer in each year/period of the Track Record Period amounted to RMB10.2 million, RMB31.0 million, RMB16.0 million and RMB4.4 million, respectively, representing 8.8%, 20.9%, 7.2% and 3.5% of our total revenue for the same periods, respectively. The following table sets forth certain information of our five largest customers during the Track Record Period.

Customer	Transaction amount <i>(RMB in million)</i>	Percentage of total revenue <i>(%)</i>	Credit/settlement terms*	Length of relationship as of the Latest Practicable Date	Principal business and background	Financial standing and scale of business operation
<i>For the year ended December 31, 2019</i>						
Retained Lepu Medical Group	10.2	8.8	Dispatch within one week upon full prepayment by cash, wire transfer etc.	September 2010 – present	Manufacturing, sales and import and export of medical devices; registered in Beijing	The registered capital of Lepu Medical was RMB1.8 billion, its revenue in 2021 was RMB10.7 billion and total assets as of December 31, 2021 was RMB20.7 billion
Customer A	7.9	6.8	Dispatch upon full prepayment by cash, wire transfer etc.	May 2017 – present	Sales of medical devices and related technical services; registered in Shanghai	Registered capital was RMB1.0 million
Customer B	5.1	4.4	Dispatch upon full prepayment by cash, wire transfer etc.	January 2017 – present	Sales and importing and exporting of medical devices; registered in Qingdao, Shandong province	Registered capital was RMB1.0 million
Customer C	4.9	4.2	Dispatch upon full prepayment by cash, wire transfer etc.	August 2012 – present	Sales of medical devices and other goods; registered in Lanzhou, Gansu province	Registered capital was RMB5.0 million
Customer D	4.1	3.4	Dispatch upon full prepayment by cash, wire transfer etc.	May 2018 – present	Sales of medical devices and chemical raw materials and technology transfer services; registered in Shanghai	Registered capital was RMB5.0 million
Total	32.2	27.6				

BUSINESS

Customer	Transaction amount	Percentage of total revenue	Credit/settlement terms*	Length of relationship as of the Latest Practicable Date	Principal business and background	Financial standing and scale of business operation
	<i>(RMB in million)</i>	<i>(%)</i>				
<i>For the year ended December 31, 2020</i>						
Retained Lepu Medical Group	31.0	20.9	Dispatch within one week upon full prepayment by cash, wire transfer etc.	September 2010 – present	Manufacturing, sales and import and export of medical devices; registered in Beijing	The registered capital of Lepu Medical was RMB1.8 billion, its revenue in 2021 was RMB10.7 billion and total assets as of December 31, 2021 was RMB20.7 billion
Customer A	10.8	7.3	Dispatch upon full prepayment by cash, wire transfer etc.	May 2017 – present	Sales of medical devices and related technical services; registered in Shanghai	Registered capital was RMB1.0 million
Customer C	6.8	4.6	Dispatch upon full prepayment by cash, wire transfer etc.	August 2012 – present	Sales of medical devices and other goods; registered in Lanzhou, Gansu province	Registered capital was RMB5.0 million
Customer E	3.8	2.5	60-day credit period upon receipt of certain forms of acceptance for products delivered	February 2019 – present	A teaching hospital providing healthcare services to the public; located in Chengdu, Sichuan province	Registered capital was RMB40.0 million
Customer D	3.6	2.5	Dispatch upon full prepayment by cash, wire transfer etc.	May 2018 – present	Sales of medical devices and chemical raw materials and technology transfer services; registered in Shanghai	Registered capital was RMB5.0 million
Total	<u>56.0</u>	<u>37.8</u>				

BUSINESS

Customer	Transaction amount	Percentage of total revenue	Credit/settlement terms*	Length of relationship as of the Latest Practicable Date	Principal business and background	Financial standing and scale of business operation
	<i>(RMB in million)</i>	<i>(%)</i>				
<i>For the year ended December 31, 2021</i>						
Retained Lepu Medical Group	16.0	7.2	Dispatch within one week upon full prepayment by cash, wire transfer etc.	September 2010 – present	Manufacturing, sales and import and export of medical devices; registered in Beijing	The registered capital of Lepu Medical was RMB1.8 billion, its revenue in 2021 was RMB10.7 billion and total assets as of December 31, 2021 was RMB20.7 billion
Customer A	11.4	5.1	Dispatch upon full prepayment by cash, wire transfer etc.	May 2017 – present	Sales of medical devices and related technical services; registered in Shanghai	Registered capital was RMB1.0 million
Customer F	9.6	4.3	Dispatch upon full prepayment by cash, wire transfer etc.	July 2021 – present	Sales of medical devices and other goods and technology import and export; registered in Shanghai	Registered capital was RMB19.0 million
Customer G	5.3	2.4	Dispatch upon full prepayment by cash, wire transfer etc.	December 2015 – present	Sales of medical devices and related development and technical services; registered in Shanghai	Registered capital was RMB0.5 million
Customer D	5.0	2.2	Dispatch upon full prepayment by cash, wire transfer etc.	May 2018 – present	Sales of medical devices and chemical raw materials and technology transfer services; registered in Shanghai	Registered capital was RMB5.0 million
Total	<u>47.2</u>	<u>21.2</u>				

BUSINESS

Customer	Transaction amount <i>(RMB in million)</i>	Percentage of total revenue <i>(%)</i>	Credit/settlement terms*	Length of relationship as of the Latest Practicable Date	Principal business and background	Financial standing and scale of business operation
<i>For the six months ended June 30, 2022</i>						
Customer H	4.4	3.5	Dispatch upon full prepayment by cash, wire transfer etc.	January 2021 – present	Sales of medical devices and chemicals, and related technology development and technology consulting services; registered in Shanghai	Registered capital was RMB1.0 million
Customer C	3.7	3.0	Dispatch upon full prepayment by cash, wire transfer etc.	August 2012 – present	Sales of medical devices; registered in Lanzhou, Gansu province	Registered capital was RMB5.0 million
Customer I	3.7	3.0	Dispatch upon full prepayment by cash, wire transfer etc.	January 2022 – present	Sales of medical devices and experiment equipment; registered in Urumchi, Xinjiang Uygur autonomous region	Registered capital was RMB5.0 million
Customer J	3.7	2.9	Dispatch upon full prepayment by cash, wire transfer etc.	December 2020 – present	Sales of medical devices and pharmaceutical R&D and medical equipment rental services; registered in Xuzhou, Jiangsu province	Registered capital was RMB10.0 million
Customer K	3.4	2.7	Payments made in US Dollars by money transfer due within seven calendars days after the order was confirmed	June 2021 – present	Distribution of medical devices; registered in Brazil	N/A ⁽¹⁾
Total	<u>18.9</u>	<u>15.1</u>				

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

(1) Customer K is a Brazil-based private company, for which there are no public records of its financial standing and scale of business operation.

BUSINESS

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

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

BUSINESS

After-sales Services

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

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

BUSINESS

RAW MATERIALS AND SUPPLIERS

Suppliers

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

Supplier	Transaction amount (RMB in million)	Percentage of total purchase (%)	Credit/settlement terms ⁽¹⁾	Length of relationship as of the Latest Practicable Date	Principal business and background	Financial standing and scale of business operation ⁽²⁾
<i>For the year ended December 31, 2019</i>						
Supplier A	2.8	26.3	Payment upon product delivery in conformity with agreed specifications	March 2009 – present	Manufacturing, processing and sales of hardware products; registered in Nantong, Jiangsu province	Registered capital was RMB0.1 million
Supplier B	1.5	14.4	50% prepayment and prepayment of the remaining prior to dispatch	March 2013 – present	Manufacturing and sales of medical devices and technology transfer services; registered in Xiangxiang, Hunan province	Registered capital was RMB10.0 million

BUSINESS

Supplier	Transaction amount	Percentage of total purchase	Credit/settlement terms⁽¹⁾	Length of relationship as of the Latest Practicable Date	Principal business and background	Financial standing and scale of business operation⁽²⁾
	<i>(RMB in million)</i>	<i>(%)</i>				
Supplier C	1.4	12.9	Dispatch within six weeks upon full prepayment	February 2012 – present	Sales of catheters and other products for minimally invasive procedures; registered in the U.S.	N/A ⁽³⁾
Retained Lepu Medical Group	1.1	10.7	Payment within one week in RMB upon product delivery	May 2014 – present	Manufacturing, sales and import and export of medical devices; registered in Beijing	The registered capital of Lepu Medical was RMB1.8 billion, its revenue in 2021 was RMB10.7 billion and total assets as of December 31, 2021 was RMB20.7 billion
Supplier D	0.6	6.3	Payment upon product delivery by wire transfer	November 2015 – present	Printing services and sales of office supplies and plastic products; registered in Shanghai	Registered capital was RMB0.5 million
Total	7.4	70.6				

BUSINESS

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

BUSINESS

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

BUSINESS

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

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

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

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

BUSINESS

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

Overlapping of Customers and Suppliers

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

Raw Materials

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

BUSINESS

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

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

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

BUSINESS

Procurement Agreements with Suppliers

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

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

INVENTORY

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

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

BUSINESS

QUALITY CONTROL

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

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

INTELLECTUAL PROPERTY

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

As of the Latest Practicable Date, we owned 232 patents in China, including 27 invention patents, 202 utility models and three industrial designs. Our invention patents include a non-core basic technology in relation to occluder product which we licensed in from a third party. As of the same date, we also had 51 pending patent applications in China, including 48 invention patents and three utility models. To facilitate our strategy to enter overseas markets, we also had 14 pending patent applications in the United States and the European Union. We are the legitimate holder on record of such patents and patent applications, and the research and development of substantially all of them relied on our internal efforts. See “Appendix VII — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights of Our Group” for a list of our material intellectual properties.

BUSINESS

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

<u>Product</u>	<u>Coverage of Patent Protection</u>	<u>Status (Number of Patents/Patent Applications)</u>	<u>Covered Regions</u>
MemoPart [®] ASD Occluder I (Double-rivet)	Occluder	Granted 4 Pending 1	PRC
MemoCarna [®] ASD Occluder III (Oxide Coating)	Occluder	Granted 2 Pending 1	PRC
MemoSorb [®] ASD Occluder IV (Biodegradable)	Occluder	Granted 8 Pending 11	PRC, PCT
MemoSorb [®] VSD Occluder IV (Biodegradable)	Occluder	Granted 10 Pending 11	PRC, PCT
MemoSorb [®] PFO Occluder II (Biodegradable)	Occluder	Granted 10 Pending 13	PRC, PCT
MemoLefort [®] LAA Closure Occluder I	Occluder + Related delivery system	Granted 2	PRC
LAA Closure Occluder II (Biodegradable)	Occluder + Related delivery system	Granted 8 Pending 15	PRC, PCT
Transcatheter aortic valve replacement (“TAVR”) system	Transcatheter aortic valve + Related delivery system	Pending 7	PRC, United States, European Union
Transapical mitral valve clip repair (“TMVr-A”) system	Clip	Granted 3 Pending 3	PRC
Transfemoral mitral valve clip repair (“TMVr-F”) system	Clip	Granted 3 Pending 3	PRC

COMPETITION

We operate in a rapidly changing and highly competitive market. While we believe our strong research and development capabilities provide us with competitive advantages, we face potential competition with major international medical device companies as well as domestic medical device companies which are developing interventional solutions for structural heart diseases. As the interventional medical device market targeting structural heart diseases continues to grow and evolve, we may face increased competition from new market entrants.

BUSINESS

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

For details of our major competitors, see “Industry Overview.”

EMPLOYEES

As of June 30, 2022 and the Latest Practicable Date, we had a total of 230 and 238 full-time employees, respectively. All of our employees are based in China. The following table sets forth a breakdown of our full-time employees by function as of the dates indicated.

Function	As of June 30, 2022		As of the Latest Practicable Date	
	Number	% of Total	Number	% of Total
Management	27	11.7	28	11.8
Research and development	76	33.0	79	33.2
Supply chain and manufacturing	45	19.6	50	21.0
Quality control	18	7.8	18	7.6
Sales and marketing	64	27.8	63	26.5
Total	230	100.0	238	100.0

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

BUSINESS

In compliance with relevant PRC laws and regulations, we enter into employment agreements with our employees to cover matters such as wages, benefits and grounds for termination. We enter into standard confidentiality agreements with all of our full-time employees, which also contain non-compete provisions. Such non-compete provisions prohibit the employees from competing with us, directly or indirectly, during his or her employment. When an employee leaves our Company, we assess whether he or she has access to our confidential information and, if necessary, require the employee to enter into a non-compete agreement for generally three years after the termination of his or her employment.

PROPERTIES

Owned Properties

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

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

BUSINESS

Leased Properties

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

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

INSURANCE

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

BUSINESS

ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE

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

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

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

BUSINESS

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

Our Company has complied with relevant PRC health, safety, social and environmental law and regulations, which are strictly enforced by local environmental protection authorities through regular inspections. While we do not operate in a highly polluting industry, we make every effort to reduce our generation of hazardous waste, non-hazardous waste, and other emissions. As such, we have implemented company-wide health, safety, social and environmental protection policies and standard operating procedures that include workplace management, process safety management, waste treatment and disposal, and emergency planning and response. For example, we utilize metal equipment rather than single-use plastic for laboratory use, and we promote precision in laboratory experiments to reduce producing unwanted hazardous waste and wastewater. Regarding any emissions and discharges which cannot be avoided, our Company has taken necessary measures to ensure compliance with all applicable national, industrial, and local standards, laws, regulations and policies. These include our air pollutants emissions, which comply with all corresponding emission limits under the Integrated Emission Standards of Air Pollutants (DB31/933-2015) after filtering and purifying; our wastewater discharges, which are categorised as level three under the Integrated Wastewater Discharge Standard (DB31/199-2018) and has been deemed to not cause material impact to surrounding water environment; and our noise emission, which was categorized as level three under the Noise Emission Standard for Industrial Enterprises at Boundary (GB12348-2008), which would not cause a material impact on the surroundings.

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

BUSINESS

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

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

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

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

BUSINESS

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

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

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

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

LICENSES, PERMITS AND APPROVALS

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

BUSINESS

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

LEGAL PROCEEDINGS AND COMPLIANCE

Legal Proceedings

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

Non-compliance

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

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

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

BUSINESS

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

Internal Control

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

- Our financial and legal departments examine the agreement terms and review all relevant documents for our business operations. Our operational teams, with the assistant our financial and legal departments, will review the qualifications of our business partners and all the other necessary underlying due diligence materials, before we enter into any agreement or business arrangements.
- Our regulatory affairs department oversees the obtaining of requisite governmental pre-approvals, consents, licenses and permits, to ensure the compliance of our research, development, manufacture and commercialization activities.
- We have maintained anti-corruption policies and code of ethics and business conduct among our employees, especially our direct sales personnel involved in our sales and marketing activities. We have also implemented protocols to ensure the integrity of our research and development as well as registration and approval processes. Further, we have also arranged training on the consequences and prevention of corruptive conducts, and monitor related activities on an on-going basis.
- We have adopted various measures and procedures regarding each aspect of our operations, such as protection of intellectual property, environmental protection and safety. We provide periodic training on these measures and procedures to our employees as part of our employee training program and regularly monitor the implementation of those measures and procedures.

BUSINESS

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

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

- We will not conduct any sales, directly or indirectly, to Iran or any other Comprehensively Sanctioned Country;
- To further enhance our existing internal risk management functions, our legal department is responsible for monitoring our exposure to sanctions risks and our implementation of the related internal control procedures. Our legal department will hold at least two meetings each year to monitor our exposure to sanctions risks;
- We will evaluate the sanctions risks prior to determining whether we should embark on any business opportunities in countries subject to International Sanctions and with Sanctioned Persons. According to our internal control procedures, our legal department needs to review and approve all relevant business transaction documentation from customers or potential customers from countries subject to International Sanctions and with Sanctioned Persons. If any potential sanctions risk or suspicious transaction is identified, we may seek advice from reputable external international legal counsel with necessary expertise and experience in International Sanctions matters;
- Our Directors will continuously monitor the [REDACTED] from the [REDACTED], as well as any other funds raised through the Stock Exchange, to ensure that such funds will not be used to finance or facilitate, directly or indirectly, activities or business with, or for the benefit of, countries subject to International Sanctions or Sanctioned Persons where this would be in breach of International Sanctions;
- Our legal department will periodically review our internal control policies and procedures with respect to sanctions matters. As and when our legal department considers necessary, we will retain external international legal counsel with necessary expertise and experience in sanctions matters for recommendations and advice; and

BUSINESS

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

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

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OVERVIEW

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 Domestic Shares and Unlisted Foreign Shares into H Shares, Lepu Medical and Target Medical will directly hold approximately [REDACTED]% and [REDACTED]% of the equity interests in our Company, respectively, assuming the [REDACTED] is not exercised. Dr. Pu is the Actual Controller of Lepu Medical with approximately [REDACTED] voting interest in Lepu Medical. According to the Listing Rules of the ChiNext Board of the Shenzhen Stock Exchange (《深圳證券交易所創業板股票上市規則》) where Lepu Medical, our Controlling Shareholder, is listed, an “actual controller” refers to an individual or entity that can control a company by way of investment relationship, contracts or other arrangements. As Dr. Pu is able to control Lepu Medical and exert substantial influence over it, we regard Dr. Pu as our Controlling Shareholder. Lepu Medical, Dr. Pu and Target Medical are considered as a group of Controlling Shareholders of our Company.

BACKGROUND OF OUR CONTROLLING SHAREHOLDERS

Lepu Medical (together with its subsidiaries including us) is principally engaged in three business segments, namely (1) research and development, manufacturing and sales of cardiovascular medical devices, (2) manufacture and sales of cardiovascular medicines, and (3) provision of other cardiovascular medical and health management services. The shares of Lepu Medical have been listed on the Shenzhen Stock Exchange (stock code: 300003) since October 30, 2009. For the year ended December 31, 2021 and the six months ended June 30, 2022, Lepu Medical Group recorded revenue of RMB10,660 million and RMB5,334 million, respectively, with total assets of RMB21.717 billion as of June 30, 2022 as reported under the PRC GAAP. The businesses of our Group fall under the research and development, manufacturing and sales of cardiovascular medical devices segment of Lepu Medical Group.

Dr. Pu is the Actual Controller of Lepu Medical. As of the Latest Practicable Date, Dr. Pu held approximately 25.25% of the voting power of Lepu Medical, through (1) a direct shareholding interest of 12.64%, (2) an indirect shareholding of 5.74% through his wholly-owned entities, and (3) an acting-in-concert arrangement with an entity holding 6.87% of Lepu Medical’s equity interests. Dr. Pu is the chairman of the board and chief technology officer of Lepu Medical. Dr. Pu was also the general manager of Lepu Medical since December 2007 and he stepped down from this role in April 2021, with a view to bequeathing his executive management responsibilities in Lepu Medical to the capable management team of Lepu Medical and shifting his focuses onto the overall strategic development and innovative R&D of Lepu Medical. As of the Latest Practicable Date, other than his voting interest in Lepu Medical, Dr. Pu did not hold or was otherwise interested in the share capital of our Company, nor had he been involved in the day-to-day management or operations of our Group. See “—

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Independence from Controlling Shareholders — Management Independence.” Dr. Pu was of the view that our Company has been amply and soundly managed by our board of Directors and senior management and hence did not take on any executive role or directorship in our Company.

Target Medical, a wholly-owned subsidiary of Lepu Medical, is principally engaged in the research, development and sales of intravascular catheters, guide wires and sheaths, injection puncture devices, transfusion devices and tubes, invasive medical sensors, infusion auxiliary devices and respiratory anesthesia or ventilation tracheal intubation products.

[REDACTED]

Pursuant to the Spin-off Circular, the offshore listing of the subsidiaries controlled by the domestic listed companies shall comply with the conditions set out in the Spin-off Circular and obtain approval from the CSRC. Lepu Medical, our Controlling Shareholder, is a company listed in the PRC. The [REDACTED] of our Company constitutes a [REDACTED] from a domestic listed company as defined under the Spin-off Circular and is subject to the approval from the CSRC. The [REDACTED] of our Company was approved by Lepu Medical’s shareholders at an annual general meeting held 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 the [REDACTED].

BUSINESS DELINEATION AND COMPETITION

The Retained Lepu Medical Group’s business is divided into three main segments, namely (i) research and development, manufacturing and sales of cardiovascular medical devices, (ii) manufacture and sales of cardiovascular medicines, and (iii) provision of other cardiovascular medical and health management services. In particular, the Retained Lepu Medical Group’s segment of cardiovascular medical devices is relevant in considering business delineation between the Retained Lepu Medical Group and us. In comparing the targeted diseases of their respective device products, our device products are targeting at structural heart diseases, including congenital heart diseases and valvular heart diseases, whereas the Retained Lepu Medical Group’s device products are mainly targeting at other cardiovascular diseases, such as arrhythmia, coronary heart disease, peripheral vascular disease, etc. Other than mechanical heart valve which also targets valvular heart disease (with detailed product differences illustrated in below chart), there is no overlap of target diseases between our Group and Retained Lepu Medical Group. According to Frost & Sullivan, the target addressable market of the heart valve products carried by the Retained Lepu Medical Group and us can be demonstrated by the number of procedures that deploy the relevant products. The number of procedures for SAVR (representing the target addressable market of the Retained Lepu Medical Group’s mechanical heart valve products and will not utilize interventional heart valve products) in China was 25.6 thousand in 2021 and is expected to reach 30.2 thousand in 2030, while the number of procedures for TAVR, TMVr and TTVI (representing the target addressable market of Company’s interventional heart valve products and will not utilize mechanical heart valve products) in 2021 was 6.6 thousand, 0.2 thousand and 0, respectively,

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

and is expected to reach 109.5 thousand, 32.3 thousand and 200.9 thousand, respectively, by 2030 based on (i) the relatively stable increase in patients with aortic valve diseases, (ii) increased patient acceptance of TAVR due to factors including enhanced market education in recent years, and (iii) relatively stable size of target patients of SAVR which led to a stable increase in the addressable market of SAVR with enhanced patients’ awareness. There were no TTVI procedures conducted in 2021 because there has been no commercialized products in China as of the end of 2021.

Beijing Sida, being part of the Retained Lepu Medical Group, provides mechanical heart valve products. The mechanical heart valve products, which involve open-chest surgical procedures, do not fall within the interventional medical device market which our Group currently operates in. There are major differences in terms of target patients based on clinical recommendations, distinct method of treatment, safety characters, product lifespan, materials used and price range between mechanical heart valve products and interventional heart valve products. Among these differences, clinical recommendations which drive the key decision of patients on the deployment of such products would be made based on the age and condition of the patient in question and with reference to clinical guidelines for valvular diseases, according to Frost & Sullivan. Taking into account the significant differences in the method of treatment, safety characters, product lifespan, materials used for mechanical and interventional heart valves and their interplay with the age factor and specific physical conditions of each patient, F&S is of the view, and our Directors concur that it is highly unlikely to have a clinical recommendation (be it from one physician or different physicians) simultaneously recommending mechanical and interventional heart valves for a patient. After due consideration of the foregoing and having discussed with the Directors and Frost & Sullivan to understand the key basis of their views, the Sole Sponsor confirms that nothing material has come to its attention that would cause it to cast doubt on the view of the Directors and Frost & Sullivan. For further details, see “ – Clear Delineation from Beijing Sida”.

We act as the sole platform under the Lepu Medical Group focusing on the research and development, manufacturing and commercialization of interventional medical devices primarily targeting structural heart diseases, including occluder products and interventional heart valve products (the “Principal Business”). For details of our products, see “Business — Our Products.” None of the members of the Retained Lepu Medical Group is engaged in the Principal Business or otherwise competes or is likely to compete with our Principal Business. We do not share any resource or administrative function with the Retained Lepu Medical Group other than what are involved in the transactions described under the section headed “Connected Transactions.” Notwithstanding the fact that Beijing Sida offers a distinct type of heart valve products (see further details below), the Retained Lepu Medical Group does not have any product offerings and is not otherwise engaged in the research, development or commercialization in the areas of occluder products and heart valve products. Based on the foregoing and the details to be further delineated in “ – Clear delineation from Beijing Sida” below, the Directors are of the view that there is a clear delineation of the business of our Group and that of the Retained Lepu Medical Group.

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Clear Delineation from Beijing Sida

Beijing Sida is a company directly wholly-owned by Lepu Medical. Beijing Sida is engaged in two business segments, being (1) the distribution of coronary stents and other ancillary products for percutaneous coronary intervention operations manufactured by Lepu Medical and (2) to a lesser extent, in terms of revenue contribution, manufacturing and sales of mechanical heart valve products. The businesses of Beijing Sida fall under the cardiovascular medical devices segment of Lepu Medical Group. According to the unaudited management accounts of Beijing Sida, revenue derived from Beijing Sida’s mechanical heart valve products segment was less than RMB20 million for each year ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022.

As further elaborated in “Industry Overview”, the interventional medical device market targeting structural heart diseases consists primarily of three major fields of application, including (1) CHD, (2) cardioembolic stroke and (3) valvular diseases, according to the F&S Report. Our current platform enables us to have a product portfolio covering all three major fields of application in the interventional medical device market targeting structural heart diseases. The mechanical heart valve products, which involve open-chest surgical procedures, do not fall within the interventional medical device market which our Group currently operates in. Our Directors consider the mechanical heart valve business of Beijing Sida is not in line with our platform’s focus on interventional medical devices, the core advantage of which is to minimize invasion by avoiding open-chest surgical procedures, according to the F&S Report.

For a patient who is in need of a heart valve replacement procedure, the physician normally makes a clinical recommendation towards either mechanical heart valve treatment or interventional heart valve treatment based on the age and condition of the patient in question and with reference to clinical guidelines for valvular diseases. Taking into account the significant differences in the method of treatment, safety characters, product lifespan, materials used for mechanical and interventional heart valves and their interplay with the age factor and specific physical conditions of each patient, F&S is of the view, and our Directors concur that it is highly unlikely to have a clinical recommendation (be it from one physician or different physicians) simultaneously recommending mechanical and interventional heart valves for a patient. After due consideration of the foregoing and having discussed with the Directors and Frost & Sullivan to understand the key basis of their views, the Sole Sponsor confirms that nothing material has come to its attention that would cause it to cast doubt on the view of the Directors and Frost & Sullivan. In addition, according to Frost & Sullivan, it is a common practice for physicians to refer to the “ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease” jointly published by the American College of Cardiology and the American Heart Association as well as other publications on similar topics by peer-reviewed journals, which vindicate that heart valve replacement operations are high-risk procedures, and patients who require heart valve replacement operations should be thoroughly assessed for age, symptoms, severity of aortic stenosis and comorbidities by the physicians. American College of Cardiology is the world’s leading professional society for cardiology, an advocate for the development of guidelines for the treatment of all heart-related diseases worldwide. American Heart Association is one of the most important societies in the field of cardiology, whose

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official journal is recognized by the industry to be providing guidelines and expert consensus on cardiovascular disease and stroke. As such, the choice of the type of heart valve product should be an informed and objective decision driven by the physicians’ assessment and recommendation taking into account the patient’s condition and the trade-off between factors such as durability, bleeding and thromboembolism, instead of driven by the patient’s free will in choosing his/her desired type of heart valve product.

The following table sets forth the major differences (including target patients with clear delineation based on clinical recommendations, distinct method of treatment, safety characters, product lifespan, materials used and price range) between mechanical heart valve products and interventional heart valve products as backed by the F&S Report.

	<u>Interventional heart valve products</u>	<u>Mechanical heart valve products</u>
Target patients	<ul style="list-style-type: none">• Clinically recommended for patients aged ≥ 70 years of age in general.• Clinically recommended for patients with any of the following conditions (including patients aged <70 years of age) (collectively, the “Specific Conditions”):<ul style="list-style-type: none">o patients who are susceptible to risks of open-chest surgical procedures;o patients who cannot be anticoagulated in the presence of bleeding factors; ando women during pregnancy, as interventional heart valve products avoid the adverse effect of anticoagulants on the fetus.	<ul style="list-style-type: none">• Clinically recommended for patients aged <70 years of age in general, <i>but</i> excluding patients with any of the Specific Conditions. In particular:<ul style="list-style-type: none">o it is particularly clinically recommended for younger patients aged <50 years of age; ando for patients aged between 50 and 70 years of age, clinical recommendations are prioritized towards mechanical heart valves, unless for patients with severe calcification conditions, short expected survival time, severe liver, renal or pulmonary diseases, mediastinal radiation.

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	<u>Interventional heart valve products</u>	<u>Mechanical heart valve products</u>
Method of treatment	<ul style="list-style-type: none"> Minimally invasive surgeries. 	<ul style="list-style-type: none"> Open-chest surgeries through an incision to the patient’s chest (sternotomy) or ribs (thoracotomy).
Corresponding department at hospitals that deploy the product	<ul style="list-style-type: none"> Mostly deployed by the cardiology departments in hospitals. 	<ul style="list-style-type: none"> Mostly deployed by the cardiac surgery departments in hospitals.
Safety characteristics	<ul style="list-style-type: none"> Minimally invasive surgeries are typically less invasive and require shorter hospital stay. Good hemodynamic function and low incidence of thromboembolism. Typically requiring only short-term anticoagulation and avoidance of fatal bleeding due to anticoagulation. Fewer surgical and post-surgical complications. 	<ul style="list-style-type: none"> Open-chest surgeries are typically highly traumatic and require longer recovery time. Life-long anticoagulation therapy required. Regular monitoring of prothrombin time required. Long-term anticoagulation therapy may result in risks of serious bleeding.
Product lifespan and incidence of reoperation	<ul style="list-style-type: none"> A lifespan typically ranging from 15 to 20 years, therefore relatively higher incidence of reoperation in patients as compared to mechanical heart valve products. 	<ul style="list-style-type: none"> Longer lifespan, therefore lower incidence of reoperation in patients as compared to interventional heart valve products.
Materials used	<ul style="list-style-type: none"> Bovine or porcine pericardium or macromolecular materials. 	<ul style="list-style-type: none"> Pyrolytic carbon and titanium alloy.
Medical cost and medical insurance coverage	<ul style="list-style-type: none"> Approximately RMB175,000. Not covered by medical insurance coverage. 	<ul style="list-style-type: none"> Approximately RMB50,000-60,000. Approximately 60-80% covered by medical insurance coverage.

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In addition to the major differences between mechanical heart valve products and interventional heart valve products as elaborated above, the clear delineation between our Principal Business and the business of Beijing Sida is also demonstrated by the following:

- (i) ***Differentiated sales channels.*** We maintain sales channels and distributor base differentiated from those of Beijing Sida. Beijing Sida’s mechanical heart valves involve open-chest surgical procedures and are therefore mostly deployed by the cardiac surgery departments in hospitals; while our commercialized occluder products are interventional medical devices and mostly deployed by the cardiology departments in hospitals. According to Frost & Sullivan, the sales channels of medical devices are generally department-specific as different hospital departments are generally covered by distinct distributors. During the Track Record Period, only six of our distributors also distributed products for Beijing Sida, accounting for less than 2% of our total number of distributors as of June 30, 2022.
- (ii) ***Distinct supply chains.*** We maintain a supplier base distinct from that of Beijing Sida. As elaborated in the table above, there are major differences in the raw materials used for interventional heart valve products and mechanical heart valve products. Additionally, the raw materials used for our occluder products as disclosed in “Business — Our Products — Occluder Products” and “Business — Raw Materials and Suppliers — Raw Materials” are also clearly differentiated from those used for Beijing Sida’s mechanical heart valve products. During the Track Record Period, other than Lepu Medical (from which Beijing Sida procured coronary stents and ancillary products for percutaneous coronary intervention operations for distribution as disclosed above and we procured certain non-core components and parts as elaborated in “Business — Raw Materials and Suppliers — Suppliers”), there had been only one overlapping supplier for us and Beijing Sida for the procurement of raw materials for sutures, which are non-core materials and commonly used for grafted medical devices.
- (iii) ***Independent R&D and manufacturing.*** Due to major differences in the materials used for Beijing Sida’s mechanical heart valve products and our occluder and interventional heart valve products as elaborated above, the key technologies applied and manufacturing facilities used by Beijing Sida and us are also clearly differentiated. The key technology applied by Beijing Sida for its mechanical heart valve products is pyrolytic carbon deposition, which is evidently distinct from the technologies applied to our products as illustrated in “Business — Our Products.” As of the Latest Practicable Date, there had been no overlap between Beijing Sida and us in terms of R&D personnel, manufacturing facilities and manufacturing personnel.

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- (iv) *Separate management teams.* As of the Latest Practicable Date, none of our Directors and members of our senior management team held any position in Beijing Sida, and vice versa. Please also see “Independence from Controlling Shareholders — Management Independence” for more disclosures with respect to our management independence from the Retained Lepu Medical Group (including Beijing Sida).

Furthermore, our planned development and expansion as illustrated in “Business — Growth Strategies” are in line with our continuous focus on the interventional medical device market targeting structural heart diseases, which consists primarily of three major fields of application, *i.e.*, CHD, cardioembolic stroke, and valvular diseases, according to the F&S Report. The mechanical heart valve business of Beijing Sida, the products of which involve open-chest surgical procedures, does not fall within the purview of our planned development and expansion in the interventional medical device market targeting structural heart diseases. Our Directors are of the view that the inclusion of the mechanical heart valve business of Beijing Sida would disrupt and deflect the clear market positioning of our Group.

Based on the foregoing, our Directors are of the view that the business of Beijing Sida is clearly delineated from our Principal Business and thus there is no competition between the business of our Group and that of the Retained Lepu Medical Group. Our Controlling Shareholders further confirmed that, as of the Latest Practicable Date, save as disclosed in this section, 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 have entered into the Non-competition Agreement, pursuant to which it/he undertook that it/he would not, and would procure its/his close associates (other than members of our Group) not to, directly or indirectly, engage in any business competing or is likely to compete with our Principal Business. For details, see “— Non-competition Agreement.”

INDEPENDENCE FROM CONTROLLING SHAREHOLDERS

Having considered the following factors, our Directors are satisfied that we are able to carry on our business independently of our Controlling Shareholders and their respective close associates after the [REDACTED].

Management Independence

Upon the [REDACTED], our Board will consist of seven Directors comprising two executive Directors, two non-executive Directors and three independent non-executive Directors. For more information, see “Directors, Supervisors and Senior Management.”

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Set out below is a table summarizing the positions held by our Directors and members of our senior management in the Retained Lepu Medical Group, if any. See “Directors, Supervisors and Senior Management.”

<u>Name</u>	<u>Position in our Company</u>	<u>Position in the Retained Lepu Medical Group upon [REDACTED]</u>
Ms. ZHANG Yuxin (張昱昕)	Executive Director, deputy general manager and chief technology officer	A research and development project manager in Lepu Medical overseeing the research and development of the Entrusted Products carried out by Lepu Medical as a designated representative of our Group
Mr. ZHENG Guorui (鄭國銳)	Non-executive Director	Deputy general manager of Lepu Medical which is responsible for the overall management (including human resource and finance related matters excluding price, sales expense ratio and appointment of sales directors) of coronary products sales center and three divisions of medical sales center

Save as disclosed above, none of our Directors or members of our senior management holds any directorship or senior management positions in the Retained Lepu Medical Group. Furthermore, Dr. Pu, one of our Controlling Shareholders, had not been involved in the day-to-day management or operations of our Group.

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We believe that our Directors and senior management are able to perform their roles in the Company independently and that the Company is capable of managing its business independently from the Retained Lepu Medical Group for the following reasons:

- (i) the position held by Ms. ZHANG Yuxin in Lepu Medical is solely for the purpose of overseeing the research and development of the Entrusted Products as a designated representative of our Group, which does not have any negative impact on our management independence for the following reasons:
 - (a) taking into account the infeasibility for us to directly take over the Relevant Activities for the Entrusted Products due to the Entrusted Products Regulatory Restrictions, we entered into the Entrustment Arrangements with Lepu Medical as further elaborated in “History, Reorganization and Corporate Structure — Our Corporate Development — Business Injection,” “Business — Our Products — Heart Valve Product Candidates” and “Connected Transactions — Non-exempt Continuing Connected Transactions — 2. Entrusted Products Related Framework Agreement”; and
 - (b) Ms. ZHANG Yuxin’s position in Lepu Medical is in line with the abovementioned arrangements with a view to implementing our Group’s control and supervision over the research and development process of the Entrusted Products;
- (ii) Mr. ZHENG Guorui, the other Director who holds positions in the Retained Lepu Medical Group is our non-executive Director and does not participate in the day-to-day management and operations of our business;
- (iii) as disclosed in “Directors, Supervisors and Senior Management — Board of Directors — Executive Directors,” our executive Directors, Ms. CHEN Juan and Ms. ZHANG Yuxin, had historically held dual roles (save for the research and development manager position in Lepu Medical held by Ms. ZHANG Yuxin relating to the Entrusted Products as described in paragraph (i) above) in the Retained Lepu Medical Group and our Group, as they were designated by Lepu Medical to spearhead the operation of Shanghai Shape Memory Alloy as well as the establishment of our Company. Both of Ms. CHEN Juan and Ms. ZHANG Yuxin have been closely involved in the operations and strategic planning of the Group’s business since the inception of the operations and business of Shanghai Shape Memory Alloy; and
- (iv) as of the Latest Practicable Date, save for certain equity interest of the Retained Lepu Medical Group held by certain of our Directors, Supervisors and members of our senior management through employee incentive platforms of the Lepu Medical Group (with none of them holding more than 0.5% equity interest in the relevant member of the Retained Lepu Medical Group) and the publicly tradable shares of Lepu Medical that may be purchased by certain of our Directors, Supervisors and

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members of our senior management on the secondary market from time to time according to relevant trading rules (with none of them holding more than 0.01% equity interest in Lepu Medical), none of our Directors, Supervisors or members of our senior management team holds any other equity interest in the Retained Lepu Medical Group.

Notwithstanding the two overlapping Directors, our Directors, including the independent non-executive Directors, are of the view that there are sufficient corporate governance measures in place to mitigate the potential conflicts of interests, including:

- (i) the decision-making mechanism of the Board as set out in our Articles of Association includes provisions that our Directors who hold positions with the Retained Lepu Medical Group are considered to be in conflict and are thus required to abstain from voting in certain circumstances, such as transactions with the Retained Lepu Medical Group. In addition, our independent non-executive Directors are required to review and approve such transactions;
- (ii) all of our Directors are aware of their respective fiduciary duties and the dual roles assumed by the two overlapping Directors in most cases will not affect the requisite degree of impartiality of our Directors in discharging their fiduciary duties owed to our Company; and
- (iii) we have appointed three independent non-executive Directors to provide sufficient independence to our Board and as the decisions of our Board will only be made after due consideration of independent and impartial opinions, thereby promoting the interests of the Company and our shareholders as a whole.

Our Directors are of the view that all of our Directors and senior management, including the two overlapping Directors, are able to devote sufficient time and resources among the Group and the Retained Group for the following reasons:

- (i) Ms. Zhang Yuxin (張昱昕) who remained as a research and development project manager in Lepu Medical was serving in such position solely to oversee the research and development of the Entrusted Products carried out by Lepu Medical as a designated representative of, and solely for the benefit of, our Group; and
- (ii) Mr. Zheng Guorui (鄭國銳) is a non-executive Director who does not participate in the daily operations and management of our Group.

Based on the above, our Directors believe that our Board together with our senior management team are able to perform their managerial roles in our Group independent of our Controlling Shareholders and their respective close associates.

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Operational Independence

Our Group is operationally independent of our Controlling Shareholders. We have established our own organizational structure, and each department is assigned to specific areas of responsibilities. Our Group holds or enjoys the benefits of all relevant licenses and intellectual properties necessary to carry on our business. We have our own facilities, equipment and employees to operate our business independent from our Controlling Shareholders. We also have independent access to our customers and an independent management team to operate our business.

During the Track Record Period, our Company conducted certain transactions with our Controlling Shareholders and their respective close associates which are expected to continue after the [REDACTED] and will constitute continuing connected transactions of our Company under the Listing Rules. See “Connected Transactions” for more details. Such transactions are entered into in the ordinary and usual course of business of our Company and our Directors confirm that the terms of such transactions are determined at arm’s length negotiations and are no less favourable to our Company than terms offered by independent third parties. Our Directors believe that the continuing connected transactions between our Company and our Controlling Shareholders and their close associates do not indicate any undue reliance by our Company on our Controlling Shareholders and are beneficial to our Company and our Shareholders as a whole.

Based on the above, our Directors are of the view that we are able to operate independently of our Controlling Shareholders and their respective close associates.

Financial Independence

We have a financial department which is independent of our Controlling Shareholders and such financial department is responsible for the Group’s finance, accounting, reporting, credit and internal control. We can make financial decisions independently without interference from our Controlling Shareholders and their associates. We maintain bank accounts with banks independently and do not share any bank accounts with our Controlling Shareholders and their associates. We believe that we are capable of obtaining financing from third parties without relying on any guarantee or security provided by our Controlling Shareholders or their associates.

All loans, advances and balances due to and from our Controlling Shareholders and their close associates will be fully settled upon [REDACTED].

Based on the above, our Directors are of the view that we are able to maintain financial independence from our Controlling Shareholders and their respective close associates.

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NON-COMPETITION AGREEMENT

Lepu Medical and Dr. Pu (collectively, the “Covenantors”) have entered into the Non-competition Agreement with our Company on January 27, 2022 in favor of us, which is effective from the [REDACTED] until the occurrence of one of the following events, whichever is earlier, (the “Relevant Period”):

- (i) when the Covenantors and their close associates, individually or taken as a whole, cease to be our controlling shareholders (as defined under the Listing Rules from time to time); or
- (ii) the date on which our H Shares cease to be [REDACTED] on the Stock Exchange.

Non-competition

Pursuant to the Non-competition Agreement, each of the Covenantors made irrevocable confirmations and/or covenants that, among other things;

- (i) as of the date of the Non-competition Agreement, each of the Covenantors or any of their respective close associates (other than members of our Group) has not engaged in or participated in any business which, directly or indirectly, competes or is likely to compete with our Principal Business (the “Restricted Business”), and has not held any direct or indirect interest in any company or enterprise engaged in the Restricted Business;
- (ii) each of the Covenantors will not and will procure its close associates (other than members of our Group) not to, at any time during the Relevant Period, (a) solely or jointly with a third party (be it a natural person, corporation, partnership or any organization), invest in, develop, engage in, participate in or acquire interest in any Restricted Business directly or indirectly in any manner (including but not limited to any joint venture, association, partnership, equity participation or acting as agent, principal, trustee, employee or any other capacity) domestically or abroad, or (b) otherwise hold any interest or rights in any Restricted Business; and
- (iii) each of the Covenantors will not, at any time during the Relevant Period, (a) take advantage of its position as the Controlling Shareholder of our Company to participate in or be engaged in any activities which may be detrimental to the interests of our Group, or (b) induce or procure any of our customers, suppliers or key business partners to terminate its relationship with us.

The above confirmations and/or covenants are not applicable to the following circumstances:

- (i) the engagement by Lepu Medical in the Relevant Activities of the Entrusted Products;

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- (ii) engaging in the Restricted Business purely through direct or indirect equity interest in members of our Group;
- (iii) the interest held by the Covenantors and/or their close associates (other than members of our Group) pursuant to the paragraph headed “— Options for New Business Opportunities” below where we decide not to proceed with the New Business Opportunities (as defined below); or
- (iv) the interest held by the Covenantors and/or their close associates in any entities other than members of our Group, provided that (a) the aggregate number of shares or equity interest held by the Covenantors and/or their close associates (other than members of our Group) is less than 10% of any class of the issued shares or the entire equity interest of any such entity, and (b) none of the Covenantors and/or their close associates (other than members of our Group) owns any right to appoint a majority of the directors of the board of any such company nor participates in the management or daily operations of any such company.

Options for New Business Opportunities

Pursuant to the Non-competition Agreement, the Covenantors undertake that, at any time during the Relevant Period, if any of the Covenantors or their respective close associates (other than members of our Group) becomes aware of any business, investment or other opportunities in connection with any Restricted Business (the “New Business Opportunities”), the Covenantors shall, and shall procure their respective close associates (other than members of our Group) to, refer or recommend the New Business Opportunities to our Group by;

- (i) providing us with a written notice (the “Offer Notice”), which shall include all reasonable and necessary information (including but not limited to the nature of the New Business Opportunities and details in connection with the investment or acquisition costs) enabling us to consider (a) whether such New Business Opportunities compete with our Principal Business, and (b) whether acquiring interest in such New Business Opportunities is in the interest of our Group; and
- (ii) assisting us in acquiring such New Business Opportunities on terms and conditions that are no less favorable than those offered to the Covenantors or their close associates (other than members of our Group) or other terms acceptable to us.

We shall respond to the Covenantors or their close associates (other than members of our Group) in writing within 20 business days upon receipt of the Offer Notice. An independent committee (the “Independent Committee”) comprising our independent non-executive Directors (excluding any independent non-executive Directors with any conflict of interests) will decide on whether we shall proceed with such New Business Opportunities. If we decide not to proceed with such New Business Opportunities or otherwise fail to provide our written

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response within 20 business days upon receipt of the Offer Notice, the Covenantors or their close associates (other than members of our Group) shall be entitled to proceed with such New Business Opportunities on terms and conditions that are no more favorable than those provided to us in the Offer Notice.

Should there be any material changes in the terms and conditions of New Business Opportunities that have been referred or recommended to us previously, the Covenantors or their close associates (other than members of our Group) shall follow the same procedures as set out above in providing us the Offer Notice reflecting the revised terms and conditions and the assistance in acquiring such revised New Business Opportunities.

Further Undertaking from the Covenantors

The Covenantors further undertake that:

- (i) upon request from our independent non-executive Directors, the Covenantors shall provide and procure their close associates to provide all necessary information to our independent non-executive Directors enabling them to review the compliance with and implementation of the Non-competition Agreement by the Covenantors and their close associates (other than members of our Group);
- (ii) we can disclose the review results by our independent non-executive Directors regarding the compliance with and implementation of the Non-competition Agreement by the Covenantors and their close associates (other than members of our Group) in our annual reports or other announcements in compliance with the requirements of the Listing Rules; and
- (iii) the Covenantors shall provide an annual confirmation regarding the compliance by the Covenantors and their close associates (other than members of our Group) with their undertakings in the Non-competition Agreement for disclosure in our annual reports or other announcements in compliance with the requirements of the Listing Rules.

We will adopt the following measures to ensure that the undertakings in the Non-competition Agreement are observed:

- (i) our independent non-executive Directors will review the compliance by the Covenantors and their close associates of their undertakings under the Non-competition Agreement; and
- (ii) our Company will disclose decisions on matters reviewed by the independent non-executive Directors relating to the compliance and enforcement of our Controlling Shareholders' undertakings in our annual reports or by way of announcement to the public in compliance with the requirements of the Listing Rules.

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CORPORATE GOVERNANCE MEASURES

In order to further safeguard the interests of our minority Shareholders, we will adopt the following corporate governance measures to manage potential conflicts of interest:

- (i) as part of our preparation for the [REDACTED], we have adopted our Articles of Association in compliance with the Listing Rules. In particular, our Articles of Association provided that, unless otherwise stipulated;
 - (a) a Director shall not vote on any resolution approving any contract or arrangement or any other proposal in which such Director or any of his/her associates have a material interest nor shall such Director be counted in the quorum present at the meeting; and
 - (b) in the event of any potential conflict of interests at the Shareholders' level, our Controlling Shareholders shall abstain from voting at the Shareholders' meeting of our Company with respect to the relevant resolutions;
- (ii) we are committed to ensure that our Board shall have a sufficiently balanced composition of executive Directors, non-executive Director and independent non-executive Directors that can facilitate the exercise of independent judgment. We believe that the independent non-executive Directors have the necessary expertise to form and exercise independent judgment in the event of any conflict of interest between our Company and our Controlling Shareholders. Further, the independent non-executive Directors will be able to seek independent professional advice from external parties in appropriate circumstances at our Company's cost in respect of matters relating to the Non-competition Agreement;
- (iii) we have appointed Halcyon Capital Limited as our compliance advisor, which will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules, including but not limited to various requirements relating to Directors' duties and corporate governance; and
- (iv) as required by the Listing Rules, our independent non-executive Directors shall review all connected transactions annually and confirm in our annual report that such transactions have been entered into in our ordinary and usual course of business, are either on normal commercial terms or on terms no less favorable to us than those available to or from independent third parties and on terms that are fair and reasonable and in the interest of our Shareholders as a whole.

CONNECTED TRANSACTIONS

Upon [REDACTED], transactions entered into between us and our connected persons will constitute connected transactions or continuing connected transactions under Chapter 14A of the Listing Rules.

OUR CONNECTED PERSONS

Lepu Medical is one of our substantial Shareholders. Accordingly, Lepu Medical and its subsidiaries (other than our Group) will become our connected persons for the purposes of connected transactions under Chapter 14A of the Listing Rules upon the [REDACTED].

SUMMARY OF OUR CONTINUING CONNECTED TRANSACTIONS

Fully Exempt Continuing Connected Transactions

Transactions	Applicable Listing Rules	Waivers sought	Historical amounts (RMB)	Proposed annual caps (RMB)
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1. Purchase of Parts Framework Agreement (expense-based)

The Group purchasing certain parts from the Retained Lepu Medical Group for production of our products	14A.34, 14A.52, N/A		2019: 0.8 million	2022: 2.0 million
	14A.53 and		2020: 1.1 million	2023: 1.6 million
	14A.76		2021: 2.3 million	2024: 1.3 million
			Six months ended	
			June 30, 2022:	0.6 million

2. Lease Agreement with Lepu (Shanghai) (revenue-based)

Shanghai Shape Memory Alloy leasing certain property to Lepu Medical Technology (Shanghai) Co., Ltd. (樂普(上海)醫療器械有限公司) (“Lepu (Shanghai)”)	14A.34, 14A.52, N/A		2019: 0.6 million	2022: 1.2 million
	14A.53 and		2020: 0.5 million	2023: 1.2 million
	14A.76		2021: 0.5 million	2024: 1.2 million
			Six months ended	
			June 30, 2022:	0.2 million

CONNECTED TRANSACTIONS

Partially-Exempt Continuing Connected Transaction

Transaction	Applicable		Historical amounts (RMB)	Proposed annual caps (RMB)
	Listing Rules	Waivers sought		
<i>1. Clinical Trial Service Framework Agreement (expense-based)</i>				
The Retained Lepu Medical Group providing the Group with clinical trail services	14A.34, 14A.35 and 14A.76	Requirements as to announcement under Chapter 14A of the Listing Rules	2019: 0.016 million 2020: nil 2021: 1.3 million Six months ended June 30, 2022: 0.7 million	2022: 9.0 million 2023: 9.5 million 2024: 9.5 million

Non-exempt Continuing Connected Transactions

Transactions	Applicable		Historical amounts (RMB)	Proposed annual caps (RMB)
	Listing Rules	Waivers sought		
<i>1. Sale of Products Framework Agreement (revenue-based)</i>				
The Group selling occluder and occluder related products system to the Retained Lepu Medical Group for distribution	14A.34, 14A.35, 14A.36, 14A.49, 14A.52 to 14A.59 and 14A.71	Requirements as to announcement, circular, shareholders’ approval, terms not exceeding three years and annual caps under Chapter 14A of the Listing Rules	2019: 10.2 million 2020: 31.0 million 2021: 15.7 million Six months ended June 30, 2022: 2.0 million	2022: 14.3 million 2023: 17.9 million 2024: 20.4 million

2. Entrusted Products Related Framework Agreement (expense-based)

Lepu Medical conducting research, development and registration of the Entrusted Products under the directions of the Group	14A.34, 14A.35, 14A.36, 14A.49, 14A.52 to 14A.59 and 14A.71	Requirements as to announcement, circular, shareholders’ approval, terms not exceeding three years and annual caps under Chapter 14A of the Listing Rules	2019: Nil 2020: Nil 2021: 28.7 million Six months ended June 30, 2022: 16.1 million	2022: 28.0 million 2023: 18.0 million 2024: 11.0 million
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CONNECTED TRANSACTIONS

FULLY EXEMPT CONTINUING CONNECTED TRANSACTIONS

1. Purchase of Parts Framework Agreement

Description of the agreement

On October 18, 2022, our Company entered into a purchase of parts framework agreement with Lepu Medical (the “Purchase of Parts Framework Agreement”), pursuant to which our Group will purchase customized parts for producing (1) congenital heart disease occluders and congenital heart disease occluder delivery systems, (2) snares, (3) LAA occluder systems, and (4) biodegradable delivery systems. We may enter into individual agreements separately with the Retained Lepu Medical Group with respect to different transactions which provide for specific terms and conditions including products, price, payment and other terms in accordance with the Purchase of Parts Framework Agreement and applicable laws. The term of the Purchase of Parts Framework Agreement shall commence from the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

Reasons for and benefits of entering into the transaction

We have procurement needs for essential parts for producing (1) congenital heart disease occluders and congenital heart disease occluder delivery systems, (2) snares, (3) LAA occluder systems, and (4) biodegradable delivery systems. Historically we have been procuring from the Retained Lepu Medical Group such parts with customized processing. The Retained Lepu Medical Group is equipped with facilities that are able to meet our needs and is most familiar with our demand for the parts we procure from it. While our Directors believe that there are alternative third party suppliers of such parts at a comparable price in the market considering the entry barrier (being the intellectual properties and techniques involved with the parts procured from the Retained Lepu Medical Group) is not high, switching to other suppliers will cause uncertainty in the orderly delivery and quality stableness in the parts we procure, and therefore possible unnecessary disruption to our business, and extra costs during the transitional period given such parts need to be customized to our specifications.

Pricing policies

The amounts to be paid by our Group to the Retained Lepu Medical Group under the Purchase of Parts Framework Agreement will be determined on normal commercial terms after arm’s length negotiations between the relevant parties, taking into consideration a number of factors including (1) the cost incurred by the Retained Lepu Medical Group, including raw materials, labor and packaging; and (2) a profit rate of 10% determined with reference to Provisions on Certain Specific Issues of Value-added Tax (《增值税若干具體問題的規定》) issued by the State Administration of Taxation in December 1993 which suggested 10% as a presumed profit rate for goods that are sold at a significantly low price or with no definitive selling price. The price to be determined shall be fair and reasonable, and in the best interests

CONNECTED TRANSACTIONS

of the shareholders of our Group and the Retained Lepu Medical Group. The Directors are of the view that such reference is reasonable because there is normally no definitive selling price for the parts with customize processing that the Group purchased from the Retained Lepu Medical Group.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amounts were approximately RMB0.8 million, RMB1.1 million, RMB2.3 million and RMB0.6 million, respectively.

Annual caps

The proposed annual caps in respect of the transactions contemplated under the Purchase of Parts Framework Agreement are approximately RMB2.0 million, RMB1.6 million and RMB1.3 million for the three years ending December 31, 2022, 2023 and 2024, respectively. We expect the annual cap to decrease for the relevant period because we expect to produce an increasing number of such parts on our own that we currently procure from the Retained Lepu Medical Group.

Basis of caps

The above proposed annual caps are determined with reference to the following factors: (1) the historical transaction amounts paid by our Group to the Retained Lepu Medical Group; (2) expected number of parts needed for production of our the occluders; (3) the expected number of parts needed for our clinical trials on new generation of delivery systems and (4) unit price of the parts agreed between the Retained Lepu Medical Group and us in the existing agreements.

Implications under the Listing Rules

Since the highest applicable percentage ratio in respect of the Purchase of Parts Framework Agreement will be less than 5% and the total consideration will be less than HK\$3,000,000, each on an annual basis, the Purchase of Parts Framework Agreement will fall within the de minimis threshold under Rule 14A.76(1)(c) of the Listing Rules and will be fully exempt from reporting, annual review, announcement, circular and independent shareholders' approval requirements under Chapter 14A of the Listing Rules pursuant to Rule 14A.76(1) of the Listing Rules.

CONNECTED TRANSACTIONS

2. Lease Agreement with Lepu Shanghai

Description of the agreement

On October 18, 2022, Shanghai Shape Memory Alloy entered into a lease agreement with Lepu Shanghai (the “Lease Agreement with Lepu Shanghai”), pursuant to which Shanghai Shape Memory Alloy agreed to lease to Lepu Shanghai certain premises located at 258 Xin Zhuan Road, Songjiang District, Shanghai, with a total gross floor area of 950.05 square meters. Such premises will be used by Lepu Shanghai for administrative, testing and research and development purposes. The term of the Lease Agreement with Lepu Shanghai shall commence on the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

Reasons for and benefits of entering into the transaction

The Group believes that it will benefit from the transaction due to the following reasons: (1) the Group will earn rental fee incomes which are at the prevailing market rates; and (2) all the utility fees and property management fees relating to the above mentioned property will be borne by Lepu Shanghai.

The Lepu Medical Group has been leasing and using the above-mentioned property for its business operation prior to and throughout the Track Record period. Any relocation may cause unnecessary disruption to Lepu Shanghai’s business.

Pricing policies

The rent is calculated at a rate of RMB1.6 per square meter per day. The amounts to be paid by Lepu Shanghai to our Group under the Lease Agreement with Lepu Shanghai was determined on normal commercial terms after arm’s length negotiations between the relevant parties with reference to the market price of properties of comparable size and use in the vicinity.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amounts were approximately RMB0.6 million, RMB0.5 million, RMB0.5 million and RMB0.2 million, respectively.

Annual caps

The proposed annual caps in respect of the transactions contemplated under the Lease Agreement with Lepu Shanghai are RMB1.2 million, RMB1.2 million and RMB1.2 million for the three years ending December 31, 2022, 2023 and 2024, respectively.

CONNECTED TRANSACTIONS

Basis of caps

The above proposed annual caps are determined with reference to (1) the floor area and agreed and unit price of the relevant premises; (2) the rentals of the existing property leases according to the existing lease agreements; (3) the estimated rentals of the property leases to be entered into for the expanded floor area; and (4) estimated utility bill amount relating to the leased property.

We have engaged an independent property valuer who has reviewed the terms of the Lease Agreement with Lepu Shanghai with reference to comparable market rental transactions for their assessment of the market rent of a property. The independent property valuer is of the view that (1) the Lease Agreement with Lepu Shanghai is entered into on arm’s length basis and on normal commercial terms, (2) the considerations in formulating the proposed annual caps are fair and reasonable, reflecting the current prevailing market rates for the similar premises in the vicinity of the relevant property in the PRC, and (3) the terms of the Lease Agreement with Lepu Shanghai are no less favorable to our Group than what we can get from parties who are independent third parties.

Implications under the Listing Rules

Since the highest applicable percentage ratio in respect of the Lease Agreement with Lepu Shanghai will be less than 5% and the total consideration will be less than HK\$3,000,000, each on an annual basis, the Lease Agreement with Lepu Shanghai will fall within the *de minimis* threshold under Rule 14A.76(1)(c) of the Listing Rules and will be fully exempt from reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules pursuant to Rule 14A.76(1) of the Listing Rules.

PARTIALLY-EXEMPT CONTINUING CONNECTED TRANSACTION

We set out below details of the partially-exempt continuing connected transaction (the “Partially-exempt Continuing Connected Transaction”) for our Group, which are subject to the announcement, reporting and annual review requirements under Chapter 14A of the Listing Rules but will be exempted from the circular and independent shareholders’ approval requirement under Chapter 14A of the Listing Rules.

1. Clinical Trial Service Framework Agreement

Description of the agreement

On October 18, 2022, our Company entered into a clinical trial service framework agreement with Lepu Medical (the “Clinical Trial Service Framework Agreement”), pursuant to which the Retained Lepu Medical Group agreed to provide clinical trial services on our products that enter into clinical trial stage from time to time for our Group. We may enter into individual agreements separately with the Retained Lepu Medical Group with respect to

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different transactions which provide for specific terms and conditions including products, price, payment and other terms in accordance with the Clinical Trial Service Framework Agreement and applicable laws. The term of the Clinical Trial Service Framework Agreement shall commence from the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

Reasons and benefits of entering into the transaction

We are a developer and manufacturer of occluders and occluder-related products and a developer of heart valve products. Clinical trial services are vital to our clinical studies for occluders and heart valve products as part of our development process. Hefei Hospital, a member of the Retained Lepu Medical Group, is a cardiovascular hospital equipped with the requisite qualification for providing clinical trial services and has a track record of having the capability of providing efficient clinical trial services since our cooperation with them in 2019. As such, we engage Hefei Hospital as one of the hospitals that provide clinical trial services for us.

Pricing policies

During the Track Record Period, the amounts paid by our Group to the Retained Lepu Medical Group under the Clinical Trial Service Framework Agreement was determined on normal commercial terms with reference to the price charged by Hefei Hospital to third-party medical device companies for its clinical trial services, as the Group was not able to obtain comparable quotations on the clinical trial services provided by Hefei Hospital to our Group due to the customization nature of such clinical trial services. During the term of the Clinical Trial Service Agreement, the price to be determined shall be based on the quotations provided by independent third-party suppliers if such suppliers are available. However, considering that the services have certain customization characteristics that third-party suppliers may not be available, then such price to be determined shall be with reference to the quotations provided by Hefei Hospital to its independent third-party customers which shall be fair and reasonable, comparable to (or better than) the price offered to independent third parties, and in the best interests of the shareholders of our Group.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amount was approximately RMB0.016 million, nil, RMB1.3 million and RMB0.7 million, respectively. The historical amount of RMB0.016 million incurred in 2019 was related to a then clinical trial project of fully biodegradable occluders which involved two participating subjects.

CONNECTED TRANSACTIONS

Annual caps

The proposed annual caps in respect of the transactions contemplated under the Clinical Trial Service Framework Agreement are RMB9.0 million, RMB9.5 million and RMB9.5 million for the three years ending December 31, 2022, 2023 and 2024, respectively.

Basis of caps

The above proposed annual caps are determined with reference to the following factors: (1) the estimated number of the research and development projects of our occluders and heart valve products, and (2) the estimated number of participating subjects to be involved in the clinical trials to be conducted by Hefei Hospital.

Implications under the Listing Rules

Since the highest of all applicable percentage ratios in respect of the Clinical Trial Service Framework Agreement will be more than 0.1% but less than 5% on an annual basis, the Clinical Trial Service Framework Agreement will be subject to the announcement, reporting and annual review requirements under Chapter 14A of the Listing Rules but will be exempted from the circular and independent shareholders’ approval requirement under Chapter 14A of the Listing Rules. [We have applied for, and the Stock Exchange has granted, waivers from these requirements as described below.]

NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

We set out below details of the non-exempt continuing connected transactions (the “Non-exempt Continuing Connected Transactions”) for our Group, which are subject to the reporting, annual review, announcement and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

1. Sale of Products Framework Agreement

Description of the agreement

On October 18, 2022, our Company entered into a sale of products framework agreement with Lepu Medical (the “Sale of Products Framework Agreement”), pursuant to which our Group may sell to (1) Lepu (Shanghai) and Anhui Magete certain products manufactured by our Group, namely, congenital heart disease occluders, congenital heart disease occluder delivery systems, LAA occluder systems, and snares, for distribution within the PRC; and (2) Lepu India congenital heart disease occluders, congenital heart disease occluder delivery systems and snares, for distribution in India. We may enter into individual agreements separately with Lepu (Shanghai), Anhui Magete and Lepu India with respect to different transactions which provide for specific terms and conditions including products, price, payment and other terms in accordance with the Sale of Products Framework Agreement and applicable laws. The term of the Sale of Products Framework Agreement shall commence from the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

CONNECTED TRANSACTIONS

Reasons for and benefits of entering into the transaction

- (a) Our principal business is the production and sales of occluder and occluder-related devices and it is in our ordinary and usual course of business to sell occluder delivery systems to other parties for distribution;
- (b) Since 2012, we have been distributing our occluders through the Retained Lepu Medical Group with its wide and developed distribution network. We have been steadily ramping up our distribution qualification and capability by means including applying for our own distribution licenses. While we have established our own sales capability, a portion of the sales of our products will be conducted through members of the Retained Lepu Medical Group as our distributors; and
- (c) Certain of the requisite certificates for conducting sales in India were registered by Lepu India. We will continue to engage them as our distribution channel in India, where the Medical Devices Rules, which were published by the central government of India in 2016 and became effective in 2017, forbid the application by a foreign entity from applying for a license for importing medical devices. It is not practicably feasible and unduly burdensome for us to establish an Indian entity within the near future to carry out as efficiently the role currently undertaken by Lepu India, due to our unfamiliarity with the local regulatory environment and the current pandemic situation caused by COVID-19.

Pricing policies

The amounts to be paid by the Retained Lepu Medical Group to our Group under the Sale of Products Framework Agreement will be determined (1) with reference to the procurement prices announced by competent local authorities, namely, the provincial tendering offices in the PRC; and (2) with reference to our sales price in other comparable regions and taking into account the sales price of similar products set by other companies comparable to us for sales in India. The price to be determined shall be fair and reasonable, comparable to (or better for the Company than) the price offered to independent third parties, and in the interests of the Company and the Shareholders.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amount was approximately RMB10.2 million, RMB31.0 million, RMB15.7 million and RMB2.0 million, respectively. Out of such transaction amount, the aggregate transaction amount of sales in India for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 accounted for 23.5%, 8.9%, 1.9% and 23.6%, respectively. Our gross profit margin generated from sales in India for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 was in general consistent with our gross profit margin for sales to the Retained Lepu Medical Group for the same period, which was approximately 64.4%, 91.4%, 90.0% and 84.8%, respectively, as there was no material difference in the cost structure.

CONNECTED TRANSACTIONS

Since 2012, we have been selling a portion of our products including occluders and delivery system through the Retained Lepu Medical Group, for both domestic and overseas distribution. In the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, our revenue generated from such sales from the Retained Lepu Medical Group contributed to 8.8%, 20.9%, 4.5% and 2.1% of our total revenue for the same periods, respectively. With the improvement of our overseas brand recognition, by the beginning of 2020, the contribution from Retained Lepu Medical Group had been reduced to our overseas distribution to an extent that its involvement and functions became similar to our PRC distributors in terms of domestic sales. Therefore, we and the Retained Lepu Medical Group adjusted the pricing model accordingly (the “Adjustment”) so that the consideration paid by the Retained Lepu Medical Group since the beginning of 2020 has been the net amount of the sales price of our products by the Lepu Medical Group to the overseas distributors deducting a profit to the Retained Lepu Medical Group calculated at a margin rate that is consistent with the prevailing market rate. The gross margin that we generated from our sales to the Retained Lepu Medical Group in 2020 has been 91.4%, which was comparable with that of the gross margin of the sales to our other distributors that are independent third parties for the same period, being approximately 88.6%.

We have engaged the transfer pricing team from one of the “big-four” accounting firms (“Tax Consultant”) to analyse and assess the reasonableness of the pricing in our connected transactions with the Retained Lepu Medical Group. Since the Adjustment, the Retained Lepu Medical Group has been receiving a proportion of the sales amount of our products, as its gross profit, at a rate comparable to that received by our other distributors that are independent third parties. As verified by the functional analysis and value chain analysis conducted by the Tax Consultant, we have been undertaking the research and development, production and operation, while the Retained Lepu Medical Group has been merely our distributor, which has less exposure to commercial risks and plays a relatively less important part compared to us. Utilising the resale price method introduced by the Measures for the Administration of Adjustments under Special Tax Investigation and Mutual Consultation Procedures (特別納稅調查調整及相互協商程序管理辦法) and OECD Transfer Pricing Guidelines (OECD轉讓定價指南), the Tax Consultant compared the gross profit margin of the Retained Lepu Medical Group with those of comparable third party distributors extracted from OSIRIS, a public data pool provided by Bureau van Dijk and commonly used by the tax bureaus in China. After a series of independent screening and comparison, the Tax Consultant concluded that the gross profit margin fell within the inter-quartile range of the gross profit of the comparable distributors. In addition, our own gross profit margin in the transactions with the Retained Lepu Medical Group has been comparable with that in an ordinary sales transaction with independent third parties. Referencing to the conclusion of the Tax Consultant, the Directors are of the view that the Group’s sales to the Retained Lepu Medical Group have been in compliance with the relevant transfer pricing laws and regulations in the PRC during the Track Record Period and the potential tax payable in relation to such sales was based on arm’s length standard and that the amount is adequate.

CONNECTED TRANSACTIONS

Annual caps

The proposed annual caps in respect of the transactions contemplated under the Sale of Products Framework Agreement are RMB14.3 million, RMB17.9 million and RMB20.4 million for the three years ending December 31, 2022, 2023 and 2024, respectively.

Basis of caps

The above proposed annual caps are determined with reference to the following factors: (1) the historical transaction amounts paid by the Retained Lepu Medical Group to our Group, (2) the estimated demand for the products to be distributed by the Retained Lepu Medical Group due to the growth of our own sales and distribution capabilities in overseas markets; and (3) the expected maximum selling prices of the relevant products for the three years ending December 31, 2024.

Implications under the Listing Rules

Since the highest of all applicable percentage ratios in respect of the Sale of Products Framework Agreement will be 5% or more, the Sale of Products Framework Agreement will be subject to the reporting, annual review, announcement and independent shareholders' approval requirements under Chapter 14A of the Listing Rules. [We have applied for, and the Stock Exchange has granted, waivers from these requirements as described below.]

2. Entrusted Products Related Framework Agreement

Description of the agreement

As part of the Reorganization and with a view to solidifying the Group's position as the sole platform under Lepu Medical Group focusing on interventional medical devices primarily targeting structural heart diseases, the interventional heart valve business was injected into Shanghai Shape Memory alloy by Lepu Medical in January 2021. Among the product candidates involved in such injection, the key research and development work of certain heart valve product candidates (i.e., the Entrusted Products) were initially conducted under the name of Lepu Medical. As at the Latest Practicable Date, due to the Entrusted Products Regulatory Restrictions, it was not feasible for us to directly take over and continue with the subsequent research and development procedures of the Entrusted Products that are expected to take place during the initial term of the Entrusted Products Related Framework Agreement, including conducting the clinical trials (notwithstanding the fact that Shanghai Shape Memory Alloy became the legal owner of all intellectual properties related to the Entrusted Products). Therefore it is only reasonable for Lepu Medical to continue the Relevant Activities for the Entrusted Products. In particular, for the R&D process of the Entrusted Products, Lepu Medical will continue to conduct the activities that are necessary to be carried out by Lepu Medical as a registration applicant under the PRC laws, including procuring the raw materials and producing the sample products used in the subsequent clinical trials, and communicating with the governmental authorities involved therein. Further, once TAVR system and TMVCRS

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become commercialized, which is expected to take place in 2024, Lepu Medical will carry out the manufacturing of TAVR system and TMVCRS which falls within the Catalogue of Medical Devices Prohibited from Entrusted Production as prescribed by the NMPA. We have built in the Entrustment Arrangements in the asset transfer agreement and an intellectual property transfer agreement as an attachment thereto with Lepu Medical in January 2021, as further elaborated in “Business — Our Products — Heart Valve Product Candidates — Entrusted Products.”

With a view to restating the Entrustment Arrangements as a continuing connected transaction under the Listing Rules, on October 18, 2022, our Company entered into a framework agreement with Lepu Medical (the “Entrusted Products Related Framework Agreement”), pursuant to which our Group agreed to engage the Retained Lepu Medical Group to conduct the Relevant Activities legally according to the directions of our Group. We will reimburse Lepu Medical of its costs and fees actually incurred for the R&D and registration related activities associated with the Entrusted Products. Our finance department will (a) scrutinize the underlying supporting documents submitted by Lepu Medical as proof of payment, e.g., contracts and invoices; (b) follow the Group’s internal cost control measures which require, among others, every payment request from Lepu Medical being submitted to the finance department for verification and to Chen Juan (陳娟), our executive Director, chairman of the Board of Directors and general manager, for approval; and (c) compare the amount of fees paid by Lepu Medical against market prevailing prices on a regular basis to determine whether the payments are in line with the value of the relevant services. See also “— Internal Control Measures for Non-Exempt Continuing Connected Transactions” in this section for more details of the internal review procedures we have adopted to ensure the fairness and reasonableness of the pricing. Upon commercialization of the Entrusted Products which may take place as early as 2024, we may purchase the TAVR system and TMVCRS to be manufactured by Lepu Medical for sales and distribution onwards as authorized by Lepu Medical irrevocably and exclusively pursuant to the asset transfer agreement. Should any product liabilities associated with the Entrusted Products arise, Lepu Medical shall be liable for such liabilities by operation of law due to the fact that it is the registrant of the Entrusted Products and will be entitled to claim compensations from our Group to the extent that such liabilities are not caused by Lepu Medical’s fault. The transaction amount pertaining to our purchase of the Entrusted Products (which will constitute connected transactions between the Retained Lepu Medical Group and us) will increase accordingly. We will continue to comply with the requirements under Chapter 14A of the Listing Rules for such purchase of the Entrusted Products. When and if the applicable laws entitle our Group to conduct the Relevant Activities, the Retained Lepu Medical Group shall immediately engage and authorize our Group to do so. For further details of the Entrustment Arrangements, see “Business — Our Products — Heart Valve Product Candidates — Entrusted Products.”

We may enter into individual agreements separately with the Retained Lepu Medical Group with respect to different transactions which provide for specific terms and conditions including target, price, payment and other terms in accordance with the Entrusted Products Related Framework Agreement and applicable laws. The term of the Entrusted Products Related Framework Agreement shall commence from the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

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Reasons for and benefits of entering into the transaction

Historically the type inspections and animal tests of the Entrusted Products were conducted under the name of Lepu Medical. As at the Latest Practicable Date, due to the Entrusted Products Regulatory Restrictions, it was not feasible for us to directly take over and continue with the Relevant Activities including conducting the clinical trials. Entrusting the Retained Lepu Medical Group with the subsequent R&D, registration and manufacturing of the Entrusted Products is crucial to the realization of their commercialization and subsequent monetization. As further elaborated in “Business — Our Products — Heart Valve Product Candidates — Entrusted Products”, the Entrustment Arrangements under this transaction, which are integral to the injection of interventional heart valve business from Lepu Medical to our Group, strategically complemented our existing product portfolio and enabled us to have a product portfolio covering all three major fields of application in the interventional medical device market targeting structural heart diseases.

Pricing policies

We will pay to the Retained Lepu Medical Group the costs, comprising raw material, labor and equipments consumption, and fees to be incurred during the R&D and registration process. Upon the commercialization of TAVR system and TMVCRS, we will purchase the TAVR system and TMVCRS manufactured by Lepu Medical at price to be determined by the actual costs and expenses for manufacturing the TAVR system and TMVCRS (including costs of raw materials, labor power, depreciation of equipment and consumption of manufacturing utilities involved) plus reasonable profits. When deciding the profit margin, we will take into consideration (i) the nature of services provided by Lepu Medical; and (ii) the expected duration and complexity of techniques involved in the manufacturing process.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amount was nil, nil, approximately RMB28.7 million and RMB16.1 million, respectively.

Annual caps

The proposed annual caps in respect of the transactions contemplated under the Entrusted Products Related Framework Agreement are RMB28.0 million, RMB18.0 million and RMB11.0 million for the three years ending December 31, 2022, 2023 and 2024 respectively. The expected decrease in the proposed annual caps is mainly based on the estimated research and development stage to be conducted in the three years ending December 31, 2024. Among all the steps, clinical trials are expected to incur relatively highest amount of fees and expenses. As an increasing number of projects are expected to complete clinical trial stage in 2022 and 2023, the associated fees and expenses are expected to decrease correspondingly. Out of the

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proposed annual cap for 2024, the R&D and registration related fees of the Entrusted Products and the payment for purchase of TAVR system and TMVCRS is expected to be RMB6.0 million and RMB5.0 million, respectively.

Basis of caps

The above proposed annual caps are determined with reference to the estimated progress of research to be made by the Retained Lepu Medical Group for the three years ending December 31, 2024, the estimated purchase volume of TAVR system and TMVCRS by us from Lepu Medical during the year of 2024 and the corresponding estimated costs, comprising those for labor, raw materials and payments made to third parties, to be incurred in conducting research and development, registering and manufacturing involved therein of the Entrusted Products by the Retained Lepu Medical Group plus the estimated profit to be charged by Lepu Medical associated with the TAVR system and TMVCRS.

Implications under the Listing Rules

Since the highest of all applicable percentage ratios in respect of the Entrusted Products Related Framework Agreement will be 5% or more, the Entrusted Products Related Framework Agreement will be subject to the reporting, annual review, announcement and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules. [We have applied for, and the Stock Exchange has granted, waivers from these requirements as described below.]

APPLICATION FOR WAIVER

The transaction described under the subsection headed “Partially-exempt Continuing Connected Transaction” above constitute our continuing connected transaction under the Listing Rules. The transactions under the Clinical Trial Service Framework Agreement will be subject to the announcement, reporting and annual review requirements under Chapter 14A of the Listing Rules but will be exempted from the circular and independent shareholders’ approval requirement under Chapter 14A of the Listing Rules.

The transactions described under the subsection headed “Non-exempt Continuing Connected Transactions” above constitute our continuing connected transactions under the Listing Rules. The transactions under the Sale of Products Framework Agreement and the Entrusted Products Related Framework Agreement will be subject to the reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

As such partially-exempt and non-exempt continuing connected transactions are expected to be carried out on a continuing basis and to extend over a period of time, and their material terms have been disclosed in this document, the Directors are of the view that strict

CONNECTED TRANSACTIONS

compliance with the aforesaid reporting, annual review, announcement, circular and independent shareholders' approval requirements under the Listing Rules would be impracticable and unduly burdensome and would impose unnecessary administrative costs upon our Company.

In respect of these continuing connected transactions, pursuant to Rule 14A.105 of the Listing Rules, we have applied for, and the Stock Exchange [has granted], a waiver exempting us from strict compliance with (i) the announcement requirement under the Listing Rules in respect of the transactions under the Clinical Trial Service Framework Agreement; and (ii) the announcement, circular and independent shareholders' approval requirements under the Listing Rules in respect of the transactions under the Sale of Products Framework Agreement and the Entrusted Products Related Framework Agreement, subject to the condition that the aggregate values of the continuing connected transactions for each financial year not exceeding the relevant amounts set forth in the respective annual caps (as stated above). We will comply with the applicable requirements under the Listing Rules, and will immediately inform the Stock Exchange if there are any changes to the non-exempt continuing connected transaction.

INTERNAL CONTROL MEASURES FOR NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

For expense-based non-exempt continuing connected transactions, we have established the following internal review procedures to ensure that the pricing under the non-exempt continuing connected transactions is fair and reasonable:

- (i) If a comparable market price is available, we shall compare the proposed price/service fee against market price to ensure that the proposed price/service fee will not be higher than that for similar part/goods/nature of service provided by independent third-party providers;
- (ii) Before selecting a part/service provider, our procurement department shall obtain quotations from certain independent third-party providers. The factors to be considered by us in conducting internal assessments shall include fee, quality, efficiency of part/service, and value added to us; and
- (iii) If no comparable market price is available, our procurement department shall conduct arm's length negotiation with the relevant connected person to determine the terms in line with the relevant pricing policies based on the value of the relevant part/service and the actual costs and expenses incurred.

We have also established the following internal review procedures to ensure that the pricing under our non-exempt continuing connected transactions is fair and reasonable:

- (i) The financial management department is responsible for preparing the accounting records, accounting, reporting, and statistical analysis of the continuing connected transactions, and for submitting the same to the Board of Directors for filing on a

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regular basis. The financial management department will also regularly collect and monitor the transaction amount of continuing connected transactions to ensure timely assessment on whether the annual caps are, or are expected to be, exceeded;

- (ii) The finance department will be responsible for identifying connected persons and the connected transactions, and submitting lists of the same to the Board of Directors for filing on a regular and timely basis;
- (iii) The Audit Committee shall conduct periodic examination of the overall situation of the continuing connected transactions, and report the review opinions to the Board of Directors;
- (iv) Our independent non-executive Directors will also conduct annual review on the non-exempt continuing connected transactions to ensure that such transactions have been entered into on normal commercial terms, are fair and reasonable, and conducted according to the terms of the relevant framework agreement; and
- (v) The auditor of our Company shall issue a letter to the Board of Directors to express opinions on the continuing connected transactions of the Group on an annual basis. The Company shall allow its auditor to review and check the relevant accounts to facilitate them to express opinions.

CONFIRMATION BY THE DIRECTORS

The Directors (including independent non-executive Directors) are of the view that the partially-exempt and non-exempt continuing connected transactions have been and will continue to be carried out in our ordinary and usual course of business of the Company and on normal commercial terms or better that are fair and reasonable and in the interests of the Company and our Shareholders as a whole, and that the proposed annual caps for the partially-exempt and non-exempt continuing connected transactions are fair and reasonable and in the interests of the Company and our Shareholders as a whole.

CONFIRMATION BY THE SOLE SPONSOR

The Sole Sponsor considers that the partially-exempt and non-exempt continuing connected transactions have been and will be carried out in the ordinary and usual course of business of the Company and on normal commercial terms or better that are fair and reasonable and in the interests of the Company and the Shareholders as a whole, and that the proposed annual caps of the partially-exempt and non-exempt continuing connected transactions are fair and reasonable and in the interests of the Company and the Shareholders as a whole.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

The Board of Directors consists of seven Directors, including two executive Directors, two non-executive Directors and three independent non-executive Directors. The Directors are elected for a term of three years and are subject to re-election upon retirement. The following table sets forth certain information regarding the Directors.

Name	Age	Date of joining the Group	Date of appointment as a Director	Position	Responsibility	Directorship and management roles in the Retained Lepu Medical Group
Ms. CHEN Juan (陳娟)	50	December 5, 2011	January 29, 2021	Executive Director, chairman of the Board of Directors and general manager	Developing overall corporate and business strategies of our Group and making key business and operational decisions of our Group	N/A
Ms. ZHANG Yuxin (張昱昕)	43	May 4, 2011	January 29, 2021	Executive Director, deputy general manager and chief technology officer	Formulating the overall development strategies and business plans and overseeing the management of R&D projects and strategic development of our Group	A research and development project manager in Lepu Medical overseeing the research and development of the Entrusted Products carried out by Lepu Medical as a designated representative of our Group
Mr. FU Shan (付山)	54	June 9, 2021	June 9, 2021	Non-executive Director	Providing professional opinion and judgment to the Board of Directors	N/A

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Date of joining the Group	Date of appointment as a Director	Position	Responsibility	Directorship and management roles in the Retained Lepu Medical Group
Mr. ZHENG Guorui (鄭國銳)	39	June 9, 2021	June 9, 2021	Non-executive Director	Providing professional opinion and judgment to the Board of Directors	Deputy general manager of Lepu Medical
Ms. CHAN Ka Lai Vanessa (陳嘉麗)	49	September 2, 2021	September 2, 2021	Independent non-executive Director	Supervising and providing independent advice on the operation and management of our Group	N/A
Mr. ZHENG Yufeng (鄭玉峰)	49	June 9, 2021	June 9, 2021	Independent non-executive Director	Supervising and providing independent advice on the operation and management of our Group	N/A
Mr. LIU Daozhi (劉道志)	58	June 9, 2021	June 9, 2021	Independent non-executive Director	Supervising and providing independent advice on the operation and management of our Group	N/A

Executive Directors

Ms. CHEN Juan (陳娟), aged 50, has been a Director, the chairman of the Board of Directors and the general manager of the Company since January 29, 2021 and was re-designated as an executive Director on June 9, 2021. She has been serving as the general manager of Shanghai Shape Memory Alloy since December 2011 and its executive director since March 2021. She is responsible for developing overall corporate and business strategies of our Group and making key business and operational decisions of our Group.

Ms. Chen joined the Lepu Medical Group in October 2006 and served on several management positions therein. By August 2021, she has resigned from all such positions.

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Prior to joining the Lepu Medical Group, Ms. Chen served as the regional manager in the vascular instrument department of Abbott Laboratories Trading (Shanghai) Co., Ltd. (雅培醫療器械貿易(上海)有限公司) from January 2005 to September 2006. She served as the regional manager at the Beijing office of Gaiteng International Trade (Shanghai) Co., Ltd.* (概騰國際貿易(上海)有限公司) (currently known as Abbott Laboratories Trading (Shanghai) Co., Ltd. (雅培醫療器械貿易(上海)有限公司)) from October 1999 to September 2006, where she was responsible for the regional sales promotion.

Ms. Chen graduated from Si Tanka University (美國斯坦卡大學) in June 2017 with a doctor’s degree in business administration, for which she received her courses in Shanghai. She obtained a master’s degree in business administration from Maastricht School of Management (荷蘭馬斯特里赫特管理學院) in the Netherlands in September 1997 and a college degree from Shaanxi Foreign Language College (陝西省外國語師範專科學校) in September 1992, respectively. She was nominated as a candidate for the Third Songjiang District Leading Talents (松江區第三屆領軍人才) in November 2019. She was awarded the Shanghai Women’s Achievement Model (上海市巾幗建功標兵稱號) in March 2018, and the Silver Prize of Leading Figure in Shanghai Medical Device Industry (2013-2015年度上海醫療器械行業領軍人物銀獎) in April 2016, respectively.

Ms. ZHANG Yuxin (張昱昕), aged 43, has been a Director of the Company since January 29, 2021 and was appointed as the deputy general manager and the chief technology officer of our Company since May 28, 2021. She was re-designated as an executive Director on June 9, 2021. She served as a deputy general manager of Shanghai Shape Memory Alloy from May 2011 to August 2013. She is primarily responsible for formulating the overall development strategies and business plans and overseeing the management of the research and development projects and strategic development of our Group.

She joined the Lepu Medical Group in April 2006 and served as a project manager of research and development department of Lepu Medical until February 2008. From January 2009 to May 2011, she served as a manager of the technical quality department at Target Medical. She served as a deputy director of the marketing department of Lepu Medical from August 2013 to March 2015 and the chairman of its machinery research center from March 2015 to May 2021. She resigned from her other positions in Lepu Medical in May 2021 yet remained as a research and development project manager in Lepu Medical to oversee the research and development projects of the Entrusted Products by Lepu Medical. For further details, see “Relationship with our Controlling Shareholders — Independence from Controlling Shareholders — Management Independence,” “Connected Transaction — Non-exempt Continuing Connected Transactions — 2. Entrusted Products Related Framework Agreement” and “Business — Our Products — Heart Valve Product Candidates.”

Before joining the Lepu Medical Group and from December 2004 to April 2006, she served as a research and development engineer at 725th Research Institute (第七二五研究所) of China State Shipbuilding Co., Ltd. (中國船舶重工集團有限公司, “China Shipbuilding Industry”). From July 2004 to November 2004, she served as a research and development engineer at CMBI Construction Co., Ltd. (中材建設有限公司).

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Ms. Zhang graduated from Xi’an University of Architecture and Technology (西安建築科技大學) with a bachelor’s degree in metallurgy in July 2001. She graduated from Xi’an Jiaotong University (西安交通大學) with a master’s degree in materials science and engineering in June 2004. She obtained the qualification of Senior Engineer (高級工程師) from the 725th Research Institute of China Shipbuilding Industry in December 2010. She was awarded as the 24th Beijing Outstanding Young Engineer (北京市優秀青年工程師) by Beijing Science and Technology Association and Beijing Human Resources and Social Security Bureau (北京市科學技術協會及北京市人力資源和社會保障局) in September 2020. In 2017 and 2012, she was awarded the third prize of Beijing Invention Patent Award (北京發明專利獎三等獎) and the second prize of Beijing Science and Technology Award (北京市科學技術獎二等獎), respectively.

Ms. Chen and Ms. Zhang were designated by Lepu Medical to spearhead the operation of Shanghai Shape Memory Alloy as well as the establishment of our Company. Each of them has been instrumental to the development of Shanghai Shape Memory Alloy and the establishment of the Company. Despite their changes in positions within the Lepu Medical Group due to a centralised management of Lepu Medical, they had spearheaded and organized the business segment that focuses on interventional medical device primarily targeting structural heart diseases of the Lepu Medical Group since 2011, which developed into the business of the Group to date, when they became the general manager and deputy general manager of Shanghai Shape memory Alloy, respectively. Ms. Chen and Ms. Zhang have been closely involved and focusing on the operations and strategic planning of the Group’s business since they joined Shanghai Shape Memory Alloy in 2011. Concurrently serving as a research and development project manager in Lepu Medical overseeing the research and development of the Entrusted Products carried out by Lepu Medical, Ms. Zhang is doing so as a designated representative of our Group and her existing role in Lepu Medical is vital to ensure smooth Entrustment Arrangements to be smoothly conducted, details of which are set out in “Business — Our Products — Heart Valve Product Candidates — Entrusted Products.”

Non-executive Directors

Mr. Fu Shan (付山) (former name as Fu Shan (傅山)), aged 54, has been serving as a non-executive Director since June 9, 2021. He is responsible for providing professional opinion and judgment to the Board of Directors.

Mr. Fu served as a managing partner, an associate chief executive officer and a chief executive officer of Greater China region in Vivo Capital (維梧資本) since October 2013. Prior to that, he served as senior managing director of the Blackstone Group from June 2008 to October 2013. He undertook various positions in the State Economic and Trade Commission of the People’s Republic of China (中華人民共和國國家經濟貿易委員會, “SETC”) and the NDRC (國家發改委), including serving as a director of the General Affairs Division of the Foreign Capital Utilization Department of the NDRC (國家發改委國外資金利用司綜合處) from August 2004 to March 2008, a director of the Policy and Regulation Division of the Foreign Capital Utilization Department of the NDRC (國家發改委國外資金利用司政策法規處) from June 2003 to August 2004, a director of the Policy and Foreign Capital Division of the

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Investment and Planning Department of the SETC (國家經貿委投資與規劃司政策與外資處) from January 2001 to June 2003, a deputy director of the Foreign Capital Division of the Investment and Planning Department of the SETC (國家經貿委投資與規劃司外資處) from July 1998 to January 2001, a deputy Director of the General Affairs Division of the Technological Transformation Department of the SETC (國家經貿委技術改造司綜合處) from October 1997 to July 1998, and an officer of the General Affairs Division of the Foreign Economic and Trade Department of the SETC (國家經貿委外經貿司綜合處) from August 1993 to October 1997. From May 1992 to August 1993, he served as an officer in the Economics and Trade Office of the State Council in China (中國國務院經濟貿易辦公室). From September 1991 to May 1992, he served as an officer in the Manufacture Office of the State Council in China (中國國務院生產辦公室). Mr. Fu has also been serving as (1) an non-executive director of TOT Biopharm International Company Limited, a company listed on the Stock Exchange (stock code: 1875), since January 19, 2016 and the chairman of its board of directors since September 28, 2018, (2) a non-executive director of InnoCare Pharma Limited, a company listed on the Stock Exchange (stock code: 9969), since September 27, 2019, (3) a non-executive director of Sinovac Biotech Co., Ltd., a company listed on the NASDAQ Global Market (stock code: SVA), since July 2018, and (4) a director of Genetron Holdings Limited, a company listed on the NASDAQ Global Market (stock code: GTH), since June 2021.

Mr. Fu obtained both his bachelor’s degree in world history and his master’s degree in world ancient history from Peking University (北京大學), in July 1988 and July 1991, respectively.

Mr. ZHENG Guorui (鄭國銳), aged 39, has been serving as a non-executive Director since June 9, 2021. He is responsible for providing professional opinion and judgment to the Board of Directors. He has been serving as a deputy general manager of Lepu Medical since April 2021. Mr. Zheng joined Lepu Medical in September 2006 as a sales manager and has served on various sales related and management positions at Lepu Medical including serving as a sales manager of the coronary artery sales team in Beijing, a manager in the northwestern region, and a manager in the eastern region. From January 2016 to October 2020, he served as a national sales director in the clinical first career department of Lepu Medical. Since October 2020, he served as a general manager assistant in Lepu Medical. See “Relationship with our Controlling Shareholders — Independence from Controlling Shareholders — Management Independence.”

Prior to joining the Lepu Medical Group, Mr. Zheng served as a sales manager in Wuhan Grand Pharmaceutical Group Trading Company* (武漢遠大製藥集團銷售有限公司) from December 2004 to September 2006.

Mr. Zheng obtained a graduation certificate for self-taught higher education examinations (高等教育自學考試) with a major in engineering management from Haikou University of Economics (海口經濟學院) in December 2020.

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Independent Non-executive Directors

Ms. CHAN Ka Lai Vanessa (陳嘉麗), aged 49, has been serving as an independent non-executive Director since September 2, 2021. She is responsible for supervising and providing independent advice on the operation and management of our Group.

Ms. Chan has been serving as an independent non-executive director at both Tycoon Group Holdings Limited (滿貫集團控股有限公司), a company listed on the Stock Exchange (Stock Code: 3390) and Innovax Holdings Limited (創陞控股有限公司), a company listed on the Stock Exchange (Stock code: 2680), since January 2020 and August 2018, respectively. Since December 2015, she has been serving as a director at WA C&E Limited (盛華商務服務有限公司). From November 2009 to December 2018, she served as the financial controller at China Agri-Industries Holdings Limited (中國糧油控股有限公司). From August 2008 to October 2009, she served as a financial controller at Changsheng Holdings Co. Ltd.. Ms. Chan also served as an accounting manager at The Kowloon Motor Bus Co. (1933) Ltd. (九龍巴士(一九三三)有限公司), a subsidiary of Transport International Holdings Limited (載通國際控股有限公司), a company listed on the Stock Exchange (Stock Code: 62) from August 2005 to February 2008. From July 1995 to August 2005, Ms. Chan worked in KPMG Hong Kong where her last position was a senior manager of the auditing department.

Ms. Chan graduated from the Hong Kong Polytechnic University in Hong Kong in October 1995 with a Bachelor of Arts degree in Accounting. She is a fellow member of the Hong Kong Institute of Certified Public Accountants and the Association of Chartered Certified Accountants. In addition, Ms. Chan is an associate member of the Hong Kong Chartered Governance Institute and a member of the Hong Kong Institute of Directors.

Mr. ZHENG Yufeng (鄭玉峰), aged 49, has been appointed as an independent non-executive Director since June 9, 2021. He is responsible for supervising and providing independent advice on the operation and management of our Group.

From September 2004, Mr. Zheng has been serving as a professor and doctoral supervisor in the Faculty of Materials Science and Engineering of Peking University. From July 1998 to August 2004, he successively served as a lecturer, an associate professor, a professor and a doctoral supervisor in Harbin Institute of Technology (哈爾濱工業大學). He served as an editor-in-chief of the Bioactive Materials Journal in Beijing Keai Senlan Culture Communication Co., Ltd (北京科愛森藍文化傳播有限公司) since May 2015.

Mr. Zheng graduated from the College of Shipbuilding Engineering of Harbin Engineering University (哈爾濱工程大學船舶工程學院) with a bachelor’s degree in metallic material and heat treatment in July 1993. He obtained his PhD degree from the School of Materials Science and Engineering of Harbin Institute of Technology (哈爾濱工業大學材料科學與工程學院) in September 1998.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. LIU Daozhi (劉道志), aged 58, has been appointed as an independent non-executive Director since June 9, 2021. He is responsible for supervising and providing independent advice on the operation and management of our Group.

Mr. Liu founded Sunland Fund (山藍資本) in 2015 and has been serving as its executive partner since January 2015. From February 2003 to December 2013, Mr. Liu served as a senior vice president in emerging business in Shanghai MicroPort Medical (Group) Co., Ltd. (上海微創醫療器械(集團)有限公司).

Mr. Liu graduated from Nankai University (南開大學) with a Bachelor of Science degree in Physics in July 1985 and a PhD degree in Science in April 1991.

BOARD OF SUPERVISORS

The PRC Company Law requires our Company to establish a board of supervisors that is responsible for supervising the performance of the Board and senior management, the Company’s financial operations, internal control and risk management. Our Board of Supervisors consists of three Supervisors, including one employees’ representative Supervisor. Our Supervisors are elected for a term of three years and are subject to re-election upon their retirement or resignation, and the cumulative term of an external Supervisor shall not exceed six years. The following table sets forth certain information about our Supervisors.

Name	Age	Date of joining the Group	Date of appointment as a Supervisor	Position	Responsibility
Mr. WANG Xinglin (王興林)	60	January 29, 2021	January 29, 2021	Supervisor	Supervising the performance of duties by our Directors and members of the senior management of our Group
Ms. WANG Xiaoyong (王曉勇)	45	January 29, 2021	January 29, 2021	Supervisor	Supervising the performance of duties by our Directors and members of the senior management of our Group
Mr. QIAN Weidong (錢衛東)	59	January 1, 2004	June 9, 2021	Supervisor and employee’s representative Supervisor	Supervising the performance of duties by our Directors and members of the senior management of our Group

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Mr. WANG Xinglin (王興林), aged 60, has been serving as a supervisor since January 29, 2021. He is responsible for supervising the performance of duties by our Directors and members of the senior management of our Group.

Mr. Wang served as the chairman of the board of supervisors at Lepu Medical since January 2020. He served as the general manager at Zhongxing Huatou (Beijing) Fund Management Co., Ltd.* (中興華投(北京)投資基金管理有限公司) since December 2016. He served as deputy chief accountant from July 2014 to January 2016 and director of the finance department from July 2015 to January 2016, respectively, in China Shipbuilding Industry. He served as deputy general manager in China State Shipbuilding Corporation Finance Co., Ltd. (中船重工財務有限責任公司, “China State Shipbuilding”) from December 2001, and was promoted to the director of its finance department in March 2004, a general manager in November 2005, the vice chairman of its board of directors in November 2011, and vice chairman of the board of directors and general manager in July 2014 respectively. He left China State Shipbuilding in August 2018. From July 1985 to January 2002, he successively served as an assistant accountant, accountant, vice director of the finance department, director of finance department, the vice chief accountant and the chief accountant at Xi’an Shipbuilding Industry Co., Ltd.* (西安船舶設備工業公司, currently known as China Shipbuilding Industry Corporation Xi’an Shipbuilding Industry Co., Ltd.* (中國船舶重工集團西安船舶工業有限公司)).

Mr. Wang graduated from Shaanxi Institute of Finance and Economics (陝西財經學院) in July 1985 with a bachelor’s degree in industrial accounting. He obtained qualification as a senior accountant from China State Shipbuilding Corporation (中國船舶工業總公司) in October 1997.

Ms. WANG Xiaoyong (王曉勇), aged 45, has been serving as a supervisor since January 29, 2021. She is responsible for supervising the performance of duties by our Directors and members of the senior management of our Group.

Ms. Wang joined Lepu Medical in April 2006 as a regional manager of the marketing center and was promoted to serve as a general manager at pharmaceuticals department from June 2013 to December 2016. From January 2015 to December 2016, she also concurrently served as a marketing director at Beijing Haihetian Technology Development Co., Ltd.* (北京海合天科技開發有限公司). She served as a marketing director of the marketing department since January 2017 in Lepu Medical.

Ms. Wang graduated from Henan University of Economics and Law (河南財經政法大學) in June 2010 with a master’s degree in business administration. She graduated from Southwest University (西南大學) in January 2019 with a bachelor’s degree in applied psychology through online courses.

Mr. QIAN Weidong (錢衛東), aged 59, has been serving as a supervisor since June 9, 2021. He is responsible for supervising the performance of duties by our Directors and members of the senior management of our Group.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Qian joined Shanghai Shape Memory Alloy as a production technician from January 2004 to 2008, and was promoted as a production supervisor from 2008 to 2012. He has been a production manager of Shanghai Shape Memory Alloy since 2012.

Mr. Qian graduated from Jiangsu Shuxun Middle School (江蘇樹勳中學) in July 1979.

SENIOR MANAGEMENT

The following table sets out certain information regarding the senior management of the Company.

Name	Age	Date of joining the Group	Date of appointment as a senior management member	Position	Responsibility
Ms. CHEN Juan (陳娟)	50	December 5, 2011	January 29, 2021	Executive Director, chairman of the Board of Directors and general manager	Developing overall corporate and business strategies of our Group and making key business and operational decisions of our Group
Ms. ZHANG Yuxin (張昱昕)	42	May 4, 2011	May 28, 2021	Executive Director, deputy general manager and chief technology officer	Formulating the overall development strategies and business plans and overseeing the management of R&D projects and strategic development of our Group
Mr. QIN Xue (秦學)	46	May 28, 2021	May 28, 2021	Chief financial officer and deputy general manager	Overseeing the financial and accounting affairs of our Group
Mr. HE Yufeng (何玉鳳)	41	August 14, 2013	May 28, 2021	Chief operating officer and deputy general manager	Overseeing the financial and accounting affairs of our Group
Ms. ZHANG Xiani (張夏妮)	38	December 5, 2011	May 28, 2021	Deputy general manager	Overseeing the sales and marketing affairs of our Group

For biographical details of Ms. Chen and Ms. Zhang, see “— Board of Directors.”

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Mr. Qin Xue (秦學), aged 46, has been a deputy general manager and the chief financial officer of our Company since May 28, 2021. He is responsible for overseeing the financial and accounting affairs of our Group. Mr. Qin joined the Lepu Medical Group in April 2007 and served as a manager of the financial department in Lepu Medical until September 2012. Mr. Qin served as Lepu Medical’s manager of the financial planning department from October 2012 to June 2015, deputy director of financial management and manager of the fund management department from July 2015 to February 2018, and internal audit director from March 2018 to April 2021, respectively.

Mr. Qin graduated from Capital University of Economics and Business in China (首都經濟貿易大學) with a bachelor’s degree in Accounting in July 1999. He obtained qualifications as a senior accountant in July 2010 and certified management accountant (CMA) in October 2019.

Mr. HE Yufeng (何玉鳳), aged 41, has been a deputy general manager and the chief operating officer of the Company since May 28, 2021. He has also been the financial director of Shanghai Shape Memory Alloy leading its finance department from August 2013 to May 2021, and the financial director of the Company from its inception to May 2021, during which he was responsible for overseeing the financial and accounting affairs of our Group.

Before joining Shanghai Shape Memory Alloy, Mr. He served as a financial manager at Shanghai Phoenix Medical Equipment Co., Ltd. (上海鳳凰醫療設備有限公司) from March 2011 to August 2013.

Mr. He received a bachelor’s degree in financial management from Zhongnan University of Economics and Law (中南財經政法大學) in June 2003.

Ms. ZHANG Xiani (張夏妮), aged 38, has been a deputy general manager of the Company since May 28, 2021. She is responsible for overseeing the sales and marketing affairs of our Group. She served as a marketing manager of Shanghai Shape Memory Alloy from December 2011 to December 2014, and was promoted to serve as a marketing director since December 2014. She has also been serving as the marketing director of the Company since its inception.

She joined the Lepu Medical Group in July 2009 and served as an assistant to chief of the marketing department of Lepu Medical until December 2011. From June 2016 to May 2017, Ms. Zhang served as the marketing director and sales director in Shanghai Yocaly Health Management Co., Ltd.* (上海優加利健康管理有限公司), currently known as Shanghai Lepu Yunzhi Technology Co., Ltd* (上海樂普雲智科技股份有限公司), and served as a sales director from June 2016 to December 2019. From July 2007 to June 2009, she served in the operations department in the Special Olympics Department of China Administration of Sport for Persons with Disabilities (中國殘疾人奧林匹克運動管理中心).

Ms. Zhang graduated from College of Education Scientific of Capital Normal University (首都師範大學教育科學學院) in China with a bachelor’s degree in education in July 2006.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Save as disclosed above, none of our Directors, Supervisors and senior management has been a director of any public company the securities of which are listed on any securities market in Hong Kong or overseas in the three years immediately preceding the date of this document.

Save as disclosed, to the best of the knowledge, information and belief of our Directors and Supervisors, having made all reasonable enquiries, there was no other matter with respect to the appointment of our Directors and Supervisors that need to be brought to the attention of our Shareholders and there was no information relating to our Directors and Supervisors that is required to be disclosed pursuant to Rule 13.51(2)(h) to (v) of the Listing Rules as of the Latest Practicable Date.

None of our Directors, Supervisors and members of our senior management is related to the other Directors, Supervisors and members of our senior management.

JOINT COMPANY SECRETARIES

Mr. Qin Xue (秦學), aged 46, was appointed as one of our joint company secretaries. For biographical details of Mr. Qin Xue see the sub-section headed “— Senior Management.”

Ms. Ng Ka Man (吳嘉雯) was appointed as one of the joint company secretaries of our Company on June 9, 2021. Ms. Ng works at TMF Hong Kong Limited, a global corporate services provider. She has over 10 years of working experience in the corporate services profession.

Ms. Ng obtained a master’s degree in corporate governance. She is an associate member of the Hong Kong Institute of Chartered Secretaries and The Chartered Governance Institute of UK and Ireland (formerly known as The Institute of Chartered Secretaries and Administrators) in the United Kingdom. Ms. Ng is currently the company secretary of various companies listed on the Stock Exchange, including Zhaojin Mining Industry Company Limited (stock code: 1818), China Pioneer Pharma Holdings Limited (stock code: 1345), China Aluminum International Engineering Corporation Limited (stock code: 2068), Duiba Group Limited (stock code: 1753), Quanzhou Huixin Micro-credit Co., Ltd. (stock code: 1577), WWPKG Holdings Company Limited (stock code: 8069) and Baiying Holdings Group Limited (stock code: 8525).

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD COMMITTEES

The Company has established three committees under the Board of Directors, namely the Audit Committee, the Remuneration Committee and the Nomination Committee.

Audit Committee

The Audit Committee consists of three Directors, namely Ms. CHAN Ka Lai Vanessa (陳嘉麗), Mr. Zheng Yufeng (鄭玉峰) and Mr. Zheng Guorui (鄭國銳) with Ms. Chan currently serving as the chairman. Ms. Chan has the appropriate professional qualification and experiences as required under Rules 3.10(2) and 3.21 of the Listing Rules. The Audit Committee is mainly responsible for reviewing and overseeing the financial reporting procedure and internal control system of the Group.

Remuneration Committee

The Remuneration Committee consists of three Directors, namely Mr. Zheng Yufeng (鄭玉峰), Ms. Chen Juan (陳娟) and Mr. Fu Shan (付山), with Mr. Zheng currently serving as the chairman. The Remuneration Committee is mainly responsible for evaluating the remuneration policies for Directors and senior management of the Group and making recommendations thereon to the Board of Directors.

Nomination Committee

The Nomination Committee consists of three Directors, namely Ms. Chen Juan (陳娟), Mr. Zheng Guorui (鄭國銳) and Mr. Liu Daozhi (劉道志), with Ms. Chen currently serving as the chairman. The Nomination Committee is mainly responsible for identifying, screening and recommending to the Board of Directors qualified candidates to serve as the Directors and monitoring the procedures for evaluating the performance of the Board of Directors.

DIVERSITY POLICY OF THE BOARD OF DIRECTORS

The Board of Directors has adopted a board diversity policy (the “**Board Diversity Policy**”) in order to enhance the effectiveness of our Board of Directors and to maintain high standard of corporate governance. The Board Diversity Policy sets out the criteria in selecting candidates to our Board of Directors, including but not limited to gender, age, cultural and educational background, ethnicity, professional experience, skills, knowledge and length of service. The ultimate decision will be based on merit and contribution that the selected candidates will bring to our Board of Directors.

Our Directors have a balanced mixed of knowledge and skills, including but not limited to overall business management, finance and accounting and material science. They obtained degrees in diversified majors including finance, accounting science, physics and history. The Board of Directors is of the view that our Board of Directors satisfies the Board Diversity Policy. In addition, our Board of Directors has a wide range of age, ranging from 39 years old

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

to 57 years old. Two of our Directors are female. Our Board of Directors will also ensure that appropriate balance of gender diversity is achieved with reference to [REDACTED] expectation, and international and local recommended best practices.

The Nomination Committee is responsible for reviewing the diversity of the Board of Directors. After [REDACTED], the Nomination Committee will monitor and evaluate the implementation of the Board Diversity Policy from time to time to ensure its continued effectiveness. The Nomination Committee will also include in successive annual reports a summary of the Board Diversity Policy, including any measurable objectives set for implementing the Board Diversity Policy and the progress on achieving these objectives.

INTEREST OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Except as disclosed above, as of the Latest Practicable Date, each of the Directors, Supervisors and senior management (1) did not hold other positions in our Group as of the Latest Practicable Date; (2) had no other relationship with any of the Directors, Supervisors and senior management as of the Latest Practicable Date; and (3) did not hold any other directorship and supervisor’s position in listed companies in the three years prior to the Latest Practicable Date. For the Directors and Supervisors’ interests in the Shares within the meaning of Part XV of the SFO, see “Appendix VII — Statutory and General Information” to this document.

None of the Directors is interested in any business, apart from our business, which competes or is likely to compete, either directly or indirectly, with our business under Rule 8.10(2) of the Listing Rules.

DEVIATION FROM CORPORATE GOVERNANCE CODE

Pursuant to code provision A.2.1 in the Corporate Governance Code as set out in Appendix 14 to the Listing Rules, the roles of chairman and chief executive officer should be separate and should not be performed by the same individual.

Ms. Chen Juan (陳娟) is currently serving as the chairman of the Board of Directors as well as the chief executive officer of the Company. She has been primarily involved in developing overall corporate and business strategies of our Group and making significant business and operational decisions of our Group. Our Directors consider that vesting the roles of both the chairman of the Board of Directors and the chief executive officer of the Company in Ms. Chen is beneficial to the business prospects of the Group by ensuring consistent leadership to the Group as well as prompt and effective decision making and implementation. In addition, our Directors believe that this structure will not impair the balance of power and authority between the Board of Directors and the management of the Company, given that: (1) decision to be made by our Board of Directors requires approval by at least a majority of our Directors; (2) Ms. Chen and the other Directors are aware of and undertake to fulfil their fiduciary duties as Directors, which require, among other things, that she acts for the benefit and in the best interests of our Company and will make decisions for our Company

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

accordingly; (3) the balance of power and authority is ensured by the operations of the Board of Directors, which consists of two executive Directors, two non-executive Directors and three independent non-executive Directors, and has a fairly strong independence element; and (4) the overall strategic and other key business, financial, and operational policies of our Company are made collectively after thorough discussion at both Board of Directors, and senior management levels.

We will continue to review our corporate governance policies and compliance with the Listing Rules, and will adhere to the relevant principles as set out in the Corporate Governance Code after the [REDACTED].

COMPENSATION OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

The compensation and remuneration of the Directors, Supervisors and members of the senior management of the Company are determined by the Shareholders’ meetings and the Board of Directors as appropriate in the form of salaries and bonuses. The Company also reimburses them for expenses which are necessary and reasonably incurred in providing services to the Company or discharging their duties in relation to the operations of the Company. When reviewing and determining the specific remuneration packages for our Directors, Supervisors and members of the senior management of the Company, the Shareholders’ meetings and the Board of Directors take into account factors such as salaries paid by comparable companies, time commitment, level of responsibilities, employment elsewhere in our Group and desirability of performance-based remuneration. As required by the relevant PRC laws and regulations, the Company also participates in various defined contribution plans organized by relevant provincial and municipal government authorities and welfare schemes for employees of the Company, including medical insurance, injury insurance, unemployment insurance, pension insurance, maternity insurance and housing provident fund.

Our Company offers executive Directors and senior management members, who are our employees, compensation in the form of salaries, bonuses, social security plans, housing provident fund plans and other benefits. The independent non-executive Directors receive compensation based on their responsibilities.

The aggregate amounts of remuneration paid to the Directors, Supervisors and members of our senior management (excluding those who are also Directors) for the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, were approximately RMB2.7 million, RMB2.9 million, RMB12.5 million and RMB5.8 million, respectively.

The aggregate amounts of remuneration (including fees, salaries, contribution to pension schemes, housing allowances, other allowances and benefits-in-kind and discretionary bonuses) paid to the five highest paid individuals for the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, were approximately RMB3.3 million, RMB3.6 million, RMB5.3 million and RMB2.6 million, respectively.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

It is estimated that remuneration equivalent to approximately RMB9.0 million in aggregate will be paid to the Directors and Supervisors by our Company for the year ending December 31, 2022, based on the arrangements in force as of the date of the document.

No remuneration was paid by the Company to the Directors or the five highest paid individuals as inducement to join or upon joining the Company or as a compensation for loss of office during the Track Record Period. Furthermore, none of the Directors had waived or agreed to waive any remuneration during the Track Record Period.

COMPLIANCE ADVISOR

The Company appointed Halcyon Capital Limited as the compliance advisor pursuant to Rules 3A.19 and 19A.05 of the Listing Rules, and the compliance advisor will advise our Company in the following circumstances.

- before the publication of any regulatory announcement, circular or financial report;
- where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases;
- where our Company proposes to use the [REDACTED] of the [REDACTED] in a manner that is different from that detailed in this document or where our business activities, developments or results deviate from any forecasts, estimates or other information in this document; and
- where the Stock Exchange makes an inquiry of our Company regarding unusual movements in the [REDACTED] or [REDACTED] of the Shares, the possible development of a false [REDACTED] in the Shares or any other matters.

The terms of the appointment of the compliance advisor will commence on the [REDACTED] and end on the date when the Company distributes the annual report of its financial results for the first full financial year commencing after the [REDACTED].

SUBSTANTIAL SHAREHOLDERS

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares (assuming the [REDACTED] is not exercised), the following persons will have, or be deemed, or taken to have an interest and/or short position in the H Shares or the underlying Shares which would fall to be disclosed to our Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company:

Name of Shareholder	Nature of interest	Shares held as of the Latest Practicable Date			Shares held immediately following the completion of the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares (assuming the [REDACTED] is not exercised)		
		Class of Shares	Number	Percentage in the relevant class of Shares	Number	Percentage in the relevant class of Shares	Percentage in the total issued share capital
Dr. Pu ⁽¹⁾	Interest in a controlled corporation	Domestic Shares	280,000,000	86.34%	[REDACTED]	[REDACTED]	[REDACTED]
		H Shares	-	-	[REDACTED]	[REDACTED]	[REDACTED]
Lepu Medical ⁽¹⁾	Beneficial owner	Domestic Shares	277,200,000	85.48%	[REDACTED]	[REDACTED]	[REDACTED]
		H Shares	-	-	[REDACTED]	[REDACTED]	[REDACTED]
	Interest in a controlled corporation	Domestic Shares	2,800,000	0.86%	[REDACTED]	[REDACTED]	[REDACTED]
		H Shares	-	-	[REDACTED]	[REDACTED]	[REDACTED]

(1) As of the Latest Practicable Date, Lepu Medical held approximately 86.34% of the shareholding interest of our Company, including approximately 0.86% indirect shareholding interest through Target Medical and approximately 85.48% direct shareholding interest. Lepu Medical held the entire share interest in Target Medical and was therefore deemed to be interested in the Shares held by Target Medical under the SFO. Dr. Pu is the actual controller of Lepu Medical and was therefore deemed to be interested in the Shares held by Lepu Medical under the SFO.

Save as disclosed herein, our Directors are not aware of any person who will, immediately following the completion of the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares (assuming the [REDACTED] is not exercised), have an interest or short position in the H Shares or underlying Shares which will be required to be disclosed to our Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company.

We are not aware of any arrangement which may result in any change of control in our Company at any subsequent date.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

SHARE CAPITAL

Our registered share capital as of the Latest Practicable Date was RMB324,294,997.00, divided into [REDACTED] Domestic Shares and [REDACTED] Unlisted Foreign Shares of par value RMB1.00 each.

Assuming the [REDACTED] is not exercised, the share capital of our Company immediately after the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares will be as follows:

Description of Shares	Number of Shares	Aggregate nominal value of Shares (RMB)
H Shares to be [REDACTED] from Domestic Shares	[REDACTED]	[REDACTED]
H Shares to be [REDACTED] from Unlisted Foreign Shares	[REDACTED]	[REDACTED]
H Shares [REDACTED] pursuant to the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	[REDACTED]

Assuming the [REDACTED] is exercised in full, the share capital of our Company immediately after the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares will be as follows:

Description of Shares	Number of Shares	Aggregate nominal value of Shares (RMB)
H Shares to be [REDACTED] from Domestic Shares	[REDACTED]	[REDACTED]
H Shares to be [REDACTED] from Unlisted Foreign Shares	[REDACTED]	[REDACTED]
H Shares [REDACTED] pursuant to the [REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	[REDACTED]

The above table assumes that the [REDACTED] has become unconditional and the H Shares are issued pursuant to the [REDACTED].

SHARE CAPITAL

RANKING

Upon the completion of the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares, the Shares will consist of H Shares only. H Shares are all ordinary Shares in the share capital of the Company.

Apart from certain qualified domestic institutional [REDACTED] in the PRC, the qualified PRC [REDACTED] under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect and other persons who are entitled to hold our H Shares pursuant to relevant PRC laws and regulations or upon approvals of any competent authorities (such as our certain existing shareholders the Domestic Shares and the Unlisted Foreign Shares held by whom will be [REDACTED] into H Shares according to the approval of the CSRC), H Shares generally cannot be subscribed for by or traded between legal or natural PRC persons.

If further issued following the completion of the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares, Domestic Shares and Unlisted Foreign Shares (collectively, the “Unlisted Shares”) and H Shares are regarded as two different classes of Shares. The differences between the Unlisted Shares and the H Shares, provisions on class rights, dispatch of notices and financial reports to Shareholders, dispute resolution, registration of Shares on different registers of Shareholders, the procedure of transfer of Shares and appointment of dividend receiving agents as contained in the Articles of Association are summarized in “Appendix IV — Summary of the Articles of Association of the Company” to this document.

Furthermore, any change or abrogation of the rights of class Shareholders shall be approved by way of a special resolution of the general meeting of Shareholders and by a separate class shareholders meeting of class Shareholders convened by the affected class of Shareholders. The circumstances under which a general meeting and/or a class meeting is required are summarized in “Appendix IV — Summary of the Articles of Association of the Company” to this document. However, the special approval process of separate classes of Shareholders is not required under the following circumstances:

- (i) issue of Unlisted Shares or H Shares of not more than 20% of existing Unlisted Shares or H Shares, respectively, either separately or concurrently in a period of 12 months, pursuant to an approval by a special resolution of the general meeting;
- (ii) proposal to issue of Unlisted Shares and H Shares of the Company upon its establishment pursuant to approval of the securities regulatory authority under the State Council, provided that such proposal is carried out within 15 months after such approval; or
- (iii) upon the approval by securities regulatory authority of the State Council, (a) transfer by holders of the Unlisted Shares to overseas [REDACTED], or (b) [REDACTED] of the Unlisted Shares held by them into overseas-listed shares, in whole or in part, and the [REDACTED] and [REDACTED] of such Shares on an overseas stock exchange.

SHARE CAPITAL

Save as disclosed above, Unlisted Shares and H Shares shall rank *pari passu* with each other in all other respects and, in particular, will rank equally for dividends or distributions declared, paid or made. All dividends for H Shares will be denominated and declared in Renminbi, and paid in Hong Kong dollars or Renminbi, whereas all dividends for Domestic Shares will be paid in Renminbi and all dividends in respect of Unlisted Foreign Shares in foreign currencies. Other than cash, dividends could also be paid in the form of shares.

CIRCUMSTANCES UNDER WHICH GENERAL MEETING AND CLASS MEETING ARE REQUIRED

For details of circumstances under which the Shareholders’ general meeting and class Shareholders’ meeting are required, please refer to “Shareholders and Shareholders’ General Meeting — General Rules for the Shareholder’s General Meeting” and “Shareholders and Shareholders’ General Meeting — Special Procedures for the Voting of Class Shareholders” under “Appendix IV — Summary of the Articles of Association of the Company” to this document.

[REDACTED] OF OUR UNLISTED SHARES INTO H SHARES

Pursuant to the regulations prescribed by the securities regulatory authorities of the State Council and the Articles of Association, the Domestic Shares and Unlisted Foreign Shares may be [REDACTED] into overseas-listed Shares. Such [REDACTED] Shares could be [REDACTED] or [REDACTED] on an overseas stock exchange, provided that prior to the [REDACTED] and [REDACTED] of such [REDACTED] Shares, any requisite internal approval process has been duly completed and the approvals from the relevant regulatory authorities, including CSRC, have been obtained. In addition, such [REDACTED] and [REDACTED] shall comply with the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. If any of the Domestic Shares and the Unlisted Foreign Shares are to be [REDACTED], [REDACTED] and [REDACTED] as H Shares on the Stock Exchange, such [REDACTED], [REDACTED] and [REDACTED] will need the approval of the relevant PRC regulatory authorities, including the CSRC, and the approval of the Stock Exchange. The [REDACTED] and [REDACTED] of such [REDACTED] H Shares on the Stock Exchange will also require the approval of the Stock Exchange.

[REDACTED] Review and Approval by the CSRC

[REDACTED]

SHARE CAPITAL

[REDACTED]

[REDACTED] Approval by the Stock Exchange

We [have applied] to the [REDACTED] Committee of the Stock Exchange for the granting of [REDACTED] of, and permission to [REDACTED] in, our H Shares to be [REDACTED] pursuant to the [REDACTED] (including any H Shares which may be [REDACTED] pursuant to the exercise of the [REDACTED]) and the H Shares to be [REDACTED] from [REDACTED] Domestic Shares and [REDACTED] Unlisted Foreign Shares on the Stock Exchange, which is subject to the approval by the Stock Exchange.

We will perform the follow procedures for the [REDACTED] of unlisted shares into H Shares after receiving the approval of the Stock Exchange: (1) giving instructions to our [REDACTED] regarding relevant share certificates of the [REDACTED] H Shares; and (2) enabling the [REDACTED] H Shares to be accepted as eligible securities by [REDACTED] for deposit, clearance and settlement in the [REDACTED]. The Participating Shareholders may only [REDACTED] in the Shares upon completion of following domestic procedures. No approval by separate class meeting is required for the [REDACTED] and [REDACTED] of such [REDACTED] Shares on an overseas stock exchange. Any application for [REDACTED] of the [REDACTED] Shares on the Stock Exchange after our initial [REDACTED] is subject to prior notification by way of announcement to inform the Shareholders and the public of any proposed [REDACTED].

After all the requisite approvals have been obtained, the relevant Domestic Shares will be withdrawn from the CSDC and our Company will re-register such Shares on our [REDACTED] maintained in Hong Kong and instruct the [REDACTED] to issue [REDACTED]. Registration on our [REDACTED] will be conditional on (i) our [REDACTED] lodged with the Stock Exchange a letter confirming the entry of the relevant

SHARE CAPITAL

H Shares on the [REDACTED] and the due dispatch of [REDACTED]; and (ii) the admission of the H Shares to be [REDACTED] on the Stock Exchange in compliance with the Listing Rules and the General Rules of [REDACTED] and the [REDACTED] Operational Procedures in force from time to time. Until the [REDACTED] Shares are re-registered on our [REDACTED], such Shares will not be [REDACTED] as H Shares.

Domestic Procedures

[REDACTED]

SHARE CAPITAL

[REDACTED]

TRANSFER OF SHARES [REDACTED] PRIOR TO THE [REDACTED]

According to the Company Law, the Shares [REDACTED] by the Company prior to the [REDACTED] are restricted from [REDACTED] within one year from the [REDACTED].

The Company will work with the [REDACTED] to be engaged by the Company to restrict the [REDACTED] of the H Shares [REDACTED] from Domestic Shares and Unlisted Foreign Shares technically within one year after the [REDACTED].

REGISTRATION OF SHARES NOT LISTED ON AN OVERSEAS STOCK EXCHANGE

According to the Notice of Centralized Registration and Deposit of Non-overseas Listed Shares of Companies Listed on an Overseas Stock Exchange (《關於境外上市公司非境外上市股份集中登記存管有關事宜的通知》) issued by the CSRC, an overseas listed company is required to register its shares that are not listed on an overseas stock exchange with the CSDC within 15 business days upon [REDACTED] and provide a written report to the CSRC regarding the centralized registration and deposit of its non-overseas listed shares as well as the current [REDACTED] and [REDACTED] of shares.

SHAREHOLDERS’ APPROVAL FOR THE [REDACTED]

Approval from holders of the Shares is required for the Company to [REDACTED] H Shares and seek the [REDACTED] of H Shares on the Stock Exchange. The Company has obtained such approval at the Shareholders’ general meeting held on June 9, 2021.

FINANCIAL INFORMATION

You should read the following discussion and analysis in conjunction with our consolidated financial statements as of and for the years ended December 31, 2019, 2020 and 2021 and the six months ended June 30, 2022, including the notes thereto, as set forth in the Accountant’s Report in Appendix I to this document. You should read the entire Accountant’s Report in Appendix I to this document and not rely merely on the information contained in this section. The Accountant’s Report has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which may differ in material aspects from generally accepted accounting principles in other jurisdictions, including the United States.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance. These statements are based on our assumptions and analysis in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, whether actual outcomes and developments will meet our expectations and predictions depends on a number of risks and uncertainties. In evaluating our business, you should carefully consider the information provided in the sections headed “Risk Factors” and “Forward-looking Statements” 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 CHD, a major field of application for structural heart diseases, in terms of market share in China’s CHD occluder products market in 2021, with a broad portfolio of marketed and pipeline products, according to the F&S Report. We are the largest manufacturer of CHD occluder products and the related procedural accessories in China, with a market share of 38.0% in terms of revenue recognized for the sales in China in 2021, according to the same source. Our PFO occluder products and LAA occluder products target cardioembolic stroke and related symptoms, another major field of application for structural heart diseases. We have also cultivated the most comprehensive product portfolio of heart valve product candidates in China, with 21 major product candidates as of the Latest Practicable Date, 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.

We generate revenue primarily from the sale of interventional medical devices and associated procedural accessories. Our business grew rapidly during the Track Record Period. Our revenue increased by 27.3% from RMB116.5 million in 2019 to RMB148.2 million in 2020, and further increased by 50.1% to RMB222.6 million in 2021. Our revenue increased by 12.5% from RMB111.0 million in the six months ended June 30, 2021 to RMB124.8 million in the six months ended June 30, 2022. Our net profit increased by 32.5% from RMB51.9 million in 2019 to RMB68.8 million in 2020. Our net profit decreased by 14.6% to RMB58.7 million in 2021. Our net profit decreased by 41.9% from RMB41.8 million in the six months ended June 30, 2021 to RMB24.3 million in the six months ended June 30, 2022. Our net profit margin was 44.6%, 46.4%, 26.4%, 37.6% and 19.4% in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively.

FINANCIAL INFORMATION

KEY FACTORS AFFECTING OUR RESULTS OF OPERATIONS

We believe that the most significant factors affecting our results of operations and financial condition include the following.

Growth and Competitive Landscape of Our Industry

Our financial performance and future growth depend on the overall growth of and our competitiveness in the interventional medical device market targeting structural heart diseases. According to the F&S Report, the interventional medical device market targeting structural heart diseases in China is still at the emerging stage of development. With the increasing prevalence and awareness of structural heart diseases and the growing acceptance of interventional medical solutions, China’s interventional medical device market targeting structural heart diseases is expected to experience continuous growth, according to the same source. Moreover, favorable government policies and rapid technological innovation in the industry are also expected to drive the growth in the market demand. According to the F&S Report, the market size of China’s interventional medical device market targeting structural heart diseases in terms of revenue is expected to increase from RMB2.0 billion in 2021 to RMB10.4 billion in 2025 at a CAGR of 51.0%.

We have a product portfolio covering all of the major fields of application for structural heart diseases. We were the largest manufacturer of CHD occluder products and the related procedural accessories in China, with a market share of 38.0% in terms of revenue recognized for the sales in China in 2021, among the five major manufacturers with the total market share of 95.3%, according to the F&S Report. For cardioembolic stroke occluder products, both the PFO and the LAA occluder therapies are still in emerging stage with their first adoption in China in 2014, much later than drug treatment, and we are among the few early-movers in the markets. As of the Latest Practicable Date, there were only four players in China’s PFO occluder products market, including those with product candidates in the clinical trial stage, and only seven major players with commercialized products in China’s LAA occluder products market, according to the F&S Report. We also have the most comprehensive product portfolio of heart valve product candidates in China, with 21 major product candidates as of the Latest Practicable Date, according to the same source. There were only a few players in the interventional medical device market targeting valvular diseases in China with commercialized products.

While we believe we retain significant leadership and early-mover advantages in the relevant markets, we face competition from multi-national and domestic companies on the basis of numerous factors, including among others, product safety and efficacy, timing and scope of regulatory approvals, availability and cost of supply, marketing and sales capabilities, reimbursement coverage, product price, and patent position. We believe that, leveraging our leading position and comprehensive product portfolio, we are well-positioned to compete effectively and capitalize on the growth opportunities in the markets in which we operate, and we expect our business and financial performance to continue to improve in the future. Meanwhile, in order to achieve a larger market share, we must devote more managerial, financial and other resources to anticipate and respond to potential changes in market conditions and industry trends both in China and globally in a timely manner.

FINANCIAL INFORMATION

Development and Commercialization of Our Product Candidates

Our business and results of operations depend on our ability to successfully develop and commercialize our product candidates. We have been actively developing new products and upgrading existing products to support a more extensive portfolio of interventional medical devices, which we believe will diversify our revenue source and enable us to maintain sustainable growth. In 2022, we obtained the NMPA approval for our biodegradable VSD occluder in February 2022 and the NMPA approval for our interventional delivery system for biodegradable occluders in May 2022. From 2023 to 2024, we plan to launch 14 new products, including our biodegradable ASD occluder product candidate, biodegradable PFO occluder product candidate, TAVR system, and TMVr-A system, which are in various pre-launch stages. In addition, we have several product candidates currently at the product design and development stage, including artificial heart valve with polymer leaflets for transcatheter implantation and TTVRS. We aim to advance these product candidates to the clinical trial and registration stage rapidly to retain early-mover advantages among competitors. See “Business — Overview — Our Product Portfolio.” 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. We expect to continue to make significant investments in research and development to keep pace with the ever-changing market demands and the evolving technological landscape.

Our results of operations also depend on our ability to successfully commercialize our product candidates upon registration, which in turn depends upon the degree of market acceptance each of such product candidates achieves, particularly among hospitals and physicians. As of June 30, 2022, we had established a nationwide network of 288 distributors covering 878 hospitals. We are selective in engaging distributors and have generally developed longstanding and stable business relationships with our major distributors. We plan to leverage our accumulated experience and established sales channels in marketing our existing products to guide our future commercialization efforts.

Our Ability to Maintain Favorable Product Pricing

Our pricing directly affects our revenue and profitability. We consider various factors when pricing our products, such as bargaining power and preferences of hospitals, prices of similar products offered by our competitors, and our cost of sales and expenses. In addition, China’s healthcare regulatory framework has undergone significant changes in recent years, such as those concerning public tender process, medical insurance reimbursement, centralized procurement regime and two-invoice system, which may also affect our pricing and our results of operations.

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We generally sell our products at uniform ex-factory prices to our distributors in China. For our products sold overseas through the Retained Lepu Medical Group during the Track Record Period, the Retained Lepu Medical Group determined prices through commercial negotiations with sub-distributors based on a number of factors, primarily including the specific market conditions of each overseas market, product specifications, the scale and potential of overseas customers, their purchase amounts and the pricing of multinational competitors in the same market. With its long-standing experience and reputation in the overseas market and established sales network, the Retained Lepu Medical Group had been actively assisting us in the overseas sales since 2012. As a result, prior to 2020, for our products for onsale to overseas markets, we sold such products to the Retained Lepu Medical Group at prices calculated by adding a prevailing margin to our cost of production. As we had gradually built up our own brand recognition and sales capabilities, by the beginning of 2020, the contribution from the Retained Lepu Medical Group to the overseas distribution of our products had been reduced to such an extent that its involvement and functions became similar to our distributors in China. We and the Retained Lepu Medical Group have agreed to adjust the pricing model for our sales to the Retained Lepu Medical Group accordingly so that the consideration paid by the Retained Lepu Medical Group since the beginning of 2020 has been calculated based on an agreed discount, at prevailing market rates, to the price paid by the overseas sub-distributors, which has resulted in a substantial increase in our selling prices to the Retained Lepu Medical Group. The gross profit margin that we generated from our sales to the Retained Lepu Medical Group in 2020 was at the comparable rate with that generated from the sales to our other distributors that are independent third parties. Furthermore, we have gradually established direct business relationships with overseas distributors since 2021 and now sell our products to such distributors directly at prevailing market rates. See “Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement.”

For our direct sales, we participate in public tender processes to secure the right to sell our products to hospitals. 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, and our bidding prices would become the public prices of our products, which generally determine the maximum retail prices that we may offer to the hospitals in direct sales. See “Business — Sales, Distribution and Marketing — Pricing.”

Our Ability to Expand Our Sales Network

We generate the majority of our revenue from sales to distributors. As of June 30, 2022, for our domestic markets in China, we had 288 distributors covering all provinces, municipalities and autonomous regions in China. In addition, we historically sold our products to overseas distributors through the Retained Lepu Medical Group, and we had established direct business relationship with most of the overseas distributors by June 2021. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, revenue generated from sales to distributors was RMB106.8 million, RMB137.3 million, RMB209.0 million, RMB105.2 million and RMB121.0 million, respectively, representing 91.8%, 92.6%, 93.9%, 94.8% and 97.0% of our revenue for the same periods, respectively. Our ability to effectively maintain and

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expand our distribution network is critical to our business and financial performance. Going forward, we intend to further enhance our extensive distribution network by providing more technical training sessions to our distributors and assess their performance more frequently. Furthermore, we also plan to accelerate our penetration into global markets. See “Business — Growth Strategies — Expand our global footprint by increasing product development and commercialization and broadening overseas sales channels.”

To a lesser extent, we also sell products directly to hospitals. In 2019, 2020, 2021 and the six months ended June 30, 2022, we sold our products directly to 10, 12, nine and five hospitals, respectively, and recognized revenue of RMB9.6 million, RMB11.0 million, RMB13.6 million and RMB3.8 million, respectively, representing 8.2%, 7.4%, 6.1% and 3.0% of our revenue for the same periods, respectively. Our ability to improve brand recognition and promote product sales through our academic promotion, training and marketing activities will also impact our future performance. We plan to enlarge our sales and marketing team to support our market penetration strategy. As we continue to grow our business, we believe we are able to recoup our investments and maintain relatively stable profit margins.

Our Ability to Increase Operational Efficiency

Our ability to effectively control our cost of sales and expenses while achieving expected business growth is critical to our profitability. Our cost of sales consisted primarily of raw materials and consumables costs, employee benefit expense and depreciation and amortization costs. Our cost of sales was RMB13.6 million, RMB15.1 million, RMB25.0 million, RMB11.9 million and RMB15.3 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 11.7%, 10.2%, 11.2%, 10.7% and 12.3% of our revenue for the same periods, respectively. The prices of raw materials are determined principally by market forces. Any fluctuation in raw materials and consumables costs from current levels would impact our cost of sales and our profit margin. We have implemented a number of measures with respect to our raw material procurement process in order to mitigate the impact of shortage of and rising prices for principal raw materials, including monitoring inventory levels based on manufacturing forecast and maintaining a list of backup suppliers.

In addition, our business and results of operations are significantly affected by our operating expense structure, which primarily comprised research and development expenses, distribution expenses, and general and administrative expenses during the Track Record Period. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we incurred research and development expenses of RMB25.8 million, RMB39.0 million, RMB41.4 million, RMB16.4 million and RMB19.6 million, respectively, accounting for 22.2%, 26.3%, 18.6%, 14.8% and 15.7% of our revenue in the same periods, respectively. We expect that our research and development expenses will continue to contribute to a large proportion of our total operating expenses for the foreseeable future as we continue the clinical development of our product candidates and move product candidates currently at earlier stage into more advanced clinical trials. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we incurred distribution expenses of RMB21.8 million, RMB23.1 million, RMB43.1 million, RMB17.4 million and RMB16.6 million, respectively, accounting for 18.7%, 15.6%, 19.4%, 15.7% and 13.3% of our revenue in the same periods, respectively. As we expect to ramp up

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sales of our recently launched products and receive registration approvals for more product candidates, we will further increase our sales and marketing activities and expand our sales and marketing team, and our distribution expenses will increase accordingly. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, we incurred general and administrative expenses of RMB9.0 million, RMB8.4 million, RMB59.9 million, RMB24.5 million and RMB16.4 million, respectively, accounting for 7.7%, 5.7%, 26.9%, 22.0% and 13.1% of our revenue in the same periods, respectively. We expect to continue to increase our general and administrative expenses in the future to support our business expansion.

The decrease in the percentage of revenue for research and development expenses in 2021 was primarily because we began to capitalize the expenses associated with certain product candidates as they had fulfilled the prerequisites for clinical trials in the second half of 2020 or 2021 and therefore met the criteria for capitalization. As a percentage of revenue, our distribution expenses and general and administrative expenses decreased from 2019 to 2020, primarily reflected greater economies of scale as we continued to grow our business and the impact from the COVID-19 outbreak in 2020. The increase in the percentage of revenue for distribution expenses in 2021 was primarily due to (1) our increased sales and traveling activities 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 significant increase in the percentage of revenue for general and administrative expenses in 2021 was primarily due to the one-off [REDACTED] expenses of RMB32.7 million.

We expect our cost and expense structure to evolve as we continue to expand our business operation and develop and launch new products. Going forward, we will continue to endeavor to improve operating efficiency and achieve economies of scale to enhance our profit margin.

Regulatory Environment in China and Overseas

The medical device market in China is highly regulated. The implementation and enforcement of government policies and regulations in China generally have a significant impact on the supply, design, manufacture, price and sale of medical devices in China, which also increase the cost of compliance with such policies and regulations for medical device companies in China. Specifically, medical devices must be filed or registered with the NMPA or its local branches at the provincial or prefectural city level before they can be manufactured or commercialized in China, and such filing or registration must be renewed periodically. Any change in laws, regulations or policies in relation to such filing or registration could affect our ability and plans to launch new products and renew registration for products. For details, see “Regulatory Overview — PRC Laws and Regulations Relating to Medical Devices.” In recent years, our revenue and profitability have benefited from policies in China to support the development and innovation of medical devices, especially domestically developed and manufactured medical devices, such as “Made in China (2025),” “Healthy China 2030,” “13th Five-Year National Science and Technology Innovation Planning” and “13th Five-Year Special Plan for Medical Device Technology Innovations.”

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The regulatory framework for the medical device industry in China is continuously evolving. In recent years, the healthcare regulatory framework in China has undergone significant changes, including the centralized procurement regime and the two-invoice system, which may affect our financial condition and results of operations. The PRC government has adopted a centralized procurement regime in an effort to regulate prices of certain types of medical devices with huge consumption through group procurement at the provincial level, which may exert downward pressure on the pricing of medical devices that are included under such regime. During the Track Record Period and up to the Latest Practicable Date, none of our medical devices was included under the said centralized procurement regime in China. However, we may face downward pricing pressure if our products are included in the centralized procurement regime or additional products of ours are included in the medical insurance reimbursement list, even if such inclusions are expected to increase the sales volume of our products. See “Business — Sales, Distribution and Marketing — Pricing.” 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.” For our domestic markets in China, we require our distributors not to sell our products to sub-distributors. 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. Therefore, the two-invoice system did not have any material effect on our financial condition and results of operations during the Track Record Period. See “Business — Sales, Distribution and Marketing.”

However, as the implementation of the centralized procurement regime and the two-invoice system is still at an early stage, and the relevant interpretations and enforcement continue to evolve, the actual effect of the centralized procurement regime and the two-invoice system on our future results of operations remains uncertain.

Furthermore, regulatory authorities outside of China also have requirements for approval of medical devices for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country, and the foreign regulatory approval process can be lengthy, costly and unpredictable.

Impact from COVID-19 and Other Pandemics

Our business and results of operations depend on our ability to effectively deal with outbreak of health pandemics, natural disasters and other extraordinary events. For example, since the outbreak of COVID-19 throughout China and other countries and regions, a number 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. As a result, the medical device industries have been negatively impacted, which in turn adversely affected our business, results

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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 the reduced demand among hospitals for medical devices along with 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.

The Chinese government gradually lifted the domestic travel restrictions and other quarantine measures, and economic activities began to recover and return to normal nationwide since the second quarter of 2020. 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. We cannot predict whether or when the impact from COVID-19 will be eradicated, and our business operations could also be adversely affected by other public health threats or pandemics. See “— COVID-19 Outbreak and Effects on Our Business” for the impact of COVID-19 outbreak on our business and “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” for the associated risks and challenges.

BASIS OF PRESENTATION

Pursuant to the Reorganization, as more fully explained in “History, Reorganization and Corporate Structure — Our Corporate Development,” our Company became the holding company of the companies now comprising our Group on January 29, 2021. The companies now comprising our Group were under the common control of Lepu Medical before and after the Reorganization. Accordingly, our financial statements for the Track Record Period have been presented on a consolidated basis by applying the principles of merger accounting as if the Reorganization had been completed at the beginning of the Track Record Period.

The consolidated statements of profit or loss and other comprehensive income, statements of changes in equity and statements of cash flows of our company for the Track Record Period include the results and cash flows of all companies now comprising our Company from the earliest date presented. The consolidated statements of financial position of our Company as of December 31, 2019, 2020 and 2021 and June 30, 2022 have been prepared to present the assets and liabilities of the subsidiaries now comprising our Company using the existing book values from Lepu Medical’s perspective. No adjustments are made to reflect fair values, or recognize any new assets or liabilities as a result of the Reorganization.

Our consolidated financial information has been prepared in accordance with all applicable IFRSs issued by International Accounting Standards Board (“IASB”). The historical financial information has been prepared under the historical cost convention, as modified by the revaluation of financial assets and financial liabilities at fair value through other comprehensive income, which were carried at fair value. The historical financial information has been prepared on a going concern basis.

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SIGNIFICANT ACCOUNTING POLICIES, JUDGMENTS AND ESTIMATES

We have identified certain accounting policies that we believe are most significant to the preparation of our consolidated financial statements. Our significant accounting policies and estimates, which are important for understanding our results of operations and financial condition, are set forth in Note 2 to the Accountant's Report in Appendix I to this document. Some of the accounting policies involve subjective assumptions and estimates, as well as complex judgements relating to accounting items. In each case, the determination of these items requires management judgment based on information and financial data that may change in future periods. When reviewing our financial statements, you should consider (1) our selection of critical accounting policies, (2) the judgment and other uncertainties affecting the application of such policies, and (3) the sensitivity of reported results to changes in conditions and assumptions. We believe the significant accounting policies of "property, plant and equipment," "impairment of non-financial assets," "investments and other financial assets," "inventories," "trade receivables," "current and deferred income tax," "redemption liabilities" and "revenue recognition" as set forth in details in Note 2.7, Note 2.11, Note 2.12, Note 2.14, Note 2.15, Note 2.19, Note 2.23 and Note 2.24 to the Accountant's Report in Appendix I to this document, are critical and involve the most significant estimates and judgment used in the preparation of our financial statements.

Revenue Recognition

Revenue is recognized as and when our Group's obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Group expects to receive in exchange for transferring products or services to a customer.

Inventories

Raw materials and stores, work in progress, and finished goods are stated at the lower of cost and net realizable value. Costs are assigned to individual items of inventory based on weighted average costs. Costs of purchased inventory are determined after deducting rebates and discounts. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

Trade Receivables

Trade receivables are amounts due from customers for goods sold in the ordinary course of business. They are generally due for settlement within one year and, therefore, all classified as current.

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Trade receivables are recognized initially at the unconditional amount of consideration unless they contain significant financing components when they are recognized at fair value. The Group holds the trade receivables intending to collect the contractual cash flows and therefore measures them subsequently at amortized cost using the effective interest method.

Property, Plant and Equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset’s carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to profit or loss during the reporting period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate their cost or revalued amounts, net of their residual values, over their estimated useful lives as follows:

- | | |
|------------------------|-------------|
| • Buildings | 25-40 years |
| • Machinery | 5-10 years |
| • Vehicles | 3-12 years |
| • Electronic equipment | 3 years |
| • Others | 3-10 years |

Investments and other financial assets

Classification

We classify our financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through other comprehensive income or through profit or loss); and
- those to be measured at amortized cost.

The classification depends on our business model for managing the financial assets and the contractual terms of the cash flows.

For assets measured at fair value, gains and losses will either be recorded in profit or loss or other comprehensive income. For investments in equity instruments that are not held for trading, the classification will depend on whether we have made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income.

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We reclassify debt investments when and only when our business model for managing those assets changes.

Recognition and derecognition

Regular-way purchases and sales of financial assets are recognized on trade date, the date on which we commit to purchase or sell the asset. Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and we have transferred substantially all the risks and benefits of ownership.

Measurement

At initial recognition, we measure a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at fair value through profit or loss are expensed in profit or loss.

Debt instruments

Subsequent measurement of debt instruments depends on our business model for managing the asset and the cash flow characteristics of the asset. There are three measurement categories into which we classify its debt instruments:

- **Amortized cost:** Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortized cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on derecognition is recognized directly in profit or loss and presented in other income and gains – net together with foreign exchange gains and losses. Impairment losses are presented as a separate line item in the consolidated statement of profit or loss and other comprehensive income.
- **Fair value through other comprehensive income:** Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets’ cash flows represent solely payments of principal and interest, are measured at fair value through other comprehensive income. Movements in the carrying amount are taken through other comprehensive income, except for the recognition of impairment gains or losses, interest income and foreign exchange gains and losses which are recognized in profit or loss. When the financial asset is derecognized, the cumulative gains or losses previously recognized in other comprehensive income will be reclassified from equity to profit or loss and recognized in other income and gains – net. Interest income from these financial assets is included in finance income

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using the effective interest rate method. Foreign exchange gains and losses are presented in other income and gains – net and impairment expenses are presented as a separate line item in the consolidated statement of profit or loss and other comprehensive income.

- Fair value through profit or loss: Assets that do not meet the criteria for amortized cost or fair value through other comprehensive income are measured at fair value through profit or loss. A gain or loss on a debt investment that is subsequently measured at fair value through profit or loss is recognized in profit or loss and presented net within other income and gains – net in the period in which it arises.

Equity instruments

We subsequently measure all equity investments at fair value. Where our management has elected to present fair value gains and losses on equity investments in other comprehensive income, there is no subsequent reclassification of fair value gains and losses to profit or loss following the derecognition of the investment. Dividends from such investments continue to be recognized in profit or loss as other income when our right to receive payments is established.

Changes in the fair value of financial assets at fair value through profit or loss are recognized in other income and gains – net in the consolidated statement of profit or loss and other comprehensive income as applicable. Impairment losses (and reversal of impairment losses) on equity investments measured at fair value through other comprehensive income are not reported separately from other changes in fair value.

Impairment

We assess on a forward-looking basis the expected credit loss associated with our debt instruments carried at amortized cost and fair value through other comprehensive income. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

For trade receivables, we apply the simplified approach permitted by IFRS 9, which requires expected lifetime losses to be recognized from initial recognition of the receivables. See Notes 3.1(b) and 23 to the Accountant’s Report in Appendix I to this document for further details.

Impairment of non-financial assets

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset’s carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset’s fair

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value, less cost of disposal costs, and value in use. For the purposes of assessing impairments, assets are grouped at the lowest levels. There are separately identifiable cash inflows largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

Current and deferred income tax

The income tax expense or credit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and unused tax losses.

(a) Current income tax

The current income tax charge is calculated on the basis of the tax laws enacted at the end of the reporting period in the countries where the Group operates and generates taxable income.

Management periodically evaluates positions taken in tax returns concerning situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

(b) Deferred income tax

Deferred income tax is provided in full, using the liability method, on temporary differences between the tax bases of assets and liabilities and their carrying amounts in the financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized, or the deferred income tax liability is settled.

Deferred income tax assets are recognized only if it is probable that future taxable amounts will be available to utilize those temporary differences and losses.

Deferred income tax liabilities and assets are not recognized for temporary differences between the carrying amount and tax bases of investments in foreign operations where the Group is able to control the timing of the reversal of the temporary differences, and, probably, the differences will not reverse in the foreseeable future.

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Deferred income tax assets and liabilities are offset where there is a legally enforceable right to offset current tax assets and liabilities and where the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset. The entity has a legally enforceable right to offset and intends to settle on a net basis or realize the asset and settle the liability simultaneously.

Current and deferred income tax is recognized in profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

Redemption liabilities

A contract that contains an obligation to purchase our equity instruments for cash or other financial assets gives rise to a financial liability for the present value of the redemption amount, even if such obligation to purchase is conditional on the counter party exercising a right to redeem. We undertake such redemption obligations as certain preferred rights granted to investors in the financing process. The related redemption liabilities are recognized as financial liabilities initially at the present value of the redemption amount and reclassified from equity. Subsequently, the redemption liabilities are measured at amortized cost with interest charged in finance costs.

We de-recognize the redemption liabilities when, and only when, the obligations are discharged, cancelled or have expired. When the preferred rights are waived by investors, the carrying amount of the redemption liability is reclassified back to equity.

Deemed distributions and deemed contributions

Shanghai Shape Memory Alloy disposed of its entire equity interest in Ningbo Bingkun to Lepu Medical at a consideration of RMB1,098,000,000 in December 2020. Part of the disposal consideration of RMB658,800,000 was received by Shanghai Shape Memory Alloy in December 2020 and the remaining consideration of RMB439,200,000 was received by our Company in January 2021. The cash receipts of the disposal consideration have been accounted for as deemed contributions from Lepu Medical.

As part of the Reorganization, Shanghai Shape Memory Alloy has acquired the interventional heart valve business from Lepu Medical at an aggregate consideration of approximately RMB72,167,000, which was treated as a deemed distribution to the shareholders of our Group. The net assets and financial results attributable to the interventional heart valve business have been included in our historical financial information based on the basis of presentation. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, the cash as injected by Lepu Medical for the development of the interventional heart valve business of RMB19,604,000, RMB33,546,000, RMB6,879,000, RMB6,879,000 and nil, respectively, have been accounted for as deemed contributions from Lepu Medical.

See Note 27(a) to the Accountant’s Report in Appendix I to this document for details.

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DESCRIPTION OF CERTAIN CONSOLIDATED STATEMENTS OF PROFIT OR LOSS ITEMS

The following table sets forth a summary of our consolidated statements of profit or loss for the periods indicated. Our historical results presented below are not necessarily indicative of the results that may be expected for any future period.

	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)
Gross profit	102,832	88.3	133,113	89.8	197,545	88.8	99,084	89.3	109,482	87.7
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 – net	15,746	13.5	13,238	8.9	22,642	10.2	4,401	4.0	(18,289)	(14.7)
Operating profit	60,219	51.7	76,537	51.6	76,387	34.3	45,663	41.1	34,359	27.5
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)
Profit before income tax	60,346	51.8	76,679	51.7	66,027	29.7	44,970	40.5	25,306	20.3
Income tax expense	(8,437)	(7.2)	(7,907)	(5.3)	(7,330)	(3.3)	(3,203)	(2.9)	(1,051)	(0.8)
Profit for the year/period	51,909	44.6	68,772	46.4	58,697	26.4	41,767	37.6	24,255	19.4

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Revenue

During the Track Record Period, we generated revenue primarily from the sales of medical devices through distributors and direct sales.

Major Product

In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, our revenue was RMB116.5 million, RMB148.2 million, RMB222.6 million, RMB111.0 million and RMB124.8 million, respectively. 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	56,058	48.1	69,677	47.0	99,809	44.8	47,791	43.1	71,270	57.1
VSD occluder products	19,322	16.6	22,076	14.9	19,771	8.9	9,958	9.0	10,287	8.2
PDA occluder products	11,336	9.8	14,856	10.0	12,893	5.8	6,374	5.7	9,142	7.3
Occluder related procedural accessories	28,912	24.8	32,004	21.6	41,568	18.7	18,385	16.6	27,060	21.7
Interventional delivery systems	17,036	14.6	18,418	12.4	25,296	11.4	11,161	10.1	18,216	14.6
Snares	11,876	10.2	13,586	9.2	16,272	7.3	7,224	6.5	8,844	7.1
PFO and LAA occluder products	474	0.4	9,524	6.4	48,457	21.8	28,424	25.6	6,980	5.6
PFO occluder products	474	0.4	1,201	0.8	4,307	1.9	1,175	1.1	3,215	2.6
LAA occluder products	-	-	8,323	5.6	44,150	19.8	27,249	24.6	3,765	3.0
Other products	349	0.3	110	0.1	85	0.0	36	0.0	66	0.1
Total	<u>116,451</u>	<u>100.0</u>	<u>148,247</u>	<u>100.0</u>	<u>222,583</u>	<u>100.0</u>	<u>110,968</u>	<u>100.0</u>	<u>124,804</u>	<u>100.0</u>

CHD Occluder Products

During the Track Record Period, a majority of our revenue was generated from sales of CHD occluder products. Revenue generated from sales of CHD occluder products increased from RMB86.7 million in 2019 to RMB132.5 million in 2021 and from RMB64.1 million in the six months ended June 30, 2021 to RMB90.7 million in the six months ended June 30, 2022, as we continued to grow our business. As a percentage of revenue, sales of CHD occluder products decreased from 74.5% in 2019 to 59.5% in 2021, consistent with the diversification of our product offerings. The percentage increased from 57.8% in the six months ended June 30, 2021 to 72.7% in the six months ended June 30, 2022, primarily due to the increased sales

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volume of our oxide-coated occluder products as they received broad market acceptance, including primarily MemoCarna[®] ASD Occluder III, MemoCarna[®] PDA Occluder III and MemoCarna[®] VSD Occluder III.

Among our CHD occluder products, revenue generated from sales of ASD occluder products increased from RMB56.1 million in 2019 to RMB99.8 million in 2021 and from RMB47.8 million in the six months ended June 30, 2021 to RMB71.3 million in the six months ended June 30, 2022. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, revenue generated from sales of ASD occluder products accounted for 48.1%, 47.0%, 44.8%, 43.1% and 57.1% of our revenue in the same periods, respectively. The percentage of revenue of ASD occluder products increased from the six months ended June 30, 2021 to the six months ended June 30, 2022, primarily attributable to revenue generated from MemoCarna[®] ASD Occluder III, which 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. Revenue generated from sales of VSD occluder products increased from RMB19.3 million in 2019 to RMB19.8 million in 2021 and from RMB10.0 million in the six months ended June 30, 2021 to RMB10.3 million in the six months ended June 30, 2022. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, revenue generated from sales of VSD occluder products accounted for 16.6%, 14.9%, 8.9%, 9.0% and 8.2% of our revenue in the same periods, respectively. Revenue generated from sales of PDA occluder products increased from RMB6.4 million in the six months ended June 30, 2021 to RMB9.1 million in the six months ended June 30, 2022, representing 5.7% and 7.3% of our revenue in the same periods, respectively. The percentage of revenue of PDA occluder products increased from the six months ended June 30, 2021 to the six months ended June 30, 2022, primarily due to the launch of MemoCarna[®] PDA Occluder III in May 2021, which started to generate revenue in the second half of 2021.

Occluder Related Procedural Accessories

Revenue generated from sales of occluder related procedural accessories was RMB28.9 million, RMB32.0 million, RMB41.6 million, RMB18.4 million and RMB27.1 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing 24.8%, 21.6%, 18.7%, 16.6% and 21.7% of our revenue in the same periods, respectively. Our occluder related procedural accessories primarily include delivery systems and snares mainly related to CHD occluder products. Interventional delivery system is the largest source of our revenue generated from sales of occluder related procedural accessories. We also intend to gradually introduced other occluder related procedural accessories and heart valve related procedural accessories.

PFO and LAA Occluder Products

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

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generate revenue in the second half of 2020. Revenue generated from sales of LAA occluder products decreased from RMB27.2 million in the six months ended June 30, 2021 to RMB3.8 million in the six months ended June 30, 2022, representing 24.6% and 3.0% of our revenue in the same periods, respectively. The decrease in the first half of 2022 was primarily due to our limited technical training and surgical assistance capabilities amid the regional resurgence of COVID-19 in Shanghai, which were critical for the implantation of LAA occluder products and therefore the related sales. The sales volume of our LAA occluder products was relatively high in the six months ended June 30, 2021 as our first generation LAA occluder product launched in June 2020 quickly captured the market potential with its compelling therapeutic effects, backed by our continued investments in the related academic promotion activities and market fairs.

Other Products

During the Track Record Period, we generated a small portion of our revenue from sales of other products, primarily including vascular plug and products with relatively low applicability or importance. Revenue generated from sales of other products was RMB0.3 million, RMB0.1 million, RMB85,000, RMB36,000 and RMB66,000 in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, accounting for 0.3%, 0.1%, 0.0%, 0.0% and 0.1% of our revenue in the same periods, respectively.

Sales Channel

During the Track Record Period, we primarily sold our products to our distributors, and to a lesser extent, directly to hospitals. The following table sets forth 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
Total	116,451	100.0	148,247	100.0	222,583	100.0	110,968	100.0	124,804	100.0

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Our revenue generated from direct sales to hospitals increased from RMB9.6 million in 2019 to RMB13.6 million in 2021, while decreased from RMB5.7 million in the six months ended June 30, 2021 to RMB3.8 million in the six months ended June 30, 2022. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, revenue generated from direct sales to hospitals accounted for 8.2%, 7.4%, 6.1%, 5.2% and 3.0% of our revenue in the same periods, respectively. Revenue generated from sales to distributors increased from RMB106.8 million in 2019 to RMB209.0 million in 2021, and from RMB105.2 million in the six months ended June 30, 2021 to RMB121.0 million in the six months ended June 30, 2022. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, revenue generated from sales to distributors accounted for 91.8%, 92.6%, 93.9%, 94.8% and 97.0% of our revenue in the same periods, respectively. Among the revenue generated from sales to distributors, revenue generated from sales to the Retained Lepu Medical Group was 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. 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.” 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.

Cost of 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 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. The following table sets forth a breakdown of our cost of sales by nature 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>									
Raw materials and consumables	5,620	41.3	5,852	38.7	10,300	41.1	5,764	48.5	5,719	37.3
Employee benefit expense	4,716	34.6	4,793	31.7	7,224	28.9	3,061	25.8	4,667	30.5
Amortization of intangible assets	239	1.8	1,500	9.9	4,168	16.6	1,360	11.4	3,344	21.8
Transportation costs	868	6.4	784	5.2	1,112	4.4	474	4.0	487	3.2

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	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>									
Depreciation of property, plant and equipment	805	5.9	803	5.3	839	3.4	405	3.4	782	5.1
Utilities and office expenses	436	3.2	412	2.7	659	2.6	265	2.2	236	1.5
Others ⁽¹⁾	935	6.8	990	6.5	736	3.0	555	4.7	87	0.6
Total	13,619	100.0	15,134	100.0	25,038	100.0	11,884	100.0	15,322	100.0

(1) Others primarily include testing fees for production environment and fees for sterilization.

Raw materials and consumables costs represent nitinol products and sheathes and other metal and plastic components used during the manufacturing process. From 2019 to 2021, the increase in raw materials and consumables costs was primarily due to increase in our sales of products and high raw materials and consumables costs in our newly launched products. Our employee benefit expense as a percentage of our total cost of sales decreased from 2019 to 2021, primarily due to greater economies of scale as we continued to grow our business. Our employee benefit expense increased from RMB4.8 million to RMB7.2 million from 2020 to 2021, and from RMB3.1 million in the six months ended June 30, 2021 to RMB4.7 million in the six months ended June 30, 2022, primarily due to increased manpower investment in our manufacturing process as a result of the more complicated manufacturing procedures required for our MemoCarna[®] ASD Occluder III and MemoLefort[®] LAA Occluder I launched in mid-2020, as well as MemoCarna[®] PDA Occluder III launched in May 2021 and MemoCarna[®] VSD Occluder III launched in July 2021. Amortization of intangible assets increased significantly during the Track Record Period, which was primarily because the patents and medical device registration certificates of our certain products commenced amortization as such products obtained their respective NMPA approvals. Transportation costs decreased from 2019 to 2020 primarily due to bulk purchases and fewer lots of product deliveries in 2020 amid the COVID-19 outbreak. Depreciation of property, plant and equipment increased in 2021 and the six months ended June 30, 2022, primarily because we purchased additional equipment for our manufacturing activities. Utilities and office expenses decreased from 2019 to 2020, primarily due to our cost control measures and a decrease in the usage of office appliances in the first half of 2020 during the COVID-19 outbreak.

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The following table sets forth a breakdown of our cost of sales by product type 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	5,333	39.2	4,857	32.1	7,364	29.4	3,229	27.2	5,430	35.4
Occluder related procedural accessories	8,049	59.1	7,797	51.5	9,788	39.1	4,153	34.9	8,641	56.4
PFO and LAA occluder products	201	1.5	2,454	16.2	7,822	31.2	4,490	37.8	1,209	7.9
Other products	36	0.3	26	0.2	64	0.3	12	0.1	42	0.3
Total cost of sales	<u>13,619</u>	<u>100.0</u>	<u>15,134</u>	<u>100.0</u>	<u>25,038</u>	<u>100.0</u>	<u>11,884</u>	<u>100.0</u>	<u>15,322</u>	<u>100.0</u>

The decrease in the percentage of cost of sales of CHD occluder products and occluder related procedural accessories and the increase in the percentage of cost of sales of PFO and LAA occluder products from 2019 to 2021 generally reflected (1) the diversification of our product offerings, particularly the ramp-up in the sales of LAA occluder products, and (2) the decrease in the sales of our CHD occluder products amid the COVID-19 outbreak. The increase in the percentage of cost of sales of CHD occluder products and occluder related procedural accessories and the decrease in the percentage of cost of sales of PFO and LAA occluder products in the six months ended June 30, 2022 generally reflected the changes in related sales volumes.

Gross Profit and Gross Profit Margin

In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, our gross profit was RMB102.8 million, RMB133.1 million, RMB197.5 million, RMB99.1 million and RMB109.5 million, respectively, representing relatively stable gross profit margin at 88.3%, 89.8%, 88.8%, 89.3% and 87.7%, respectively, for the same periods. The gross profit margin for CHD occluder products is generally higher than occluder related procedural accessories and other products, primarily due to the higher pricing for our CHD occluder products as a result of more sophisticated manufacturing process used in CHD occluder products. Moreover, the gross profit margin for CHD occluder products is higher than that of PFO and LAA occluder products, primarily due to greater economies of scale for CHD occluder products as a result of the larger production volumes and more streamlined and standardized manufacturing processes.

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

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin
	<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	313	89.7	84	76.4	21	25.8	24	66.7	24	36.1
Total	102,832	88.3	133,113	89.8	197,545	88.8	99,084	89.3	109,482	87.7

The following table sets forth our gross profit margin by sales channels for the periods indicated.

	Year ended December 31,						Six months ended June 30,			
	2019		2020		2021		2021		2022	
	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin	Amount	Gross profit margin
	<i>(RMB in thousands, except for percentages)</i>									
	<i>(Unaudited)</i>									
Sales to distributors	93,606	87.6	122,489	89.2	184,642	88.3	93,557	88.9	105,962	87.6
– Sales to the Retained Lepu Medical Group	6,573	64.4	28,362	91.4	14,219	89.1	10,372	90.4	2,242	87.6
– Sales to other distributors	87,033	90.1	94,127	88.6	170,422	88.3	83,185	88.7	103,720	87.6
– For domestic market	87,033	90.1	94,127	88.6	159,723	88.2	82,211	88.7	87,680	87.8
– For overseas markets	–	–	–	–	10,699	88.8	974	90.1	16,039	86.0
Direct sales to hospitals	9,226	96.1	10,624	96.7	12,904	95.1	5,527	96.4	3,520	93.0
Total	102,832	88.3	133,113	89.8	197,545	88.8	99,084	89.3	109,482	87.7

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Our gross profit margin for sales to independent third party distributors and direct sales to hospitals remained relatively stable during the Track Record Period. Our gross profit margin for sales to the Retained Lepu Medical Group increased significantly in 2020, primarily due to the increase in pricing per unit for our products sold overseas through the Retained Lepu Medical Group. See “— Revenue — Sales Channel” and “Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement.”

In 2020, our gross profit margin for sales to the Retained Lepu Medical Group was 91.4%, higher than that for sales to other distributors at 88.6%, primarily because revenue generated from sales of CHD occluder products, with higher gross profit margin of 95.4% compared to that for other product types, accounted for 81.1% of the revenue generated from sales to the Retained Lepu Medical Group, while for only 67.8% of the revenue generated from sales to other distributors, in the same year. In addition, our gross profit margin in 2020 for sales to other distributors was to some extent negatively affected due to the launch of our LAA occluder product in June 2020, which was distributed solely in domestic market through independent third party distributors and had relatively lower gross profit margin compared to that for CHD occluder products, primarily due to the greater economies of scale as a result of the larger production volumes and more streamlined and standardized manufacturing processes for CHD occluder products. However, it did not have a similar effect on the gross profit margin for overseas markets, which constituted the majority part for our sales to the Retained Lepu Medical Group. Therefore, the gross profit margin for sales to our other distributors, which was solely in connection with domestic distribution, was relatively lower for 2020 compared with that for sales to the Retained Lepu Medical Group, which was mainly for further distribution in overseas markets.

Distribution Expenses

Our distribution expenses consisted primarily of employee benefit expense for our sales and marketing staff, marketing and consulting fees, travel expenses, and taxes and surcharges fees. 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 greater 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 was primarily due to (1) our increased sales and traveling activities 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 was primarily due to the decreased travel expenses and marketing and consulting fees amid the regional resurgence of COVID-19 in Shanghai, partially offset by an increase in employee benefit expense as a result of our enlarged sales and marketing team to accommodate our expanding product pipeline and business scale.

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The following table sets forth a breakdown of our distribution expenses 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>									
Employee benefit expense	6,254	28.7	7,867	34.0	18,699	43.4	6,664	38.3	9,208	55.4
Marketing and consulting fees	8,282	38.1	9,204	39.8	14,370	33.4	5,238	30.1	4,500	27.1
Travel expenses	4,561	21.0	3,326	14.4	5,590	13.0	2,702	15.5	1,151	6.9
Taxes and surcharges fees	2,412	11.1	2,427	10.5	3,744	8.7	2,406	13.8	1,693	10.2
Others ⁽¹⁾	251	1.1	322	1.3	669	1.5	373	2.1	74	0.4
Total	21,760	100.0	23,146	100.0	43,072	100.0	17,383	100.0	16,626	100.0

(1) Others primarily include utilities and office expenses and depreciation.

Marketing and consulting fees represent promotion fees and consulting services fees, as part of our sales and marketing efforts in expanding our business. Consulting services fees primarily represent consultation and market research service fees. See “Business — Sales, Distribution and Marketing — Marketing Model.” Marketing and consulting fees increased from 2019 to 2021, which primarily reflected our academic promotion activities and market fairs for our newly launched LAA occluder products in 2020, and the increased sales activities driven by the effective containment of the COVID-19 outbreak in China and the new products launched in mid-2020 and 2021. Marketing and consulting fees decreased from the six months ended June 30, 2021 to the six months ended June 30, 2022, primarily due to our decreased sales and traveling activities amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022.

General and Administrative Expenses

Our general and administrative expenses consisted primarily of employee benefit expense for our administrative staff, depreciation and amortization, office, travel and miscellaneous expenses and [REDACTED] expenses. 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 greater economies of scale as we continued to grow our business and the impact of 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].

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The decrease in the six months ended June 30, 2022 as compared to the same period in 2021 was primarily due to a decrease in [REDACTED] expenses, partially offset by an increase in employee benefit expenses primarily in relation to share-based compensation to motivate our management team.

The following table sets forth a breakdown of our general and administrative expenses 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>									
Employee benefit expense	4,237	47.2	3,889	46.4	17,141	28.6	4,523	18.5	9,045	55.2
Depreciation and amortization	3,039	33.8	2,879	34.3	2,728	4.6	1,325	5.4	1,182	7.2
Office, travel and miscellaneous expenses	1,031	11.5	1,133	13.5	2,359	3.9	607	2.5	508	3.1
[REDACTED] expenses	-	-	-	-	32,690	54.6	17,219	70.4	5,124	31.2
Others ⁽¹⁾	674	7.5	482	5.8	4,956	8.3	783	3.2	543	3.3
Total	8,981	100.0	8,383	100.0	59,874	100.0	24,457	100.0	16,402	100.0

(1) Others primarily include recruitment fees, insurance fees, consulting fees and courier fees.

Research and Development Expenses

Our research and development expenses consisted primarily of employee benefit expense for our research and development staff, testing and animal studies fees, raw materials and consumables expenses, depreciation, and utilities and office expenses. 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 portion of the employee benefit expense and raw materials and consumables expenses relating to the development of MemoSorb[®] PFO Occluder II, TAVR system, balloon dilatation catheter for aortic valve, MemoSorb[®] 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

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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 “— Discussion of Major Balance Sheet Items — Intangible Assets” and Note 18 to the Accountant’s Report in Appendix I to this document.

The following table sets forth a breakdown of our research and development expenses 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>									
Employee benefit expense	16,053	62.1	15,813	40.6	15,482	37.4	4,525	27.5	8,228	41.9
Testing and animal studies fees	2,606	10.1	11,739	30.1	11,254	27.2	5,535	33.7	2,807	14.3
Raw materials and consumables	4,129	16.0	6,834	17.6	9,536	23.0	4,817	29.3	5,704	29.0
Depreciation	1,235	4.8	2,222	5.7	2,020	4.9	814	4.9	1,443	7.3
Utilities and office expenses	618	2.4	907	2.3	368	0.9	19	0.1	247	1.3
Others ⁽¹⁾	1,189	4.6	1,442	3.7	2,727	6.6	736	4.5	1,208	6.2
Total	25,830	100.0	38,957	100.0	41,387	100.0	16,446	100.0	19,637	100.0

(1) Others primarily include travel expenses and training expenses.

Net provision for/(reversal of) impairment losses on financial assets

Our net provision for impairment losses on financial assets primarily represented impairment loss provision for the period from trade receivable and other receivables. Our net reversal of impairment losses on financial assets primarily represented reversal of such impairment losses. In 2019, our net provision for impairment losses on financial assets was RMB1.8 million, representing 1.5% of our revenue for the same period. In 2020 and 2021, we recorded net reversal of impairment losses on financial assets of RMB0.7 million and RMB0.5 million, respectively, representing 0.5% and 0.2% of our revenue for the same periods, respectively. In the six months ended June 30, 2021 and 2022, we recorded net reversal of impairment losses on financial assets of RMB0.5 million and net provision for impairment losses on financial assets of RMB4.2 million, respectively, representing 0.4% and 3.3% of our revenue for the same periods, respectively. Net provision for loss allowance on trade receivables increased in the six months ended June 30, 2022 as compared to the same period in 2021, primarily because of the increase in our trade receivables as of June 30, 2022, primarily due to an increase in the trade receivables due from our third-party customers as a result of (1) the extended payment cycle caused by the regional resurgence of COVID-19 in Shanghai in the first half of 2022, (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. See “– Discussion on Major Balance Sheet Items – Trade Receivables.”

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The following table sets forth a breakdown of our net provision for/(reversal of) impairment losses on financial assets 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>	
<i>Net provision</i>					
<i>for/(reversal of) loss</i>					
<i>allowance on:</i>					
– trade receivables	1,622	(1,152)	939	1,040	3,621
– other receivables	166	480	(1,472)	(1,504)	548
Total	1,788	(672)	(533)	(464)	4,169

Other Income and Gains/(Losses) – Net

Our other income and gains/(losses) – net consisted primarily of government grants, gains on disposal of investment properties, and rental income from investment properties. Our other income and gains – net was RMB15.7 million, RMB13.2 million, RMB22.6 million and RMB4.4 million in 2019, 2020, 2021 and the six months ended June 30, 2021, respectively, and our other losses – net was RMB18.3 million in the six months ended June 30, 2022, representing 13.5%, 8.9%, 10.2%, 4.0% and 14.7% of our revenue for the same periods, respectively.

The following table sets forth a breakdown of our other income and gains/(losses) – net 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>	
Government grants	8,998	5,630	7,743	4,476	2,574
Commission income from related party ⁽¹⁾	–	–	–	–	734
Rental income from investment properties	3,027	2,454	2,564	1,253	215
Investment income on wealth management products	–	–	6,669	–	4,809
Others ⁽²⁾	1,234	249	414	378	40
Total other income – net	13,259	8,333	17,390	6,107	8,372

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	Year ended December 31,			Six months ended June 30,	
	2019	2020	2021	2021	2022
	<i>(RMB in thousands)</i>				
	<i>(Unaudited)</i>				
Gains on disposal of investment properties	2,436	5,111	–	–	–
Fair value gains on financial assets at fair value through profit or loss	–	–	–	–	4
Net loss on disposal of financial assets at fair value through other comprehensive income	–	(139)	–	–	–
Net loss on disposal or write-off of property, plant and equipment	(9)	(19)	(1)	(1)	(1)
Net foreign exchange gains/(losses)	–	–	5,192	(1,766)	(26,864)
– in relation to the retranslation of redemption liabilities resulted from exchange rate fluctuations	–	–	2,837	(4,678)	(30,352)
– in relation to the retranslation of cash and cash equivalents resulted from exchange rate fluctuations	–	–	2,355	2,912	3,382
– arising from operation	–	–	–	–	106
Others	60	(48)	61	61	200
Total other gain/(loss) – net	2,487	4,905	5,252	(1,706)	(26,661)
Total	15,746	13,238	22,642	4,401	(18,289)

(1) Represents the commission income in relation to the distribution of COVID-19 antigen reagents primarily to the local government, where we acted as an agent following the instructions from a subsidiary of Lepu Medical, amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022. See Note 21(a) to the Accountant’s Report included in Appendix I to this document for details.

(2) Represents primarily (i) the income generated through certain advisory services unrelated to our principal business operations in connection with the distribution of surgical dressing products for an independent third party, which was terminated in the second half of 2019, and (ii) the income generated through certain testing services.

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Investment and treasury management policies

We believe making appropriate investments in short-term investment products will optimize our cash position and potential return, which would generate income without interfering with our business operation or capital expenditures. Our investment decisions with respect to financial products are made on a case-by-case basis and after due and careful consideration of a number of factors, including the overall economic developments in China, the market conditions, the anticipated investment conditions, the investment cost, the duration of the investment and the expected benefit and potential loss of the investment.

Our senior management and the finance department are mainly responsible for making, implementing and supervising our investment decisions. We have established a set of internal control measures which allow us to achieve reasonable returns on our investment while mitigating our exposure to high investment risks. We implemented during the Track Record Period, and will continue to implement, the following investment and treasury policies;

- the purpose of our investment in wealth management products is to preserve the time value of our cash reserves and to fund our business;
- we only invest in wealth management products when we have surplus cash that is not required for our short-term working capital purposes;
- our senior management is responsible for the overall planning and approval of our investment in wealth management products;
- our finance department is responsible for the purchase and management of our wealth management products and evaluates their respective terms including, among others, liquidity, risk and expected return before submitting them to our chief financial officer, with the authorization by our Board of Directors, for final decision;
- we mainly make investments in short-term wealth management products issued by reputable commercial banks with low risk, high liquidity and reasonable returns, and diversify our investment portfolio to minimize risk exposure; and
- we assess the risk associated with the underlying financial instruments based on the risk classification provided by the issuing bank.

Our Board of Directors is responsible and has the general power to supervise the operations of our business, including our investment decisions and activities. For the professional qualifications and experiences of the members of our Board of Directors, see the section headed “Directors, Supervisors and Senior Management” in this document. We may continue to purchase wealth management products that meet the above criteria as part of our treasury management where we believe it is prudent to do so after the [REDACTED], subject to the compliance requirement under Chapter 14 of the Listing Rules.

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Finance Income/(Costs) – Net

Our finance income – net was RMB0.1 million and RMB0.1 million in 2019 and 2020. We had finance costs – net of RMB10.4 million, RMB0.7 million and RMB9.1 million in 2021 and the six months ended June 30, 2021 and 2022, which primarily represented interest expense on redemption liabilities.

Income Tax Expense

We incurred income tax expense of RMB8.4 million, RMB7.9 million, RMB7.3 million, RMB3.2 million and RMB1.1 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively, representing an effective tax rate of 14.0%, 10.3%, 11.1%, 7.1% and 4.2%, respectively, for the same periods. The effective tax rate decreased from 14.0% for 2019 to 10.3% for 2020, primarily due to the application of certain Super Deduction (as defined below) for our research and development expenses related to the research and development for our valvular product candidates in 2020. The effective tax rate increased from 10.3% for 2020 to 11.1% for 2021, primarily due to an increase in the tax effect of expenses not deductible for tax purpose, including share-based payment expenses and interest expense on redemption liabilities. The effective tax rate decreased from 7.1% for the six months ended June 30, 2021 to 4.2% for the six months ended June 30, 2022, primarily due to our deductible tax losses, which was primarily in relation to the net foreign exchange losses incurred by our Company. See Note 12 and Note 20 to the Accountant’s Report in Appendix I to this document.

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 EIT rate of 15% instead of the standard EIT rate of 25% in China.

In addition, according to relevant laws and regulations promulgated by the State Council, enterprises engaging in research and development activities are entitled to claim 150% of their research and development expenses so incurred as tax deductible expenses when determining their assessable profits for that year (“Super Deduction”). The SAT announced in September 2018 that enterprises engaging in research and development activities shall be entitled to claim 175% of their research and development expenses as Super Deduction from January 1, 2018 to December 31, 2020, which was further extended to December 31, 2023. From 2021 onwards, the Super Deduction ratio has increased to 200%. We have made our best estimate for the Super Deduction to be claimed in ascertaining assessable profits. 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.”

Profit for the Year/Period

As a result of the foregoing, our net profit was RMB51.9 million, RMB68.8 million, RMB58.7 million, RMB41.8 million and RMB24.3 million in 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, respectively.

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PERIOD TO PERIOD COMPARISON OF RESULTS OF OPERATIONS

Six Months Ended June 30, 2022 Compared to Six Months Ended June 30, 2021

Revenue

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, for the following reasons.

- *CHD occluder products.* Our 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 due to the increased sales volume of our oxide-coated occluder products as they received broad market acceptance, including primarily MemoCarna[®] ASD Occluder III, MemoCarna[®] PDA Occluder III and MemoCarna[®] VSD Occluder III.
- *Occluder related procedural accessories.* Our 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 due 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.
- *PFO and LAA occluder products.* Our revenue generated from PFO and LAA occluder products decreased by 75.4% 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. The sales volume of our LAA occluder products was relatively high in the six months ended June 30, 2021 as our first generation LAA occluder product launched in June 2020 quickly captured the market potential with its compelling therapeutic effects, backed by our continued investments in the related academic promotion activities and market fairs.

Cost of sales

Our cost of sales increased by 28.9% from RMB11.9 million in the six months ended June 30, 2021 to RMB15.3 million in the six months ended June 30, 2022, primarily due to (1) an increase of RMB2.0 million in amortization of intangible assets due to the commencement of amortization on the patents and medical device registration certificates of our certain products as they obtained their respective NMPA approvals in mid-2021 and 2022, and (2) an increase

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of RMB1.6 million in employee benefit expense as a result of increased manpower investment in our manufacturing process because of the more complicated manufacturing procedures required for our new products launched in mid-2021.

- *CHD occluder products.* Our cost of sales incurred for CHD occluder products increased by 68.2% from RMB3.2 million in the six months ended June 30, 2021 to RMB5.4 million in the six months ended June 30, 2022, primarily due to the increased employee benefit expense and raw materials and consumables costs primarily in relation to the increased sales of our MemoCarna[®] ASD Occluder III.
- *Occluder related procedural accessories.* Our cost of sales incurred for occluder related procedural accessories increased significantly from RMB4.2 million in the six months ended June 30, 2021 to RMB8.6 million in the six months ended June 30, 2022, primarily due to the increased employee benefit expense in relation to the increased sales of our integrated intervention delivery system II.
- *PFO and LAA occluder products.* Our cost of sales incurred for PFO and LAA occluder products decreased by 73.1% from RMB4.5 million in the six months ended June 30, 2021 to RMB1.2 million in the six months ended June 30, 2022, generally consistent with the decrease in the sales volume of our PFO and LAA occluder products.

Gross profit and gross profit margin

Our gross profit increased by 10.5% from RMB99.1 million in the six months ended June 30, 2021 to RMB109.5 million in the six months ended June 30, 2022. Our gross profit margin decreased by 1.6 percentage points from 89.3% in the six months ended June 30, 2021 to 87.7% in the six months ended June 30, 2022.

- *CHD occluder products.* Our gross profit margin for CHD occluder products decreased by 1.0 percentage points from 95.0% in the six months ended June 30, 2021 to 94.0% in the six months ended June 30, 2022, primarily due to increased manpower investment in our manufacturing process as a result of the more complicated manufacturing procedures required by our oxide-coated occluder products including primarily MemoCarna[®] ASD Occluder III, the sales volume of which increased in the first half of 2022, MemoCarna[®] PDA Occluder III launched in May 2021 and MemoCarna[®] VSD Occluder III launched in July 2021.
- *Occluder related procedural accessories.* Our gross profit margin for occluder related procedural accessories decreased by 9.3 percentage points from 77.4% in the six months ended June 30, 2021 to 68.1% 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.

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- *PFO and LAA occluder products.* Our gross profit margin for PFO and LAA occluder products decreased by 1.5 percentage points from 84.2% in the six months ended June 30, 2021 to 82.7% 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.

Distribution expenses

Our distribution expenses decreased by 4.4% from RMB17.4 million in the six months ended June 30, 2021 to RMB16.6 million in the six months ended June 30, 2022, primarily due to (1) a decrease of RMB1.6 million in travel expenses and a decrease of RMB0.7 million in marketing and consulting fees as a result of decreased sales and marketing activities amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022, and (2) a decrease of RMB0.7 million in taxes and surcharges fees, partially offset by an increase in employee benefit expense of RMB2.5 million as a result of our enlarged sales and marketing team to accommodate our expanding product pipeline and business scale.

General and administrative expenses

Our general and administrative expenses decreased by 32.9% from RMB24.5 million in the six months ended June 30, 2021 to RMB16.4 million in the six months ended June 30, 2022, primarily due to a decrease in [REDACTED] expenses of RMB12.1 million, partially offset by an increase in employee benefit expenses of RMB4.5 million primarily in relation to share-based compensation to motivate our management team.

Research and development expenses

Our research and development expenses increased by 19.4% from RMB16.4 million in the six months ended June 30, 2021 to RMB19.6 million in the six months ended June 30, 2022, primarily due to an increase in employee benefit expenses of RMB3.7 million primarily in relation to share-based compensation to motivate our R&D personnel, an increase in raw materials and consumables costs of RMB0.9 million and an increase in depreciation costs of RMB0.6 million primarily in relation to the establishment and continued development of our Beijing branch since March 2021 along with the injection of the interventional heart valve business, partially offset by a decrease in testing and animal studies fees of RMB2.7 million as there were less R&D projects in type inspection or animal studies in the six months ended June 30, 2022 as compared to the same period in 2021.

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Net (reversal of)/provision for impairment losses on financial assets

We had net provision for impairment losses on financial assets of RMB4.2 million in the six months ended June 30, 2022, compared to the net reversal of impairment losses on financial assets of RMB0.5 million in the six months ended June 30, 2021, primarily due to an increase in provision for impairment losses on trade receivables primarily as a result of delayed collection caused by the regional resurgence of COVID-19 in Shanghai in the first half of 2022.

Other income and gains/(losses) – net

We had other losses – net of RMB18.3 million in the six months ended June 30, 2022, compared to other income and gains – net of RMB4.4 million in the six months ended June 30, 2021, primarily due to an increase in net foreign exchange losses of RMB25.1 million primarily in relation to the retranslation of redemption liabilities resulted from exchange rate fluctuations.

Finance income/(costs) – net

Our finance costs – net increased significantly from RMB0.7 million in the six months ended June 30, 2021 to RMB9.1 million in the six months ended June 30, 2022, primarily due to an increase in interest expense on redemption liabilities of RMB9.7 million, which commenced provision since the initial recognition of redemption liabilities in May 2021.

Income tax expense

Our income tax expense decreased by 67.2% from RMB3.2 million in the six months ended June 30, 2021 to RMB1.1 million in the six months ended June 30, 2022, primarily due to a decrease in tax calculated at the statutory tax rate as a result of decreased profit before income tax, partially offset by an increase in the tax effect of expenses not deductible for tax purpose, including primarily interest expense on redemption liabilities and share-based payment expenses. Our effective tax rate decreased from 7.1% for the six months ended June 30, 2021 to 4.2% for the six months ended June 30, 2022, primarily due to our deductible tax losses, which was primarily in relation to the net foreign exchange losses incurred by our Company.

Profit for the period

As a result of the foregoing, our profit for the period 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.

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Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

Revenue

Our revenue increased by 50.1% from RMB148.2 million in 2020 to RMB222.6 million in 2021, for the following reasons.

- *CHD occluder products.* Our 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[®] ASD Occluder III in May 2020, which started to generate revenue in the second half of 2020. 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.
- *Occluder related procedural accessories.* Our 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[®] ASD Occluder III launched in May 2020.
- *PFO and LAA occluder products.* Our 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. Revenue generated from MemoLefort[®] LAA Occluder I increased from RMB8.3 million in 2020 to RMB44.2 million in 2021, accounting for 5.6% and 19.8% of the total revenue in the same periods, respectively.

Cost of sales

Our cost of sales increased by 65.4% from RMB15.1 million in 2020 to RMB25.0 million in 2021, primarily due to (1) an increase of RMB4.4 million in raw materials and consumables costs, in line with our business growth and the expansion of our production lines, (2) an increase of RMB2.7 million in amortization of intangible assets due to the commencement of amortization on the patents and medical device registration certificates of our certain products as they obtained their respective NMPA approvals in mid-2020 and 2021, and (3) an increase of RMB2.4 million in employee benefit expense as a result of increased manpower investment in our manufacturing process because of the more complicated manufacturing procedures required for our new products launched in mid-2020 and 2021.

- *CHD occluder products.* Our cost of sales incurred for CHD occluder products increased by 51.6% from RMB4.9 million in 2020 to RMB7.4 million in 2021, primarily due to the increased raw materials and consumables costs and employee benefit expense in relation to our MemoCarna[®] ASD Occluder III launched in May 2020.

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- *Occluder related procedural accessories.* Our cost of sales incurred for occluder related procedural accessories increased by 25.5% from RMB7.8 million in 2020 to RMB9.8 million in 2021, generally consistent with the increase in the sales volume of our occluder related procedural accessories in 2021.
- *PFO and LAA occluder products.* Our cost of sales incurred for PFO and LAA occluder products increased significantly from RMB2.5 million in 2020 to RMB7.8 million in 2021, primarily due to the increased raw materials and consumables costs and employee benefit expense in relation to our LAA occluder product launched in June 2020.

Gross profit and gross profit margin

Our gross profit increased by 48.4% from RMB133.1 million in 2020 to RMB197.5 million in 2021. Our gross profit margin remained relatively stable at 89.8% and 88.8% in 2020 and 2021, respectively.

- *CHD occluder products.* Our gross profit margin for CHD occluder products decreased by 1.0 percentage points from 95.4% in 2020 to 94.4% in 2021, primarily due to the increase in raw materials and consumables costs and employee benefit expense in relation to our MemoCarna[®] ASD Occluder III launched in May 2020.
- *Occluder related procedural accessories.* Our gross profit margin for occluder related procedural accessories increased by 0.9 percentage points from 75.6% in 2020 to 76.5% in 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.
- *PFO and LAA occluder products.* Our gross profit margin for PFO and LAA occluder products increased by 9.7 percentage points from 74.2% in 2020 to 83.9% in 2021, primarily due to the greater economies of scale in manufacturing LAA occluder product as a result of the large production volumes and streamlined and standardized manufacturing processes.

Distribution expenses

Our distribution expenses increased by 86.1% from RMB23.1 million in 2020 to RMB43.1 million in 2021, primarily due to (1) an increase of RMB10.8 million in employee benefit expense as a result of our enlarged sales and marketing team as we continuously roll out new products, and (2) an increase of RMB5.2 million in marketing and consulting fees and an increase of RMB2.3 million in travel expenses as a result of increased sales and traveling activities driven by the effective containment of the COVID-19 outbreak in China and the new products launched in mid-2020 and 2021.

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General and administrative expenses

Our general and administrative expenses increased significantly from RMB8.4 million in 2020 to RMB59.9 million in 2021, primarily due to (1) [REDACTED] expenses of RMB32.7 million as incurred in connection with the [REDACTED], and (2) an increase of RMB13.3 million in employee benefit expense primarily in relation to share-based compensation to motivate our employees.

Research and development expenses

Our research and development expenses increased by 6.2% from RMB39.0 million in 2020 to RMB41.4 million in 2021, primarily due to an increase of RMB2.7 million in raw materials and consumables for the research and development activities as well as pre-clinical trial activities of our product candidates.

Net (provision for)/reversal of impairment losses on financial assets

Our net reversal of impairment losses on financial assets remained relatively stable at RMB0.7 million and RMB0.5 million in 2020 and 2021, respectively.

Other income and gains – net

Our other income and gains – net increased by 71.0% from RMB13.2 million in 2020 to RMB22.6 million in 2021, primarily due to (1) investment income on wealth management products of RMB6.7 million, and (2) net foreign exchange gains of RMB5.2 million from retranslation of U.S. dollar-denominated bank balances and redemption liabilities, partially offset by the impact of the non-recurring gains on disposal of investment properties of RMB5.1 million as recognized in 2020.

Finance income/(costs) – net

We had finance costs – net of RMB10.4 million in 2021, compared to finance income – net of RMB0.1 million in 2020, primarily due to interest expense on redemption liabilities of RMB11.3 million since the initial recognition of redemption liabilities in 2021, partially offset by an increase in bank interest income of RMB1.0 million.

Income tax expense

Our income tax expense decreased by 7.3% from RMB7.9 million in 2020 to RMB7.3 million in 2021, primarily due to the increases in Super Deduction and tax effect of preferential tax rate and a decrease in tax calculated at the statutory tax rate as a result of decreased profit before income tax, partially offset by an increase in the tax effect of expenses not deductible for tax purpose, including share-based payment expenses and interest expense on redemption liabilities. Accordingly, our effective tax rate increased from 10.3% in 2020 to 11.1% in 2021.

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Profit for the period

As a result of the foregoing, our net profit was RMB68.8 million and RMB58.7 million in 2020 and 2021, respectively.

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

Revenue

Our revenue increased by 27.3% from RMB116.5 million in 2019 to RMB148.2 million in 2020 primarily for the following reasons.

- *CHD occluder products.* Our revenue generated from CHD occluder products increased by 22.9% from RMB86.7 million in 2019 to RMB106.6 million in 2020, primarily due to the increase in pricing per unit for our CHD 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. See “Connected Transactions — Non-exempt Continuing Connected Transactions — 1. Sale of Products Framework Agreement.”
- *Occluder related procedural accessories.* Our revenue generated from occluder related procedural accessories increased by 10.7% from RMB28.9 million in 2019 to RMB32.0 million in 2020, primarily due to the 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.
- *PFO and LAA occluder products.* Our revenue generated from PFO and LAA occluder products increased significantly from RMB0.5 million in 2019 to RMB9.5 million in 2020, primarily due to the launch of our LAA occluder products in June 2020.

Cost of sales

Our cost of sales increased by 11.1% from RMB13.6 million in 2019 to RMB15.1 million in 2020, primarily due to (1) an increase of RMB1.3 million in amortization of intangible assets for the expenses related to our newly obtained registration certificates for our products which commenced amortization in 2020, (2) an increase of RMB0.2 million in our raw materials and consumables costs, in line with our business growth and the expansion of our production lines,

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partially offset by a decrease of RMB0.1 million in transportation costs primarily due to bulk purchases and fewer lots of product deliveries as a result of the travel restrictions imposed during the COVID-19 outbreak in 2020.

- *CHD occluder products.* Our cost of sales incurred for CHD occluder products decreased by 8.9% from RMB5.3 million in 2019 to RMB4.9 million in 2020, generally consistent with the slight decrease in sales volume of our CHD occluder products in 2020 amid the COVID-19 outbreak.
- *Occluder related procedural accessories.* Our cost of sales incurred for occluder related procedural accessories decreased slightly from RMB8.0 million in 2019 to RMB7.8 million in 2020, generally consistent with the slight decrease in the sales volume of our CHD occluder products in 2020.
- *PFO and LAA occluder products.* Our cost of sales incurred for PFO and LAA occluder products increased significantly from RMB0.2 million in 2019 to RMB2.5 million in 2020, as we incurred cost related to raw materials and consumables used in relation to the launch of our LAA occluder products in June 2020.

Gross profit and gross profit margin

Our gross profit increased by 29.4% from RMB102.8 million in 2019 to RMB133.1 million in 2020. Our gross profit margin increased by 1.5 percentage points from 88.3% in 2019 to 89.8% in 2020.

- *CHD occluder products.* Our gross profit margin for CHD occluder products increased by 1.5 percentage points from 93.9% in 2019 to 95.4% in 2020, primarily due to the increase in pricing per unit for our CHD occluder products sold overseas through the Retained Lepu Medical Group in 2020.
- *Occluder related procedural accessories.* Our gross profit margin for occluder related procedural accessories increased by 3.4 percentage points from 72.2% in 2019 to 75.6% in 2020, primarily due to the increase in pricing per unit for our occluder related procedural accessories sold overseas through the Retained Lepu Medical Group in 2020.
- *PFO and LAA occluder products.* Our gross profit margin for PFO and LAA occluder products increased by 16.6 percentage points from 57.6% in 2019 to 74.2% in 2020, primarily due to (1) the launch of our LAA occluder products, which have relatively higher gross profit margin, and to a lesser extent, (2) the increase in pricing per unit for our PFO occluder products sold overseas through the Retained Lepu Medical Group in 2020.

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Distribution expenses

Our distribution expenses increased by 6.4% from RMB21.8 million in 2019 to RMB23.1 million in 2020, primarily due to (1) an increase of RMB1.6 million in employee benefit expense, as a result of the increase in headcount for our sales and marketing staff driven by our enhanced sales and marketing activities, and (2) an increase of RMB0.9 million in marketing and consulting fees primarily for promotion, consultation and market research services, which primarily reflected our academic promotion activities and market fairs for our newly launched LAA occluder products, partially offset by (3) a decrease of RMB1.2 million in travel expenses from the impact of the COVID-19 outbreak.

General and administrative expenses

Our general and administrative expenses decreased by 6.7% from RMB9.0 million in 2019 to RMB8.4 million in 2020, primarily due to (1) a decrease of RMB0.3 million in employee benefit expense as a result of the decrease in corporate events and activities during the COVID-19 outbreak, and (2) a decrease of RMB0.2 million in depreciation and amortization as we disposed of certain owned properties in 2020.

Research and development expenses

Our research and development expenses increased by 50.8% from RMB25.8 million in 2019 to RMB39.0 million in 2020, primarily due to (1) an increase of RMB9.1 million in testing and animal studies fees for our valvular product candidates and occluder product candidates, as we increased pre-clinical trial activities for our product candidates in 2020, and (2) an increase of RMB2.7 million in raw materials and consumables expenses for our valvular product candidates and occluder product candidates, as we consumed more raw materials for the research and development for our product candidates in 2020.

Net (provision for)/reversal of impairment losses on financial assets

We had net reversal of impairment losses on financial assets of RMB0.7 million in 2020, compared to net provision for impairment losses on financial assets of RMB1.8 million in 2019, primarily due to a decrease of impairment loss provision from trade receivables.

Other income and gains – net

Our other income and gains – net decreased by 15.9% from RMB15.7 million in 2019 to RMB13.2 million in 2020, primarily due to (1) a decrease of RMB3.4 million in government grants primarily as we received certain one-off government grants in 2019, (2) a decrease of RMB0.6 million in rental income from investment properties as we disposed of certain owned properties in 2020, partially offset by an increase of RMB2.7 million in gains on such disposal.

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Finance income – net

Our finance income – net remained relatively stable at RMB0.1 million in 2019 and 2020, respectively.

Income tax expense

Our income tax expense decreased by 6.3% from RMB8.4 million in 2019 to RMB7.9 million in 2020, primarily due to the application of certain Super Deduction for our research and development expenses related to the research and development for our valvular product candidates in 2020. Accordingly, our effective tax rate decreased from 14.0% in 2019 to 10.3% in 2020.

Profit for the year

As a result of the foregoing, our profit for the year increased by 32.5% from RMB51.9 million in 2019 to RMB68.8 million in 2020.

DISCUSSION OF MAJOR BALANCE SHEET ITEMS

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

	As of December 31,			As of June 30,
	2019	2020	2021	2022
	<i>(RMB in thousands)</i>			
NON-CURRENT ASSETS				
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	222,617	226,748	327,174	365,701

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	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
CURRENT ASSETS				
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	85,944	105,762	792,516	860,497
TOTAL ASSETS	308,561	332,510	1,119,690	1,226,198
	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
NON-CURRENT LIABILITIES				
Lease liabilities	–	–	4,044	4,294
Deferred income	2,148	1,315	482	152
Total non-current liabilities	2,148	1,315	4,526	4,446
CURRENT LIABILITIES				
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	74,544	77,596	729,973	804,505
TOTAL LIABILITIES	76,692	78,911	734,499	808,951

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	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
EQUITY				
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
TOTAL EQUITY	231,869	253,599	385,191	417,247
TOTAL EQUITY AND LIABILITIES	308,561	332,510	1,119,690	1,226,198

Property, Plant and Equipment

Our property, plant and equipment consisted primarily of buildings, machinery, vehicles and electronic equipment. We had property, plant and equipment of RMB68.5 million, RMB67.2 million, RMB76.3 million and RMB82.4 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. Our property, plant and equipment increased from RMB68.5 million as of December 31, 2019 to RMB82.4 million as of June 30, 2022, primarily because we purchased additional equipment for our research and development and manufacturing activities.

Right-of-use Assets

During the Track Record Period, we recognized right-of-use assets for leases of warehouses and staff dormitories. We had right-of-use assets of RMB0.5 million, RMB0.2 million, RMB6.8 million and RMB5.8 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. Our right-of-use assets increased significantly from RMB0.2 million as of December 31, 2020 to RMB6.8 million as of December 31, 2021, primarily because we newly leased properties in March 2021 for interventional heart valve business, which was injected into Shanghai Shape Memory Alloy in January 2021. Our right-of-use assets decreased to RMB5.8 million as of June 30, 2022, primarily due to the depreciation of our leased properties. See “Business — Our Products — Heart Valve Product Candidates — Entrusted Products.”

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Investment Properties

Our investment properties consist of buildings owned by us for rental yields. The net book value of our owned investment properties decreased from RMB42.7 million as of December 31, 2019 to RMB40.6 million as of December 31, 2020, primarily as we disposed of certain of our properties in 2020. The net book value of our owned investment properties remained relatively stable at RMB39.6 million and RMB39.1 million as of December 31, 2021 and June 30, 2022. See “Appendix III — Property Valuation Report” to this document for more information.

Reconciliation with the Property Evaluation Report

A reconciliation of our buildings under property, plant and equipment and our investment properties as of July 31, 2022 in the property valuation report and such properties in our financial statements as of June 30, 2022, as required under Rule 5.07 of the Listing Rules, is set out below.

	<i>RMB in thousands</i>
Carrying amount of the properties as of June 30, 2022	94,571
Net decrease during the one-month period ended July 31, 2022	(222)
Valuation surplus	<u>14,451</u>
Valuation of properties as of July 31, 2022 in the property valuation report	<u><u>108,800</u></u>

Goodwill

Our goodwill remained at RMB48.3 million, as of December 31, 2019, 2020 and 2021 and June 30, 2022, primarily due to the acquisition of Shanghai Shape Memory Alloy, our wholly-owned subsidiary, by Lepu Medical, one of our Controlling Shareholders, in 2008. Impairment assessments for goodwill and intangible assets not subject to amortization are undertaken annually or more frequently if events or changes in circumstances indicate a potential impairment. We have conducted impairment assessment on our goodwill and intangible assets not subject to amortization as of December 31, 2019, and an independent qualified valuer was appointed to assist our management to conduct impairment assessment on our goodwill and intangible assets not subject to amortization as of December 31, 2020 and 2021.

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For the purpose of impairment testing, goodwill acquired in a business combination or intangible assets not subject to amortization are allocated to each of the CGU. Determining whether goodwill or intangible assets not subject to amortization is impaired requires us to estimate the recoverable amount of the CGU to which we have allocated goodwill or intangible assets not subject to amortization. This recoverable amount calculation requires us to estimate the future cash flows expected to arise from the CGU and a suitable discount rate to calculate the present value.

For the purpose of impairment review for goodwill and intangible assets not subject to amortization which are attributable to the CGU of occluder business, the recoverable amount of the CGU is determined based on value-in-use calculations. These calculations use pre-tax cash flow projections based on financial budgets prepared by our management covering a five-year period. Cash flows beyond the five-year period are extrapolated using the estimated terminal growth rates stated below.

The key assumptions used for value-in-use calculations are as follows:

	Gross profit margin	Growth rate of revenue	Terminal growth rate	Pre-tax discount rate
As of December 31, 2019	88.68% – 91.15%	1.00% – 5.00%	1.00%	14.86%
As of December 31, 2020	88.39% – 90.59%	1.00% – 5.00%	1.00%	14.75%
As of December 31, 2021	85.93% – 88.35%	1.00% – 4.00%	0.00%	15.73%

The growth rate for the first five years and budgeted gross profit margin were determined by our management based on past performance and its expectation for market and product development. The terminal growth rate used does not exceed the industry growth forecast for the market in which our Group operates. The discount rate used is pre-tax and reflects market assessments of the time value and the specific risks relating to the industry.

The result of the impairment testing reveals that the estimated recoverable amount of the CGU of occluder business far exceeded its carrying amount with sufficient headroom amounted to of approximately RMB196.4 million, RMB240.2 million and RMB484.3 million as of December 31, 2019, 2020 and 2021, respectively.

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We perform the sensitivity analysis based on the assumptions that budgeted gross profit margin, growth rate of revenue, terminal growth rate or the pre-tax discount rate used in the value-in-use calculation for the CGU of occluder business have been changed, with all other variables held constant, and the headroom would be changed as below.

	As of December 31,		
	2019	2020	2021
	Headroom Amount	Headroom Amount	Headroom Amount
	<i>(RMB in thousands)</i>		
Gross profit margin decreases by 10%	98,386	137,504	398,664
Growth rate of revenue decreases by 1%	168,761	201,099	465,126
Terminal growth rate decreases by 1%	191,711	235,160	455,062
Pre-tax discount rate increases by 1%	191,490	234,553	436,852

Our Directors have not identified that a reasonable possible change in any of the key assumptions that could cause the carrying amount of goodwill or intangible assets not subject to amortization attributable to the CGU of occluder business to exceed their recoverable amount. Accordingly, our Directors have concluded that no provision for impairment is required to be recognized as of the respective balance sheet dates.

As there were no indicators for impairment of the CGU of occluder business as of June 30, 2022, our management have not updated any of the impairment calculations since December 31, 2021 and our Directors have concluded that no provision for impairment of the CGU of occluder business is required to be recognized as of June 30, 2022.

Prior to December 31, 2020, all the capitalized development costs are attributable to the CGU of occluder business. For the year ended December 31, 2021, part of the eligible development costs attributable to the CGU of heart valve business of RMB41.5 million were capitalized.

Development costs which are attributable to the CGU of heart valve business are not available for use and are tested for impairment on an annual basis on December 31 for each year, or more frequently if events or changes in circumstances indicate that they might be impaired in accordance with International Accounting Standard 36 “Impairment of Assets.” The recoverable amount is determined based on fair value less cost of disposal.

We involved an independent qualified valuer to perform impairment assessment to assess the fair value less cost of disposal of the development costs which were attributable to the CGU of heart valve business as of December 31, 2021 by using the discounted cash flow approach. For the discounted cash flows, the estimated revenue was based on our management’s expected timing of the product candidates’ commercialization, production volume and sales volume. Management estimated the product candidates’ sales volume based on market conditions and the status of technology development. Management then adjusted the estimated revenue to

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profit contributed from the development costs which are attributable to the CGU of heart valve business by considering a percentage of costs and operating expenses to the revenue (“cost component ratio”), which was determined by reference to the current operating margin levels of comparable companies, with adjustments made based on management’s industry experience as well as the research and development plans. Finally, management estimated the discount rate based on the uncertain success rate of commercialization for the applicable product candidates.

Considering the development stage and expected market conditions, our management currently expects that the first year of commercialization for related heart valve product candidates will be 2025. Based on the related heart valve product candidates’ life cycle and industry practice, our management expected that the estimated useful life of related heart valve products is at least 10 years. The cash flow projections for the first five years from 2026 to 2030 are based on financial budgets prepared by our management based on market conditions. The cash flow projections for the subsequent years from 2031 to 2035 are extrapolated based on the forecasts using a steady growth rate of revenue of 2%, which does not exceed the long term industry growth forecast for the market in which we operate. The key assumptions used in the fair value less cost of disposal calculation for the CGU of heart valve business are as follows:

		Growth rate of revenue			
Gross profit margin	2026-2030	2031-2035	Cost component ratio	Post-tax discount rate	
As of December 31, 2021	70% – 85%	24.4% – 188.4%	2%	54.3% – 68.3%	17.90%

Based on the result of impairment assessment, the recoverable amount of the CGU of the heart valve business is estimated to exceed its carrying amount as of December 31, 2021 by approximately RMB21.3 million.

The recoverable amount of the CGU of the heart valve business would equal its carrying amount, if each of the key assumptions were to change as follows, with all other variables held constant. Our management believes that the key assumptions would not be likely to change as follows.

	As of December 31, 2021
Gross profit margin	–12.54%
Growth rate of revenue	–7.68%
Cost component ratio	+8.40%
Post-tax discount rate	+3.57%

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Our Directors have not identified that a reasonably possible change in any of the key assumptions that could cause the carrying amount of CGU of our heart valve business to exceed its recoverable amount. Our Directors have concluded that no provision for impairment of the CGU of the heart valve business is required to be recognized as of December 31, 2021.

As there were no indicators for impairment of the CGU of heart valve business as of June 30, 2022, our management have not updated any of the impairment calculations since December 31, 2021 and our Directors have concluded that no provision for impairment of the CGU of heart valve business is required to be recognized as of June 30, 2022.

See “Risk Factors — Risks Relating to Our Business and Industries — Risks Relating to Our Operations — Impairment of goodwill may materially and adversely affect our results of operations” and Note 2.10, Note 17 and Note 18 to the Accountant’s Report in Appendix I to this document.

Intangible Assets

Our intangible assets consist primarily of development costs in connection with our clinical trial activities and other contemporaneous research and development efforts, patents and licenses, and software we purchased from third parties for book-keeping purpose. The carrying amount of our intangible assets increased from RMB54.3 million as of December 31, 2019 to RMB66.0 million as of December 31, 2020, generally in line with our continued investment in development activities. Our intangible assets further increased to RMB136.6 million as of December 31, 2021, primarily due to (1) the capitalization of a portion of the expenses incurred for the development of certain product candidates, including MemoSorb[®] PFO Occluder II, TAVR system, balloon dilatation catheter for aortic valve. MemoSorb[®] ASD Occluder IV, TMVr-A system, TMVCRS and IASD I, as they had fulfilled the prerequisites for clinical trials and therefore met the criteria for capitalization, and (2) the recognition of MemoCarna[®] PDA Occluder III and MemoCarna[®] VSD Occluder III as intangible assets as they had obtained the NMPA approvals in 2021. Our intangible assets further increased to RMB161.6 million as of June 30, 2022, primarily attributable to the recognition of fully-biodegradable MemoSorb[®] VSD Occluder IV and interventional delivery system for biodegradable occluders as intangible assets, as they had obtained the NMPA approvals in the six months ended June 30, 2022. Intangible assets not available for use are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. See “— Goodwill” and Notes 2.9 and 18 to the Accountant’s Report in Appendix I to this document.

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Financial Assets at Fair Value through Other Comprehensive Income

Our financial assets at fair value through other comprehensive income, or FVOCI, primarily represents our equity investment in an enterprise where we held 10% equity interest. We had financial assets at fair value through other comprehensive income of RMB0.8 million, nil, nil and nil as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively, as we disposed of our equity interest in such enterprise by the end of 2020.

In relation to the valuation of the level 3 financial assets at FVOCI during the Track Record Period, our Directors adopted the following procedures, where they (1) reviewed the terms of all relevant agreements of equity investment; (2) obtained all material documents and information from the investment investee enterprise which were true, accurate and complete and were likely to affect the valuation to ensure that the valuation took into account all relevant matters; and (3) reviewed the valuation results prepared by the valuation team in our finance department. Based on the above procedures, our Directors are of the view that the valuation analysis of our Group’s level 3 financial instruments is fair and reasonable, and our Group’s financial statements are properly prepared. Moreover, the balances of FVOCI and fair value change of FVOCI are not material for 2019, and our Directors have not identified that a reasonable change in any of the inputs that could cause the significant change of fair value. Should any of the estimates and assumptions changed, it may lead to a change in the fair value of the level 3 instruments. See Note 3.3 to the Accountant’s Report in Appendix I to this document.

Details of the fair value measurement of the FVOCI, particularly the fair value hierarchy, the valuation techniques and key inputs, the valuation processes, including those for level 3 measurements, are disclosed in Note 3.3 to the Accountant’s Report in Appendix I to this document. The Reporting Accountant has carried out audit procedures in accordance with Hong Kong Standard on Investment Circular Reporting Engagement 200 “Accountants’ Reports on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants. The Reporting Accountant’s opinion on our historical financial information for the Track Record Period as a whole is set out in Appendix I to the document.

In relation to the valuation of the level 3 financial assets at FVOCI, the Sole Sponsor has conducted relevant due diligence work, including (1) the review of relevant notes in the Accountant’s Report in Appendix I to this document, (2) the interview with the chief financial officer of our Company on the valuation methodology of the level 3 financial assets, and (3) the discussion with the Reporting Accountant in respect of the audit work and procedures they have conducted in this regard. Having considered the work done by the Directors and Reporting Accountant and the relevant due diligence work conducted as stated above, nothing has come to the Sole Sponsor’s attention that would cause the Sole Sponsor to question the valuation analysis performed by the Company of the Group’s financial assets at FVOCI categorized within level 3 of fair value measurements.

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Deferred Income Tax Assets

Our deferred income tax assets relate to deductible temporary differences between the tax bases of assets and liabilities and their carrying amounts to the extent that the utilization of such differences and losses against future taxable profits is probable. Our deferred income tax assets are primarily attributable to our research and development expenses, contractual liabilities, allowances for receivables and tax losses. We had deferred income tax assets of RMB7.0 million, RMB3.5 million, RMB8.6 million and RMB16.1 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. The increase from December 31, 2020 to December 31, 2021 was primarily due to our deductible tax losses, which was primarily in relation to the [REDACTED] expenses incurred by our Company. See Note 20 to the Accountant’s Report in Appendix I to this document. The increase from December 31, 2021 to June 30, 2022 was primarily due to our deductible tax losses, which was primarily in relation to the net foreign exchange losses incurred by our Company.

Prepayments and Other Receivables

Our prepayments and other receivables consisted primarily of prepayment to third parties and related parties and other receivables due from third parties and related parties. Prepayments and other receivables with a collection period over one year based on the contract terms are classified as non-current assets and, otherwise, are classified as current assets. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had prepayments and other receivables of RMB14.1 million, RMB21.2 million, RMB33.0 million and RMB64.1 million, respectively. The following table sets forth the details of our prepayment and other receivables as of the dates indicated.

	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
Other receivables				
Receivables due from related parties	6,788	8,034	–	–
Payment of expense on behalf of an investee company	1,800	1,800	–	–
Proceeds receivables from disposal of an investment property	–	1,351	–	–
Deposits	776	676	1,348	1,634

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	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
Staff advance	176	285	397	633
Receivables from sales on behalf of a related party	–	–	–	17,098
Others	221	195	259	295
Less: provision for impairment of other receivables	(1,180)	(1,660)	(188)	(736)
Total other receivables – net	<u>8,581</u>	<u>10,681</u>	<u>1,816</u>	<u>18,924</u>
Prepayments				
Prepayment to related parties	–	303	58	1,234
Prepayment for purchases of property, plant and equipment	632	1,000	11,187	12,304
Prepayment for raw materials	1,828	5,266	9,948	20,235
[REDACTED] expenses prepaid or to be capitalized	–	–	3,474	3,540
Prepayment for products testing and clinical trial fee	2,871	3,021	3,547	5,405
Value-added tax recoverable	–	–	1,705	912
Prepayment for consulting service fees	138	691	522	357
Others	24	220	695	1,200
Total prepayments	<u>5,493</u>	<u>10,501</u>	<u>31,136</u>	<u>45,187</u>
Total prepayments and other receivables	14,074	21,182	32,952	64,111
Less: non-current portion	(632)	(1,000)	(11,187)	(12,304)
Current portion	<u><u>13,442</u></u>	<u><u>20,182</u></u>	<u><u>21,765</u></u>	<u><u>51,807</u></u>

Prepayments and other receivables increased from RMB14.1 million as of December 31, 2019 to RMB21.2 million as of December 31, 2020, primarily due to (1) an increase of RMB3.4 million of prepayment for raw materials to third parties to support our increased research and development activities and business growth, and (2) an increase of RMB1.4 million of proceeds receivables from disposal of an investment property related to receivables for disposed properties in 2020. Prepayments and other receivables increased from RMB21.2 million as of December 31, 2020 to RMB33.0 million as of December 31, 2021, primarily due to (1) an increase of RMB10.2 million of prepayment for purchases of property, plant and

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equipment and an increase of RMB4.7 million of prepayment for raw materials to third parties to support our increased research and development activities and business growth, (2) an increase of RMB3.5 million of [REDACTED] expenses prepaid or to be capitalized in connection with the [REDACTED], (3) an increase in value-added tax recoverable of RMB1.7 million, and (4) a decrease of RMB1.5 million of provision for impairment of other receivables in line with the decrease in other receivables due from related parties, partially offset by (1) a decrease of RMB8.0 million of other receivables due from related parties as a result of our enhanced collection efforts, and (2) a decrease of RMB1.8 million of payment of expense on behalf of an investee as the amount was settled. Prepayments and other receivables increased from RMB33.0 million as of December 31, 2021 to RMB64.1 million as of June 30, 2022, primarily due to (1) receivables from sales on behalf of a related party of RMB17.1 million in relation to the purchase of COVID-19 antigen reagents by the local government from us amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022, where we provided distribution services (as an agent) following the instructions from a subsidiary of Lepu Medical, which were terminated in June 2022, with details set out below, and (2) an increase in prepayment for raw materials of RMB10.3 million to support our resumed manufacturing activities following the containment of COVID-19. In the first half of 2022, we provided COVID-19 antigen reagents distribution services (as an agent) to a subsidiary of Lepu Medical, or the Fellow Subsidiary. Under the distribution arrangement, we purchased the COVID-19 antigen reagents from the Fellow Subsidiary with carrying amount of approximately RMB22,681,000, and then sold them to the end customers, primarily including the local government in Shanghai, following the instructions from the Fellow Subsidiary. In the transaction, we merely acted as an agent on behalf of the Fellow Subsidiary. Except for the commission income of approximately RMB734,000 (representing approximately 3.24% of the transaction carrying amount) that we recognized from the provision of such distribution services on net basis, no other revenue or income was recognized by us under the distribution arrangement. See Note 21(a) and Note 35(b) to the Accountant’s Report included in Appendix I to this document for details. We entered into the distribution arrangement with the Fellow Subsidiary to act as its agent primarily because that, the local government in Shanghai preferred to deal with local enterprises in light of the logistics delays and restrictions amid the COVID-19 resurgence in Shanghai in the first half of 2022, to ensure timely delivery. We terminated such arrangement in June 2022 along with the containment of the COVID-19 resurgence, in addition to the fact that nucleic acid amplification testing, instead of antigen testing, has been widely recognized as the primary testing method for COVID-19, leading to local government’s reduced demand for antigen reagents. As of August 31, 2022, we had fully utilized or recovered our prepayments and other receivables due from related parties outstanding as of June 30, 2022.

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Inventories

Our inventories consisted of raw materials, work-in-progress, and finished goods. Under our inventory control policy, we regularly monitor and analyze our historical procurement, production and sales statistics and adjust our inventories to meet customer demand in a timely manner without causing inventory accumulation. The following table sets forth the details of our inventories as of the dates indicated.

	As of December 31,			As of June 30,
	2019	2020	2021	2022
	<i>(RMB in thousands)</i>			
Raw materials	4,962	13,688	11,266	15,319
Work-in-progress	1,794	4,440	8,734	11,427
Finished goods	4,296	5,191	13,402	13,523
Total	11,052	23,319	33,402	40,269

The following table sets forth the number of our inventory turnover days for the periods indicated.

	Year ended December 31,			Six months ended June 30,
	2019	2020	2021	2022
Inventory turnover days ⁽¹⁾	277	414	413	435

(1) The inventory turnover days are calculated by dividing the arithmetic mean of the opening and ending balance of inventories in that period by cost of sales for the corresponding period and then multiplying by the number of days in that period.

Our inventories increased from RMB11.1 million as of December 31, 2019 to RMB23.3 million as of December 31, 2020, and our inventory turnover days increased from 277 days in 2019 to 414 days in 2020, primarily because (1) we purchased raw materials to develop our product candidates, including primarily our heart valve product candidates, the amount of which was not reflected in our cost of sales as such product candidates had not yet started to generate revenue; (2) we strategically purchased surplus inventory of raw materials as part of our provisional strategies amid the COVID-19 outbreak; and (3) we purchased additional raw materials for our LAA occluder products, launched in June 2020, in anticipation of robust market demand. See “Business — Inventory” and “Business — Raw Materials and Suppliers — Raw Materials.” Our inventories increased from RMB23.3 million as of December 31, 2020 to RMB33.4 million as of December 31, 2021, primarily because (1) we strategically purchased surplus inventory of raw materials as part of our provisional strategies amid the COVID-19 outbreak, and (2) we purchased raw materials for our fully biodegradable VSD occluder product, which obtained the NMPA approval in February 2022, in anticipation of robust market

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demand. Our inventory turnover days remained relatively stable at 413 days in 2021. Our inventories increased from RMB33.4 million as of December 31, 2021 to RMB40.3 million as of June 30, 2022, and our inventory turnover days increased from 413 days in 2021 to 435 days in the six months ended June 30, 2022, primarily due to (1) delayed consumption of raw materials as our manufacturing and sales activities were temporarily interrupted amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022, and (2) our purchase of raw materials to support our resumed manufacturing activities following the containment of COVID-19.

As of August 31, 2022, 44.9% or RMB18.1 million of our inventories as of June 30, 2022 had been subsequently consumed for research and development as well as production or transformed to finished goods and sold.

Our Directors are of the view that there is no recoverability issue for our inventories for the reasons that (1) a substantial portion of the inventories as of June 30, 2022 were aged less than one year, (2) we strategically purchased raw materials as part of our provisional strategies amid the COVID-19 outbreak, which primarily consisted of metal tubes not subject to expiration, and purchased raw materials with an view to stock up for sales of our fully biodegradable VSD occluder product, which obtained the NMPA approval in February 2022, and we do not consider there to be any material difficulty in the utilization of our inventories as of June 30, 2022, (3) our products are generally subject to a shelf life of three years, and the finished goods aged over one year are not perishable or fragile products and can maintain saleable value, and (4) based on the estimated selling prices and gross profit margins of our products, the net realizable value of the inventories is higher than the book value. As a result, we did not make any provisions for our inventories during the Track Record Period.

Trade Receivables

Our trade receivables consisted of amounts due from our third-party customers or our related-party customers. We had trade receivables of RMB45.3 million, RMB38.3 million, RMB23.9 million and RMB32.9 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. The following table sets forth the details of our trade receivables as of the dates indicated.

	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
From third parties	34,882	35,588	31,887	43,086
From related parties	18,950	10,078	270	1,706
Less: allowance for impairment	(8,501)	(7,349)	(8,288)	(11,909)
Total	45,331	38,317	23,869	32,883

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The following table sets forth our trade receivables turnover days for the periods indicated.

	Year ended December 31,			Six months ended June 30,
	2019	2020	2021	2022
	Trade receivables turnover days ⁽¹⁾	144	122	64

- (1) The trade receivables turnover days are calculated by dividing the arithmetic mean of the opening and ending balance of gross trade receivables in that period by revenue for the corresponding period and then multiplying by the number of days in that period.

Our trade receivables decreased from RMB45.3 million as of December 31, 2019 to RMB38.3 million as of December 31, 2020, and further to RMB23.9 million as of December 31, 2021, as we enhanced our collection efforts primarily over our related parties. Our trade receivables then increased to RMB32.9 million as of June 30, 2022, primarily due to an increase in the trade receivables due from our third-party customers as a result of (1) the extended payment cycle caused by the regional resurgence of COVID-19 in Shanghai in the first half of 2022, (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. Our trade receivables turnover days decreased from 144 days in 2019 to 122 days in 2020, to 64 days in 2021 and further to 56 days as of June 30, 2022, as we enhanced our collection efforts. As of August 31, 2022, 31.6% or RMB14.1 million of our gross trade receivables as of June 30, 2022 had been settled. As of August 31, 2022, 64.5% or RMB1.1 million of our trade receivables from related parties outstanding as of June 30, 2022 had been settled.

The following table sets forth our turnover days of trade receivables from related parties for the periods indicated.

	Year ended December 31,			Six months ended June 30,
	2019	2020	2021	2022
	Turnover days of trade receivables from related parties ⁽¹⁾	470	171	118

- (1) Calculated by dividing the arithmetic mean of the opening and ending balance of gross trade receivables from related parties in that period by revenue generated from related parties for the corresponding period and then multiplying by the number of days in that period.

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Our turnover days of trade receivables from related parties were generally longer than our trade receivables turnover days, primarily because we did not collect payments from our related parties as frequently as we did from third parties, as we considered that the default risk of our related parties was low and as a result, it took a longer time for related party customers to settle their trade receivables. Our turnover days of trade receivables from related parties decreased from 470 days in 2019 to 70 days in the six months ended June 30, 2022, as we enhanced our collection efforts.

We generally do not grant a credit period to hospitals. However, hospitals typically have a relatively long payment cycle, usually ranging from six to nine months. We consider various factors, such as reputation, creditworthiness, length of business relationship and past payment records, in managing our trade receivables due from hospitals.

We generally do not grant a credit period to our distributors. Under limited circumstances, we may grant distributors who have a good track record, long-term business relationship and significant transaction volume with us a credit period.

We recorded substantial trade receivables balances during the Track Record Period primarily because (1) we granted credit periods for certain distributors with whom we had a long-term business relationship and significant transaction volume, (2) we recorded substantial trade receivables balances from related parties as a result of the relatively flexible settlement arrangements between us and our related parties which were previously intra-group transactions prior to the Reorganization, and (3) hospitals typically have relatively long payment cycles.

We perform an impairment analysis at the end of each reporting period using a provision matrix to measure expected credit losses for our trade receivables and assess our credit risk exposure. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we recorded allowance for impairment of RMB8.5 million, RMB7.3 million, RMB8.3 million and RMB11.9 million, respectively, along with our business expansion. We determine the expected credit losses on trade receivables by using a provision matrix analysis, based on shared credit risk characteristics by reference to repayment histories for customers. We estimate the provision rates using the historical observed default rates of the debtors taking into consideration forward-looking information that is reasonably and supportably available without undue costs or effort. At the end of each reporting period, we reassessed and updated the historical loss rates after considering the forward-looking information then available to our Directors. In this regard, our Directors consider that our credit risk is significantly reduced. See Note 3 and Note 19 to the Accountant's Report in Appendix I to this document.

We have formulated a credit management policy and will continue to follow the steps and measures stipulated in our credit management policy to manage our trade receivables. Our senior management regularly reviews our trade receivables balance and overdue balance, and we follow up with customers with past due trade receivables. As required under our credit management policy, our accounting personnel will direct sales and marketing staff to deliver collection notices to customers whose bills have been overdue for less than 30 days. For

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customers whose bills have been overdue for 30 days to 90 days, our accounting personnel will escalate the matter to our vice president, and both our sales and marketing staff and our vice president will deliver collection notices to our customers. For customers whose bills have been overdue for more than 90 days, our accounting personnel will escalate the matter to our president to confirm whether we should cease further transactions with such customers. For customers who refuse to pay the bills despite numerous notices, we may consider initiating lawsuits. See “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Commercialization and Distribution — We are exposed to credit risk in relation to our trade and other receivables.”

The following table sets forth an aging analysis of our trade receivables based on the invoice dates as of the dates indicated.

	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
Within one year	36,613	35,265	25,332	32,811
One year to two years	12,886	6,483	1,992	6,916
Over two years	4,333	3,918	4,833	5,065
Total	53,832	45,666	32,157	44,792

As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had trade receivables aged over one year of RMB17.2 million, RMB10.4 million, RMB6.8 million and RMB12.0 million, respectively. However, we did not have significant losses which exceeded the loss rate applied during the Track Record Period, except for the trade receivables we specifically identified as credit impaired. Having considered that (1) the trade receivables balances were mainly due from customers with ongoing business relationship with our Group, (2) there were no on-going disputes with such customers, (3) these customers had been making continuous subsequent repayment to our Group and their historical repayment pattern was generally consistent during the Track Record Period, and (4) we have continuously carried out stringent credit management policy and increased effort in credit control, evidenced by the decrease in trade receivables turnover days since 2019, our Directors are of the view that there is no recoverability issue for our trade receivables, including for the balances aged more than one year as of June 30, 2022, and, accordingly, we have made sufficient provision. Having considered the work done by the Directors and the Reporting Accountant and the relevant due diligence work performed, nothing material has come to the Sole Sponsor’s attention that indicates that the provision made on the Group’s trade receivables by the Company during the Track Record Period is not sufficient.

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Prepaid Income Tax

Our prepaid income tax consisted primarily of the surplus tax amount at the end of the relevant taxable year. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had prepaid income tax of nil, RMB5.2 million, nil and nil, respectively. The significant increase in our prepaid income tax from December 31, 2019 to December 31, 2020 was primarily due to the payment of the prepaid income tax deferred from 2019 together with the prepaid income tax of 2020.

Cash and Cash Equivalents

Our cash and cash equivalents consisted primarily of cash on hand and deposits held at call with banks. As of December 31, 2019 and 2020, all of our cash and cash equivalents were denominated in RMB. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had cash and cash equivalents of RMB16.1 million, RMB18.8 million, RMB713.5 million and RMB664.5 million, respectively. The increase in our cash and cash equivalents from December 31, 2019 to December 31, 2020 was primarily due to the increase in operating cash flow as a result of our business growth. The significant increase in our cash and cash equivalents from December 31, 2020 to December 31, 2021 was primarily due to the capital contribution by the [REDACTED] of RMB609.7 million, cash received for the disposal of Ningbo Bingkun of RMB439.2 million and capital contribution by Ningbo Jiacheng and Ningbo Jiadu of RMB51.3 million, partially offset by dividend paid to Lepu Medical of RMB320.0 million, deemed distribution of RMB72.2 million in connection with the injection of interventional heart valve business, and settlements of payable to related parties of RMB45.9 million. 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.

Deferred Income

Our deferred income represents government grants we received from PRC governments to support the expansion of our production lines. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had deferred income of RMB2.1 million, RMB1.3 million, RMB0.5 million and RMB0.2 million, respectively. The gradual decrease was primarily due to the amortization of the government grants related to assets over the expected useful life of the relevant assets.

Redemption Liabilities

Our redemption liabilities relate to financial instruments with preferred rights held by [REDACTED]. Pursuant to the [REDACTED] Shareholders Agreement dated May 28, 2021, the [REDACTED] might be granted certain preferred rights, including, among others, liquidation preference, only if and when we failed to consummate the [REDACTED] prior to December 31, 2022 or other triggering events. The liquidation preference constituted our obligations to repurchase our own equity instruments and was therefore recognized as redemption liabilities. We recognized such financial instruments with potential preferred rights as financial liabilities as all triggering events for the grant of the key preferred rights to the

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[REDACTED] or their effectiveness are out of our control. As of December 31, 2021 and June 30, 2022, we had redemption liabilities of RMB680.0 million and RMB720.9 million, respectively. The increase was primarily due to interest expense on redemption liabilities and foreign exchange losses in relation to the retranslation of redemption liabilities resulted from exchange rate fluctuations. See Note 30 to the Accountant’s Report included in Appendix I to this document for details. No preferred right has been granted to the [REDACTED] yet. See “History, Reorganization and Corporate Structure — [REDACTED].”

Trade and Other Payables

Our trade and other payables consisted primarily of trade payables to related parties and third parties, employee benefit payables, other taxes payables, and other payables to related and third parties. We had trade and other payables of RMB57.3 million, RMB62.1 million, RMB26.3 million and RMB54.4 million as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively. Our suppliers typically grant us a credit period from one to four months.

The following table sets forth the details of our trade and other payables as of the dates indicated.

	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
Trade payables	4,464	4,420	6,680	5,683
– to related parties	1,243	2,019	–	147
– to third parties	3,221	2,401	6,680	5,536
Other payables to related parties	42,866	45,754	–	25,629
Employee benefits payable	4,379	6,988	7,139	6,172
Other taxes payables	4,014	3,526	5,167	8,183
Deposits received from customers	651	608	326	271
Accrual of [REDACTED] expenses	–	–	5,535	7,045
Payables for equipment acquisition	–	–	430	95
Others	912	841	1,023	1,349
Total	57,286	62,137	26,300	54,427

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The following table sets forth our trade payables turnover days for the periods indicated.

	Year ended December 31,			Six months ended June 30,
	2019	2020	2021	2022
	Trade payables turnover days ⁽¹⁾	93	107	80

(1) The trade payables turnover days are calculated by dividing the arithmetic mean of the opening and ending balance of trade payables in that period by cost of sales for the corresponding period and then multiplying by the number of days in that period.

Our trade payables increased from RMB4.5 million as of December 31, 2019 and RMB4.4 million as of December 31, 2020 to RMB6.7 million as of December 31, 2021, generally in line with our business growth. Our trade payables turnover days increased from 93 days in 2019 to 107 days in 2020, primarily because the increase in average trade payables outpaced the increase in our cost of sales. Our trade payables turnover days decreased to 80 days in 2021, primarily because the increase in average trade payables was outpaced by the increase in our cost of sales as we enhanced our settlement efforts. Our trade payables decreased to RMB5.7 million as of June 30, 2022 and trade payables turnover days decreased to 73 days in the six months ended June 30, 2022, as we enhanced our settlement efforts. As of August 31, 2022, 59.8% or RMB3.4 million of our trade payables as of June 30, 2022 had been settled. As of July 31, 2022, we had fully settled our trade payables to related parties outstanding as of June 30, 2022.

Our other payables to related parties primarily represented (1) the payment of surgical dressing products to an overseas independent third party that Lepu Medical made on behalf of us, which was related to our distribution services provided for such overseas independent third party in relation to the surgical dressing products, as at that time we did not have the qualifications to engage in import and export business, (2) the contributions of salaries, social insurance and housing provident fund Lepu Medical made on behalf of us for our employees located in Beijing, as we did not have a subsidiary or branch in Beijing to make local contributions of salaries, social insurance and housing provident fund for certain of our employees based in Beijing, (3) the payment of rental in relation to properties newly leased from Lepu Medical in March 2021 for our interventional heart valve business, and (4) the payment to a subsidiary of Lepu Medical in relation to the distribution of COVID-19 antigen reagents to the local government, where we acted as an agent following the instructions from such subsidiary of Lepu Medical, amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022. See Note 21(a) to the Accountant’s Report included in Appendix I to this document for details. We terminated such distribution arrangement in June 2022. In 2019, 2020, 2021 and the six months ended June 30, 2022, the total amount of payments involved for the surgical dressing products that Lepu Medical made on behalf of us was RMB9.0 million, nil, nil and nil, respectively. In the same periods, the contributions of salaries, social insurance and housing provident fund for our employees located in Beijing that Lepu Medical made on behalf of us was RMB3.8 million, RMB3.5 million, RMB0.1 million and nil, respectively. During the Track Record Period, we had properly recognized the relevant expenses in our consolidated financial statements. In May 2019, we terminated the surgical dressing products

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distribution services and the related indirect payment arrangement with Lepu Medical, because such business was unrelated to our principal business operations. In April 2021, we terminated the arrangement with Lepu Medical regarding the contributions of salaries, social insurance and housing provident fund for our employees located in Beijing, as we established our Beijing branch in March 2021 to directly make payments for salaries, social insurance and housing provident fund for our employees located in Beijing. Our other payables to related parties increased from RMB42.9 million as of December 31, 2019 to RMB45.8 million as of December 31, 2020, primarily due to the accumulated other payables to related parties that we had not settled. Our other payables to related parties decreased from RMB45.8 million as of December 31, 2020 to nil as of December 31, 2021, primarily due to our enhanced settlement efforts. Our other payables to related parties increased to RMB25.6 million as of June 30, 2022, primarily in relation to the distribution of COVID-19 antigen reagents to the local government, where we acted as an agent following the instructions from a subsidiary of Lepu Medical, amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022. See “— Trade Receivables” and Note 21(a) to the Accountant’s Report included in Appendix I to this document for details. As of August 31, 2022, none of our other payables to related parties outstanding as of June 30, 2022 had been settled, which we expect to fully settle prior to the [REDACTED].

The following table sets forth an aging analysis of our trade payables based on the invoice dates as of the dates indicated.

	As of December 31,			As of
	2019	2020	2021	June 30, 2022
	<i>(RMB in thousands)</i>			
Within one year	4,132	3,179	6,533	5,536
One year to two years	186	1,002	–	–
Over two years	146	239	147	147
Total	4,464	4,420	6,680	5,683

Contract Liabilities

Our contract liabilities consisted primarily of customers’ rights to claim for additional units, volume rebates to customers, and nonrefundable prepayment from customers. According to the F&S Report, in line with industry practice, our customers generally have the right to claim of additional units that are discarded during the process of implantation, primarily as a result of limited surgical equipment and surgical skills of the surgeons administering our products, which is unrelated to the quality and functionality of our product, upon our confirmation based on the evidence, such as photographs and product serial number, provided by the customers. We also offer a volume rebate to our distributors who outperformed the pre-determined sales levels. The considerations for products that are used as settlement for our unsatisfied performance obligations with respect to the aforementioned claims for additional units and volume rebates have been deferred and accounted for as our contract liabilities. See Note 32 to the Accountant’s Report in Appendix I to this document. Our contract liabilities increased from RMB12.2 million as of December 31, 2019 to RMB15.3 million as of December 31, 2020, generally consistent with our increased sales volumes. Our contract liabilities

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remained relatively stable at RMB14.8 million as of December 31, 2021 and RMB14.4 million as of June 30, 2022. Our contract liabilities as of December 31, 2019 and 2020 had been fully recognized as our revenue in 2020 and 2021, respectively. As of August 31, 2022, 95.1% or RMB13.7 million of our contract liabilities as of June 30, 2022 had been recognized as our revenue.

LIQUIDITY AND CAPITAL RESOURCES

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. Going forward, we believe that our liquidity requirements will be satisfied with a combination of cash flows generated from our operating activities, bank loans and other borrowings, [REDACTED] from the [REDACTED] and other funds raised from the capital markets from time to time. Any significant decrease in the demand or market prices of our interventional medical devices targeting structural heart diseases, or a significant decrease in the availability of bank loans or other financing may adversely impact our liquidity. As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had cash and cash equivalents of RMB16.1 million, RMB18.8 million, RMB713.5 million and RMB664.5 million, respectively.

Cash Flows

The following table sets forth a summary of our 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>

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Net cash flows generated from operating activities

Net cash generated from operating activities was RMB52.7 million in the six months ended June 30, 2022, primarily due to profit before tax of RMB25.3 million plus interest received of RMB1.6 million and minus income tax paid of RMB2.5 million, as adjusted for (1) certain non-cash or non-operating items, primarily including net foreign exchange losses of RMB26.9 million primarily in relation to the retranslation of redemption liabilities resulted from exchange rate fluctuations, finance costs of RMB9.1 million, share-based compensation expenses of RMB7.1 million and depreciation and amortization of RMB6.8 million, (2) changes in the working capital that positively affected the cash flow from operating activities, primarily including an increase in trade and other payables of RMB26.8 million primarily in relation to the distribution of COVID-19 antigen reagents to the local government, where we acted as an agent following the instructions from a subsidiary of Lepu Medical, amid the regional resurgence of COVID-19 in Shanghai in the first half of 2022, partially offset by changes in working capital that negatively affected the cash flow from operating activities, primarily including an increase in prepayments and other receivables of RMB27.7 million primarily due to (i) receivables from sales on behalf of a related party in relation to the COVID-19 antigen reagents as discussed above, and (ii) an increase in prepayment for raw materials to support our resumed manufacturing activities following the containment of COVID-19, an increase in trade receivables of RMB12.5 million as a result of (i) the extended payment cycle caused by the regional resurgence of COVID-19 in Shanghai in the first half of 2022, (ii) the relatively loosened credit policy to some of our trusted customers to boost our recovery following the containment of COVID-19, and (iii) the increased scale of our business, and an increase in inventories of RMB6.9 million primarily due to (i) delayed consumption of raw materials as our manufacturing and sales activities were temporarily interrupted amid the regional resurgence of COVID-19 in Shanghai, and (ii) our purchase of raw materials to support our resumed manufacturing activities following the containment of COVID-19.

Net cash generated from operating activities was RMB105.3 million in 2021, primarily due to profit before tax of RMB66.0 million plus interest received of RMB1.2 million and minus income tax paid of RMB0.5 million, as adjusted for (1) certain non-cash or non-operating items, primarily including share-based compensation expenses of RMB17.8 million, finance costs of RMB10.4 million, and depreciation and amortization of RMB9.8 million related to office furniture and equipment, (2) changes in working capital that positively affected the cash flow from operating activities, primarily including a decrease in trade receivables of RMB13.5 million, as we enhanced our collection efforts, and an increase in trade and other payables of RMB9.9 million driven by our business growth, partially offset by changes in working capital that negatively affected the cash flow from operating activities, primarily including an increase in inventories of RMB10.1 million, primarily because (i) we strategically purchased surplus inventory of raw materials amid the COVID-19 outbreak, and (ii) we purchased raw materials for our fully biodegradable VSD occluder product, which obtained the NMPA approval in February 2022, in anticipation of robust market demand.

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Net cash generated from operating activities was RMB59.1 million in 2020, primarily due to profit before tax of RMB76.7 million plus interest received of RMB0.1 million and minus income tax paid of RMB14.1 million, as adjusted for (1) certain non-cash and non-operating items, primarily including depreciation and amortization of RMB6.1 million related to office furniture and equipment, and net gains on disposal of investment properties of RMB5.1 million, primarily reflected the disposal of certain of our properties in 2020, (2) changes in working capital that negatively affected the cash flow from operating activities, primarily including an increase of RMB12.3 million in inventories, primarily as (i) we strategically purchased surplus inventory of raw materials as part of our provisional strategies amid the COVID-19 outbreak, and (ii) we purchased additional raw materials for our newly launched LAA occluder product in anticipation of robust market demand, and an increase of RMB7.0 million in prepayments and other receivables, primarily due to an increase of prepayment of raw materials to third parties to support our increased research and development activities and business growth, partially offset by changes in working capital that positively affected the cash flow from operating activities, primarily including a decrease of RMB8.2 million in trade receivables, as we enhanced our collection efforts, an increase of RMB4.9 million in trade and other payables, driven by our business growth, and an increase of RMB3.1 million in contract liabilities, primarily driven by our increased sales volumes.

Net cash generated from operating activities was RMB54.5 million in 2019, primarily due to profit before tax of RMB60.3 million plus interest received of RMB0.2 million and minus income tax paid of RMB6.5 million, as adjusted for (1) certain non-cash and non-operating items, primarily including depreciation and amortization of RMB4.7 million related to office furniture and equipment, (2) changes in working capital that negatively affected the cash flow from operating activities, primarily including an increase of RMB15.9 million in trade receivables, along with our business growth, and an increase of RMB5.2 million in prepayments and other receivables, primarily due to the increases in (i) other receivables from related parties as a result of the increase in the accumulated rental receivables from related parties, and (ii) prepayment to third parties, which represented the increased prepayment of testing and animal studies fees and materials, generally in line with our business growth, partially offset by changes in working capital that positively affected the cash flow from operating activities, primarily including an increase of RMB19.6 million in trade and other payables, primarily as a result of the accumulated other payables to related parties that we had not settled as of December 31, 2019.

Net cash flows used in investing activities

Net cash used in investing activities was RMB102.8 million in the six months ended June 30, 2022, primarily due to (1) placement of bank deposit with initial term of over three months of RMB70.0 million, (2) payment of internal development costs capitalized as intangible assets of RMB26.6 million, and (3) purchases of property, plant and equipment of RMB9.5 million.

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Net cash used in investing activities was RMB85.2 million in 2021, primarily due to (1) payment of internal development costs capitalized as intangible assets of RMB69.4 million, and (2) purchases of property, plant and equipment of RMB22.5 million.

Net cash used in investing activities was RMB8.5 million in 2020, primarily due to (1) payment of internal development costs capitalized as intangible assets of RMB12.1 million, (2) purchases of property, plant and equipment of RMB2.5 million, and (3) purchases of intangible assets of RMB1.0 million, partially offset by (1) proceeds from sale of investment properties of RMB6.1 million, and (2) proceeds from sale of financial assets at fair value through other comprehensive income of RMB1.0 million.

Net cash used in investing activities was RMB13.1 million in 2019, primarily due to (1) payment of internal development costs capitalized as intangible assets of RMB11.8 million, (2) purchases of property, plant and equipment of RMB3.3 million, and (3) purchases of intangible assets of RMB0.9 million, partially offset by proceeds from sale of investment properties of RMB3.0 million.

Net cash flows (used in)/generated from financing activities

Net cash used in financing activities was RMB2.2 million in the six months ended June 30, 2022, primarily due to payment for [REDACTED] expenses of RMB1.9 million.

Net cash generated from financing activities was RMB672.2 million in 2021, primarily due to (1) capital contribution by the [REDACTED] of RMB609.7 million, (2) deemed contribution of RMB446.1 million primarily in relation to 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) 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.

Net cash used in financing activities was RMB48.0 million in 2020, primarily due to deemed distribution of RMB777.6 million in relation to our Reorganization, partially offset by deemed contribution of RMB730.2 million in relation to our Reorganization.

Net cash used in financing activities was RMB41.9 million in 2019, primarily due to deemed distribution of RMB61.0 million in relation to our Reorganization, partially offset by deemed contribution of RMB19.6 million in relation to our Reorganization.

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Current Assets and Current Liabilities

The following table sets forth our current assets and liabilities as of the dates indicated.

	As of December 31,			As of	As of
	2019	2020	2021	June 30, 2022	August 31, 2022
	<i>(RMB in thousands)</i>				<i>(Unaudited)</i>
CURRENT ASSETS					
Inventories	11,052	23,319	33,402	40,269	46,906
Trade receivables	45,331	38,317	23,869	32,883	24,604
Prepayments and other receivables	13,442	20,182	21,765	51,807	64,112
Prepaid income tax	–	5,152	–	–	–
Financial assets at fair value through profit or loss	–	–	–	1,004	66,283
Bank deposit with initial term of over three months	–	–	–	70,000	70,000
Cash and cash equivalents	16,119	18,792	713,480	664,534	615,535
Total current assets	<u>85,944</u>	<u>105,762</u>	<u>792,516</u>	<u>860,497</u>	<u>887,440</u>
CURRENT LIABILITIES					
Redemption liabilities	–	–	679,986	720,861	740,968
Trade and other payables	57,286	62,137	26,300	54,427	64,815
Contract liabilities	12,206	15,343	14,783	14,426	17,704
Current income tax liabilities	4,683	–	6,761	12,797	12,060
Lease liabilities	369	116	2,143	1,994	1,830
Total current liabilities	<u>74,544</u>	<u>77,596</u>	<u>729,973</u>	<u>804,505</u>	<u>836,747</u>
NET CURRENT ASSETS	<u>11,400</u>	<u>28,166</u>	<u>62,543</u>	<u>55,992</u>	<u>50,693</u>

We had net current assets of RMB11.4 million, RMB28.2 million, RMB62.5 million, RMB56.0 million and RMB50.7 million as of December 31, 2019, 2020 and 2021, June 30, 2022 and August 31, 2022, respectively. Our net current assets position as of each of these dates was mainly attributable to our inventories, prepayments and other receivables, trade receivables, bank deposit with initial term of over three months and cash and cash equivalents, partially offset by our redemption liabilities, trade and other payables, contract liabilities, current income tax liabilities and lease liabilities. 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, generally consistent with our business growth. Our net current assets increased from RMB28.2 million as of December 31, 2020 to RMB62.5

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million as of December 31, 2021, primarily due to (1) an increase in cash and cash equivalents of RMB694.7 million mainly as a result of the capital contribution by [REDACTED] and the cash received for the disposal of Ningbo Bingkun, partially offset by the 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 the financial instruments with preferred rights held by the [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 upon completion of the [REDACTED]. Our net current assets decreased to RMB56.0 million as of June 30, 2022 and further to RMB50.7 million as of August 31, 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.

Working Capital

Our primary use of cash is to fund the daily operations of our business. During the Track Record Period, we financed our capital expenditures and working capital requirements primarily through cash generated from our operations and financing activities. Going forward, we believe that our liquidity requirements will be satisfied with a combination of cash flows generated from our operating activities, [REDACTED] from the [REDACTED] and other funds raised from the capital markets from time to time. As of June 30, 2022, we had cash and cash equivalents of RMB664.5 million.

Taking into account the financial resources available to us, including cash flow from operating activities and the estimated [REDACTED] from the [REDACTED], our Directors are of the view that we have sufficient working capital to meet our present requirements and for the next 12 months from the date of this document.

Based on the relevant due diligence work carried out by the Sole Sponsor, the Sole Sponsor is satisfied that the Directors’ confirmation above regarding the working capital sufficiency was made after due and careful enquiry by the Company and the Directors.

We intend to continue to finance our working capital with cash generated from our operations, [REDACTED] from the [REDACTED] and other funds raised from the capital markets from time to time. We will closely monitor the level of our working capital, and diligently review future cash flow requirements and adjust our operation and expansion plans, if necessary, to ensure that we maintain sufficient working capital to support our business operations.

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CAPITAL COMMITMENTS

As of December 31, 2019, 2020 and 2021 and June 30, 2022, we had capital commitments of nil, nil, RMB10.8 million and RMB6.5 million, respectively, primarily in connection with purchase of fixed assets. See Note 34 to the Accountant’s Report included in Appendix I to this document for details.

INDEBTEDNESS

Our indebtedness during the Track Record Period primarily consisted of lease liabilities and redemption liabilities. The following table sets forth a breakdown of our indebtedness as of the dates indicated.

	As of December 31,			As of	As of
	2019	2020	2021	June 30, 2022	August 31, 2022
	<i>(RMB in thousands)</i>				<i>(Unaudited)</i>
Borrowings	–	–	–	–	–
Lease liabilities	369	116	6,187	6,288	5,103
Redemption liabilities	–	–	679,986	720,861	740,968
Total indebtedness	369	116	686,173	727,149	746,071

Borrowings

As of August 31, 2022, being the latest practicable date for the purpose of this indebtedness statement, we had no outstanding balance of borrowings or unutilized banking facilities.

Lease Liabilities

The following table sets forth the breakdown of our lease liabilities as of the dates indicated.

	As of December 31,			As of	As of
	2019	2020	2021	June 30, 2022	August 31, 2022
	<i>(RMB in thousands)</i>				<i>(Unaudited)</i>
Lease liabilities					
Non-current portion	–	–	4,044	4,294	3,273
Current portion	369	116	2,143	1,994	1,830
Total	369	116	6,187	6,288	5,103

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Redemption Liabilities

The following table sets forth our redemption liabilities as of the dates indicated.

	As of December 31,			As of	As of
	2019	2020	2021	June 30, 2022	August 31, 2022
					<i>(Unaudited)</i>
Redemption liabilities	–	–	679,986	720,861	740,968

Contingent Liabilities

As of the Latest Practicable Date, we did not have any material contingent liability, guarantee or any litigation or claim of material importance, pending or threatened against us or any member of our Group that is likely to have a material and adverse effect on our business, financial condition and result of operations.

Saved as disclosed above, as of August 31, 2022, we did not have any outstanding mortgages, charges, debentures, other issued debt capital, bank overdrafts, borrowings, liabilities under acceptance or other similar indebtedness, any guarantees or other material contingent liabilities. Our Directors confirm that there had not been any material adverse change in our indebtedness since August 31, 2022 and up to the Latest Practicable Date.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transaction.

[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 [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 [REDACTED] related expenses of approximately RMB[REDACTED] million. Among the estimated [REDACTED] expenses, approximately RMB[REDACTED] million is directly attributable to the [REDACTED] of H Shares to the public and is expected to be 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

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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 profit or loss of the six months ending 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. Our Directors would like to emphasize that the expenses in relation to the [REDACTED] are a current estimate for reference only and the amounts to be recognized in the equity and the statement of results of operation of our Group are subject to adjustment due to changes in estimates and assumptions.

In view of the above, prospective [REDACTED] should note that the financial results of our Group for 2022 will be adversely affected by the non-recurring [REDACTED] expenses in relation to the [REDACTED].

RELATED PARTY TRANSACTIONS

We enter into transactions with our related parties from time to time during our ordinary course of business and on terms comparable to the terms of transactions with other entities that are not related parties. During the Track Record Period, we entered into a number of related party transactions, primarily including (1) sales of medical devices to related parties, (2) purchases of raw materials from related parties, (3) rental income from related parties, and (4) commission income from related parties. All the trade receivables, trade payables and prepayments balances with our related parties during the Track Record Period are trade in nature. Other receivables due from related parties and other payables due to related parties are non-trade in nature. As of July 31, 2022, we had fully settled the non-trade balances with related parties outstanding as of June 30, 2022. We expect to continue to receive rental income and incur rental payment from time to time pursuant to the lease agreements entered into with our related parties after [REDACTED]. See Note 35 to the Accountant’s Report included in Appendix I to this document for details.

Our Directors are of the view that our related party transactions during the Track Record Period were conducted in the ordinary course of business at arm’s length with reference to normal commercial terms, and would not distort our track record results or make our historical results not reflective of our future performance.

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KEY FINANCIAL RATIOS

	As of/for the year ended December 31,			As of/for the six months ended June 30,
	2019	2020	2021	2022
Profitability ratios				
Gross profit margin ⁽¹⁾	88.3%	89.8%	88.8%	87.7%
Net profit margin ⁽²⁾	44.6%	46.4%	26.4%	19.4%
Return on equity ⁽³⁾	22.9%	28.3%	18.4%	12.1% ⁽⁷⁾
Return on total assets ⁽⁴⁾	17.8%	21.5%	8.1%	4.1% ⁽⁷⁾
Liquidity ratios				
Current ratio ⁽⁵⁾	1.2	1.4	1.1	1.1
Quick ratio ⁽⁶⁾	1.0	1.1	1.0	1.0

(1) The calculation of gross profit margin is based on gross profit for the period divided by revenue for the respective period and multiplied by 100.0%.

(2) The calculation of net profit margin is based on profit for the period divided by revenue for the respective period and multiplied by 100.0%.

(3) The calculation of return on equity is based on profit for the period divided by average total equity attributable to equity holders of our Company as of the beginning and end of the period and multiplied by 100.0%.

(4) The calculation of return on total assets is based on profit for the period divided by average total assets as of the beginning and end of the period and multiplied by 100.0%.

(5) The calculation of current ratio is based on current assets divided by current liabilities as of period end.

(6) The calculation of quick ratio is based on current assets less inventories divided by current liabilities as of period end.

(7) 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.

Analysis of Key Financial Ratios

Gross Profit Margin and Net Profit Margin

See “— Period to Period Comparison of Results of Operations” for a discussion of the factors affecting our gross profit margin and net profit margin during the Track Record Period.

Return on Equity and Return on Total Assets

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

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share issuance to the [REDACTED]. Our return on equity decreased to 12.1% in the six months ended June 30, 2022, 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. See Note 26 and Note 27 to the Accountant’s Report in Appendix I to this document for details.

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 the [REDACTED] and cash received for the disposal of Ningbo Bingkun, partially offset by dividend paid to Lepu Medical. Our return on total assets decreased to 4.1% in the six months ended June 30, 2022, 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. See Note 10 and Note 25 to the Accountant’s Report in Appendix I to this document for details.

Current Ratio and Quick Ratio

Our current ratio remained relatively stable at 1.2, 1.4, 1.1 and 1.1 as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively.

Our quick ratio remained relatively stable at 1.0, 1.1, 1.0 and 1.0 as of December 31, 2019, 2020 and 2021 and June 30, 2022, respectively.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our principal financial instruments include trade receivables, other receivables, cash and cash equivalents, financial assets at fair value through other comprehensive income, bank deposit with initial term of over three months, trade and other payables, and lease liabilities. We have various other financial assets and liabilities such as trade receivables, trade payables and other payables. We are exposed to various financial risks including foreign exchange risk, credit risk and liquidity risk. Our overall risk management focuses on the unpredictability of financial markets to minimize potential adverse effects on our financial performance. Our senior management is responsible for our risk management.

Our Directors reviewed and agreed policies for managing each of these risks as summarized below. For details of our financial risk management, see Note 3 to the Accountant’s Report in Appendix I to this document.

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Foreign Exchange Risk

Foreign exchange risk arises when future commercial transactions or recognized assets and liabilities are denominated in a currency that is not our functional currency. Our functional currency is RMB.

We expose ourselves to foreign exchange risk because certain of our trade payables, financial instruments with preferred rights at amortized cost and cash and cash equivalents are denominated in foreign currencies. We will mitigate such a risk by constantly reviewing the economic situation and foreign exchange risk, and applying hedging measures when necessary. See Note 3.1(a) to the Accountant’s Report in Appendix I to this document for details.

Credit Risk

Our maximum exposure to credit risk in relation to financial assets is the carrying amounts of cash and cash equivalents, bank deposit with initial term of over three months, trade receivables, and other receivables. We do not expect there is significant credit risk associate with our cash and cash equivalents and bank deposit with initial term of over three months because we deposit them in state-owned banks and other reputable commercial banks.

Our trade receivables and other receivables are subject to expected credit loss model. See Note 3.1(b) to the Accountant’s Report in Appendix I to this document for details on impairment of financial assets.

Liquidity Risk

In order to manage liquidity risk, we monitor and maintain a level of cash and cash equivalents deemed adequate by our senior management to finance our operations and mitigate the effects of fluctuations in cash flows. See Note 3.1(c) to the Accountant’s Report in Appendix I to this document for details.

DIVIDEND POLICY

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” for further details.

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DISTRIBUTABLE RESERVES

As of June 30, 2022, we had distributable reserves of RMB163.3 million.

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 market, primarily including Brazil and India, where hospitals 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

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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 of 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.

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.

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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.

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.”

FINANCIAL INFORMATION

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

DISCLOSURE REQUIRED UNDER CHAPTER 13 OF THE LISTING RULES

Our Directors have confirmed that, as of the Latest Practicable Date, they were not aware of any circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

RECENT DEVELOPMENT

We currently expect an increase in our expenses and a corresponding decrease in our net profit and net profit margin 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.

FUTURE PLANS AND [REDACTED]

FUTURE PLANS

See “Business — Growth Strategies” for a detailed description of our future plans.

[REDACTED]

Assuming the [REDACTED] is not exercised and 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, we estimate that the [REDACTED] of the [REDACTED], after deducting the estimated [REDACTED] and other fees and expenses payable by us in connection with the [REDACTED], will be approximately HK\$[REDACTED] million.

We intend to use the [REDACTED] from the [REDACTED] for the purposes and in the amounts set out below.

- 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, including:
 - (1) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for development and expansion of our product pipeline, including advancing the development and registration of our product candidates, and conducting clinical trials for a period of up to five years for certain products and product candidates upon commercialization as required by relevant regulations. Specifically, we intend to allocate the [REDACTED] to material and equipment procurement, animal study, type inspection, clinical trial, registration, sampling and clinical trial upon commercialization for continued evaluation of efficacy and safety of our marketed products. As of the Latest Practicable Date, we had 30 major product candidates in our pipeline, of which one was in the clinical trial preparation stage, two in the registration process with the NMPA, two in the registration preparation process with the NMPA, seven in clinical trials, eight in the type inspection stage, and 10 in the product design stage. We expect to continue to expand our product pipelines. See “Business — Growth Strategy — Promote the development and clinical trial progress of our product candidates” and “Business — Growth Strategies — Expand our global footprint by increasing product development and commercialization and broadening overseas sales channels.” Our product candidates and research and development activities have focused, and will continue to focus, mainly on various kinds of valvular product candidates or biodegradable materials for occluder product candidates, which involve more advanced or innovative technologies and more complex processes, and therefore require higher research and development investments. The following sets forth our usage of such [REDACTED] divided by product types:

FUTURE PLANS AND [REDACTED]

- (a) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for the research and development material procurement and related experiments, clinical trial prior to commercialization, clinical trial upon commercialization for continued evaluation of efficacy and safety, and registration for our valvular product candidates, mainly including our TAVR system, TMVCRS, and TMVr systems. Set forth below is the current development stage and next milestone of our major valvular product candidates.
- (i) *TAVR system*. As of the Latest Practicable Date, we had initiated the clinical trial and expect to submit registration application for our TAVR system with the NMPA in the fourth quarter of 2023. We are also evaluating the opportunities to market our TAVR system overseas, especially in emerging markets that recognize the CE Mark. We plan to initiate the clinical trial for TAVR system in the European Union in the fourth quarter of 2024.
- (ii) *TMVCRS*. As of the Latest Practicable Date, we had initiated the clinical trial for TMVCRS in China and expect to submit the registration application with the NMPA in the third quarter of 2024.
- (iii) *TMVr-A system*. As of the Latest Practicable Date, our TMVr-A system was at the clinical trial stage. We plan to submit the registration application with the NMPA in the fourth quarter of 2023.
- (iv) *TMVr-F system*. As of the Latest Practicable Date, our TMVr-F system was in the type inspection stage. We plan to commence the clinical trial for TMVr-F in China in the fourth quarter of 2022 and submit registration application with the NMPA in the fourth quarter of 2024. See “Business — Our Products — Heart Valve Product Candidates.”

According to the F&S Report, the market size of the global valvular disease interventional device market is expected to increase from US\$7.1 billion in 2021 to US\$14.5 billion in 2025 at a CAGR of 19.7%, and further to US\$39.7 billion in 2030 at a CAGR of 22.3% from 2025 to 2030. 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 further to RMB41.9 billion in 2030 at a CAGR of 39.6% from 2025 to 2030, according to the same source. Heart valve products primarily include aortic valve products and mitral valve products. TAVR system is a major aortic valve product and mitral valve products primarily include the TMVCRS and TMVr systems;

FUTURE PLANS AND [REDACTED]

- (b) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for research and development material procurement and related experiments, clinical trial prior to commercialization, clinical trial upon commercialization for continued evaluation of efficacy and safety, and registration for our occluder product and product candidates, mainly including our MemoSorb[®] ASD Occluder IV, MemoSorb[®] VSD Occluder IV, MemoSorb[®] PFO Occluder II, and LAA Closure Occluder II. Set forth below is the current development stage and next milestone of our major occluder product and product candidates.
- (i) *MemoSorb[®] ASD Occluder IV*. As of the Latest Practicable Date, our MemoSorb[®] ASD Occluder IV was in the clinical trial process, and we expect to submit application to the NMPA in the second quarter of 2023 and receive approval in the second quarter of 2024. We plan to commence clinical trial for MemoSorb[®] ASD Occluder IV in the European Union and the United States in the fourth quarter of 2024.
 - (ii) *MemoSorb[®] VSD Occluder IV*. We obtained the NMPA approval for our MemoSorb[®] VSD Occluder IV in February 2022. We plan to commence clinical trial for MemoSorb[®] VSD Occluder IV in the European Union and the United States in the fourth quarter of 2022 and the fourth quarter of 2023, respectively.
 - (iii) *MemoSorb[®] PFO Occluder II*. As of the Latest Practicable Date, our MemoSorb[®] PFO Occluder II was in the registration preparation process with the NMPA, which is expected to submit the application in the fourth quarter of 2022 and receive the approval in the fourth quarter of 2023. We plan to commence clinical trial for MemoSorb[®] PFO Occluder II in the European Union and the United States in the fourth quarter of 2024.
 - (iv) *LAA Closure Occluder II*. As of the Latest Practicable Date, our LAA Closure Occluder II was at the stage of clinical trial preparation. We plan to commence the clinical trial for LAA Closure Occluder II in China in the fourth quarter of 2022 and in the European Union and the United States thereafter. See “Business — Our Products — Occluder Products.”

FUTURE PLANS AND [REDACTED]

According to the F&S Report, there are approximately 150,000 newborns with CHD in China each year. However, compared with the high treatment rate of CHD in Europe and the United States, the current treatment of CHD patients in China is low, and so is the penetration rate of CHD occluder products in China. The domestic market for CHD occluder devices is expected to proliferate in the future.

According to the F&S Report, in 2021, the penetration rate of PFO occluder products in China was approximately 42.4%, which is expected to grow to 59.9% by 2025. According to the same source, in 2021, the penetration rate of LAA occluder products in China was approximately 5.9%, as compared to 44.9% in the United States and 14.6% in Europe, respectively. The penetration rate of LAA occluder products in China is expected to grow to 19.4% by 2025.

Our design for biodegradable occluder product and product candidates not only ensures effective autologous tissue closure but also minimizes potential compression and wear on surrounding tissues caused by metal implants, which lowers the risk of long-term complications. In addition, we believe it leaves available for patients additional future treatment options, especially transseptal procedures, as the biodegradable occluders would not be a permanent implant in the human body, benefiting all patients receiving occluder implants, and in particular, to children who constitute the majority of patients suffering from CHD and also expect a significantly longer remaining life span and better life quality. According to the F&S Report, the emergence of biodegradable occluder products provides an alternative option for patients with lower risk and flexibility for future treatment. Therefore, it is foreseeable that biodegradable occluder products will gain market prevalence and become a future trend in the occluder product market.

The manufacturing of biodegradable occluders is expected to produce waste similar to that was produced when manufacturing our marketed products. We will closely follow our established environmental protection policies and waste reclamation and disposal standards to ensure ongoing compliance with applicable PRC environmental laws and regulations. See “Business — Environmental, Social and Corporate Governance.”

- (c) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for research and development material procurement and related experiments, clinical trial prior to commercialization, clinical trial upon commercialization for continued evaluation of efficacy and safety, and registration for our occluder product and product candidates, mainly including our MemoFlex[®] Plug

FUTURE PLANS AND [REDACTED]

III, MemoPart[®] Snare II, Interatrial Shunt Device II, and Interatrial Shunt Device III. Set forth below is the current development stage and next milestone of our major other products.

- (i) *MemoFlex[®] Plug III*. As of the Latest Practicable Date, we had initiated the clinical trial for MemoFlex[®] Plug III in China, and expect to submit the registration application with the NMPA in the fourth quarter of 2023 and receive approval in the fourth quarter of 2024.
- (ii) *MemoPart[®] Snare II*. As of the Latest Practicable Date, MemoPart[®] Snare II was in the registration process with the NMPA, which is exempted from clinical trial requirements in accordance with the Catalogues of Medical Devices Exempted from Clinical Trials. We submitted our registration application with the NMPA in September 2022 and expect its approval in the third quarter of 2023.
- (iii) *Interatrial Shunt Device II (IASD II)*. As of the Latest Practicable Date, our IASD II was in the design stage. We plan to initiate the clinical trial for IASD II in China in the third quarter of 2023, and in the European Union and the United States thereafter.
- (iv) *Interatrial Shunt Device III (IASD III)*. As of the Latest Practicable Date, our IASD III was in the type inspection stage. We plan to initiate the clinical trial for IASD III in China in the fourth quarter of 2023. See “Business — Our Products — Other Products.”

As part of the total solutions offered by our occluder products and heart valve product candidates, our procedural accessories and other ancillary products are designed to deliver and deploy our products and product candidates. Accordingly, we expect these products to witness proportional genuine market demand as those for our products and product candidates.

- (2) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for recruiting approximately 70 to 100 research and development and registration personnel within 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. For instance, we plan to participate in live broadcasting of medical and surgical procedures of the administration of our occluder and heart valve products and case report meetings, organized by hospitals, to promote the application of our products. In addition, we plan to circulate patient manuals and

FUTURE PLANS AND [REDACTED]

education videos at our product display and training center to educate end users on our products. We also plan to organize regular training sessions at our product display and training center to introduce our new products to physicians, and familiarize them with the structures and materials of our products, to assist smooth administration of our products. Specifically, our [REDACTED] for sales and marketing activities include (1) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for recruiting approximately 100 to 150 sales and marketing personnel to expand our sales team for our CHD, LAA occluder products, and valvular products. We plan to continue to expand our sales and marketing team for both domestic and overseas distribution. Specifically, we plan to establish overseas sales offices and recruit sales and marketing personnel located in key overseas markets in the future to facilitate our overseas distribution. In addition, we plan to further develop our sales and marketing training system to provide training sessions to all of our existing and newly recruited sales and marketing personnel. The training sessions will include basic knowledge of structural heart disease related surgery and interventional medical device, industry knowledge of domestic and interventional medical device targeting structural heart diseases, knowledge of our products, and sales skills, especially targeting the cardiology departments in hospitals, where our products are mostly deployed; (2) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for conducting more marketing activities to promote the general market awareness and acceptance of our products, such as industry conferences and academic promotion activities both in China and overseas markets. Specifically, we will continue to participate in or organize medical conferences and industry exhibitions to circulate marketing and education materials describing the benefits and functions of our products to introduce our products to potential customers of hospitals and distributors, as well as physicians who may administer our products. We plan to hold more trainings and seminars to communicate with physicians and hospitals that already used our products, in order to monitor the actual usage of our products and to collect feedback on our products. In overseas markets, we plan to attend international medical conferences, industry exhibitions and trade fairs to meet existing and potential customers, enhance our brand recognition and introduce our products to overseas physicians and hospitals; (3) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for traveling and office expenses incurred in connection with our daily sales activities that aim to facilitate our sales growth, such as expanding our customer base, maintaining customer relationship and monitoring the sales performance of our products; (4) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for establishing a product display and training center at our headquarters to offer clinical education and showcase products to physicians and hospitals. At such center, we plan to deploy heart models to demonstrate implantation procedures of our products in surgical environment to offer both online and offline clinical education for physicians. After the COVID-19 subsidies, we also plan to invite overseas physicians and distributors to attend the

FUTURE PLANS AND [REDACTED]

offline clinical education at the center to showcase our products and the implantation procedures; and (5) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for miscellaneous fees incurred in connection with our daily sales and marketing activities, such as rental and depreciation and amortization.

- 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, including (1) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used for expanding our manufacturing facilities, physics laboratories, chemistry laboratories, and micro-biology laboratories and purchasing additional equipment, such as clean air-conditioning and purified water systems, within the next five years; and (2) approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, to be used to build up new production lines for pipeline products, including the production lines for biodegradable occlude product candidates with expected annual production capacity of approximately 8,000 to 10,000 units of occluder products, and the production lines for heart valve product candidates with expected annual production capacity of approximately 3,000 to 5,000 units of heart valve products, within the next five years. Utilizing the new production lines to be built for the heart valve product candidates which is designed to have the flexibility to manufacture all of our heart valve product candidates upon commercialization, we plan to manufacture all of our heart valve product candidates, including our Entrusted Products, with (i) TMVCRS and balloon dilatation catheter for aortic valve that we are not restricted for manufacturing, and (ii) TAVR system upon the regulatory changes lifting the restriction on commercial manufacturing for us. Specifically, we intend to purchase relevant machinery and equipment, and recruit and train production workers. See “Business — Our Products — Heart Valve Product Candidates — Entrusted Products — Future Plan for the Entrusted Products and the Entire Heart Valve Product Candidates.” In addition, we also plan to expand the production capacity of our marketed products, including purchasing additional machinery and equipment. We also intend to recruit and train approximately 30 to 50 production workers, within the next five years. In 2019, 2020, 2021 and the six months ended June 30, 2021 and 2022, our cost of sales was RMB13.6 million, RMB15.1 million, RMB25.0 million, RMB11.9 million and RMB15.3 million, respectively, representing costs incurred during our manufacturing procedures. As we continue to expand our business and advance the development and commercialization of our product candidates, we expect to further enhance our manufacturing capabilities.

FUTURE PLANS AND [REDACTED]

- approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, will be used to fund potential strategic investment and acquisitions within the next five years that could complement and expand our product portfolio and technologies. The types of opportunities on which we intend to focus include, among others, (1) companies that offer products or product candidates which complement our product portfolio and that we do not currently produce; (2) companies that manufacture product components for occluder or heart valve products which can enhance our upstream supply, strengthen our bargaining power, and achieve potential synergies along the industry value chain; and (3) companies with advanced technologies or research and development capabilities that represent significant future growth opportunities, with which we can collaborate on technology and product development, registration and commercialization. For investments and acquisitions related to products and product components, we intend to primarily consider domestic companies leveraging our in-depth understanding of China’s interventional medical device market targeting structural heart diseases, which we believe will enable us to effectively identify suitable targets and execute our investment and acquisition strategies. For investments and acquisitions related to advanced technologies or strong research and development capabilities primarily in the field of biodegradable materials, we expect to focus mainly on overseas opportunities in countries and regions such as the United States and Europe, where more cutting-edge technologies and products related to interventional medical devices are under development, according to the F&S Report. As advised by our industry consultant based on its industry research as of the Latest Practicable Date, there were more than 40 companies in China and overseas markets which may be considered as potential targets for investment and acquisition, subject to further commercial consideration and assessment. See “Business — Growth Strategies.” As of the Latest Practicable Date, we had not identified any specific acquisition targets, formed any specific acquisition plans or entered into any agreements with potential targets; and
- approximately [REDACTED]% of the [REDACTED], or approximately HK\$[REDACTED] million, will be used for our working capital and general corporate purposes.

The above allocation of the [REDACTED] from the [REDACTED] will be adjusted on a pro-rata basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the indicative [REDACTED] stated in this document.

To the extent that the [REDACTED] from the [REDACTED] are not immediately applied to the above purposes and to the extent permitted by applicable law and regulations, we will deposit the [REDACTED] into short-term demand deposits with licensed banks or authorized financial institutions in Hong Kong or China (as defined under SFO or applicable laws and regulations in the PRC). In such event, we will comply with the appropriate disclosure requirements under the Listing Rules.

[REDACTED]

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APPENDIX I

ACCOUNTANT’S REPORT

The following is the text of a report set out on pages I-[●] to I-[●], received from the Company’s reporting accountant, PricewaterhouseCoopers, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document. It is prepared and addressed to the directors of the Company and to the Sponsor pursuant to the requirements of HKSIR 200, Accountants’ Reports on Historical Financial Information in Investment Circulars issued by the Hong Kong Institute of Certified Public Accountants.

[DRAFT]

[Letterhead of PricewaterhouseCoopers]

ACCOUNTANT’S REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF LEPU SCIENSTECH MEDICAL TECHNOLOGY (SHANGHAI) CO., LTD. AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED

Introduction

We report on the historical financial information of LEPU ScienTech Medical Technology (Shanghai) Co., Ltd. (the “Company”) and its subsidiary (together, the “Group”) set out on pages I-[●] to I-86, which comprises the consolidated balance sheets as at 31 December 2019, 2020 and 2021 and 30 June 2022, the balance sheets of the Company as at 31 December 2021 and 30 June 2022, and the consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows for each of the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2022 (the “Track Record Period”) and a summary of significant accounting policies and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages I-[●] to I-86 forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [Date] (the “Document”) in connection with the [REDACTED] of H shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited.

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of Historical Financial Information that is free from material misstatement, whether due to fraud or error.

APPENDIX I**ACCOUNTANT’S REPORT**

Reporting accountant’s responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200, *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountant’s judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountant considers internal control relevant to the entity’s preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountant’s report, a true and fair view of the financial position of the Company as at 31 December 2021 and 30 June 2022 and the consolidated financial position of the Group as at 31 December 2019, 2020 and 2021 and 30 June 2022 and of its consolidated financial performance and its consolidated cash flows for the Track Record Period in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the Historical Financial Information.

Review of stub period comparative financial information

We have reviewed the stub period comparative financial information of the Group which comprises the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the six months ended 30 June 2021 and other explanatory information (the “Stub Period Comparative Financial Information”). The directors of the Company are responsible for the presentation and preparation of the Stub Period Comparative Financial Information in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the

APPENDIX I

ACCOUNTANT’S REPORT

Historical Financial Information. Our responsibility is to express a conclusion on the Stub Period Comparative Financial Information based on our review. We conducted our review in accordance with International Standard on Review Engagements 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the International Auditing and Assurance Standards Board (“IAASB”). A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Stub Period Comparative Financial Information, for the purposes of the accountant’s report, is not prepared, in all material respects, in accordance with the basis of presentation and preparation set out in Notes 1.3 and 2.1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “Listing Rules”) and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-[4] have been made.

Dividends

We refer to Note 37 to the Historical Financial Information which contains information about the dividends paid by the companies now comprising the Group in respect of the Track Record Period. No dividends have been paid by LEPU ScienTech Medical Technology (Shanghai) Co., Ltd. in respect of the Track Record Period.

No statutory financial statements for the Company

No statutory financial statements have been prepared for the Company since its date of incorporation.

[PricewaterhouseCoopers]
Certified Public Accountants

Hong Kong, [Date]

I. HISTORICAL FINANCIAL INFORMATION OF THE GROUP

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountant’s report. The financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, were audited by PricewaterhouseCoopers in accordance with International Standards on Auditing issued by the International Auditing and Assurance Standards Board (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“**RMB**”) and all values are rounded to the nearest thousand of RMB (RMB’000) except when otherwise indicated.

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ACCOUNTANT’S REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	Note	Year ended 31 December			Six months ended 30 June	
		2019	2020	2021	2021	2022
		RMB'000	RMB'000	RMB'000	RMB'000 (Unaudited)	RMB'000
Revenue	6	116,451	148,247	222,583	110,968	124,804
Cost of sales	7	(13,619)	(15,134)	(25,038)	(11,884)	(15,322)
Gross profit		102,832	133,113	197,545	99,084	109,482
Distribution expenses	7	(21,760)	(23,146)	(43,072)	(17,383)	(16,626)
General and administrative expenses	7	(8,981)	(8,383)	(59,874)	(24,457)	(16,402)
Research and development expenses	7	(25,830)	(38,957)	(41,387)	(16,446)	(19,637)
Net (provision for)/reversal of impairment losses on financial assets	9	(1,788)	672	533	464	(4,169)
Other income and gains/(losses) – net	10	15,746	13,238	22,642	4,401	(18,289)
Operating profit		60,219	76,537	76,387	45,663	34,359
Finance income		151	149	1,185	221	1,645
Finance costs		(24)	(7)	(11,545)	(914)	(10,698)
Finance income/(costs) – net	11	127	142	(10,360)	(693)	(9,053)
Profit before income tax		60,346	76,679	66,027	44,970	25,306
Income tax expense	12	(8,437)	(7,907)	(7,330)	(3,203)	(1,051)
Profit for the year/period		51,909	68,772	58,697	41,767	24,255
Other comprehensive income: Items that will not be reclassified to profit or loss: – Changes in the fair value of equity investment at fair value through other comprehensive income		138	427	–	–	–
Other comprehensive income for the year/period, net of tax		138	427	–	–	–
Total comprehensive income for the year/period		52,047	69,199	58,697	41,767	24,255
Profit attributable to: – Owners of the Company		51,909	68,772	58,697	41,767	24,255
Total comprehensive income attributable to: – Owners of the Company		52,047	69,199	58,697	41,767	24,255
Earnings per share attributable to the owners of the Company (expressed in RMB per share) Basic and diluted earnings per share	13	0.19	0.25	0.19	0.15	0.07

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ACCOUNTANT’S REPORT

CONSOLIDATED BALANCE SHEETS

	Note	As at 31 December			As at
		2019	2020	2021	30 June
		RMB'000	RMB'000	RMB'000	2022
				RMB'000	
ASSETS					
Non-current assets					
Property, plant and equipment	14	68,459	67,196	76,261	82,446
Right-of-use assets	15	454	216	6,763	5,841
Investment properties	16	42,673	40,623	39,553	39,102
Goodwill	17	48,282	48,282	48,282	48,282
Intangible assets	18	54,259	65,959	136,557	161,649
Financial assets at fair value through other comprehensive income		849	–	–	–
Deferred income tax assets	20	7,009	3,472	8,571	16,077
Prepayments	21	632	1,000	11,187	12,304
Total non-current assets		222,617	226,748	327,174	365,701
Current assets					
Inventories	22	11,052	23,319	33,402	40,269
Trade receivables	23	45,331	38,317	23,869	32,883
Prepayments and other receivables	21	13,442	20,182	21,765	51,807
Prepaid income tax		–	5,152	–	–
Financial assets at fair value through profit or loss	24	–	–	–	1,004
Bank deposit with initial term of over three months	25	–	–	–	70,000
Cash and cash equivalents	25	16,119	18,792	713,480	664,534
Total current assets		85,944	105,762	792,516	860,497
Total assets		308,561	332,510	1,119,690	1,226,198
EQUITY					
Equity attributable to owners of the Company					
Share capital	26	–	–	324,295	324,295
Treasury stock	27	–	–	(671,507)	(671,507)
Other reserves	27	(98,745)	(146,766)	593,341	601,142
Retained earnings		330,614	400,365	139,062	163,317
Total equity		231,869	253,599	385,191	417,247

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	<i>Note</i>	As at 31 December			As at
		2019	2020	2021	30 June
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	2022
				<i>RMB’000</i>	
LIABILITIES					
Non-current liabilities					
Lease liabilities	15	–	–	4,044	4,294
Deferred income	29	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>
Current liabilities					
Redemption liabilities	30	–	–	679,986	720,861
Trade and other payables	31	57,286	62,137	26,300	54,427
Contract liabilities	32	12,206	15,343	14,783	14,426
Current income tax liabilities		4,683	–	6,761	12,797
Lease liabilities	15	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>
Total liabilities		<u>76,692</u>	<u>78,911</u>	<u>734,499</u>	<u>808,951</u>
Total equity and liabilities		<u>308,561</u>	<u>332,510</u>	<u>1,119,690</u>	<u>1,226,198</u>

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BALANCE SHEETS OF THE COMPANY

		As at 31 December	As at 30 June
	<i>Note</i>	2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
ASSETS			
Non-current assets			
Investments in subsidiary	26(a)	713,776	713,776
Deferred income tax assets	20	5,652	12,200
Total non-current assets		<u>719,428</u>	<u>725,976</u>
Current assets			
Prepayments and other receivables	21	4,566	25,958
Financial assets at fair value through profit or loss	24	–	1,004
Bank deposit with initial term of over three months	25	–	70,000
Cash and cash equivalents	25	694,946	556,491
Total current assets		<u>699,512</u>	<u>653,453</u>
Total assets		<u><u>1,418,940</u></u>	<u><u>1,379,429</u></u>
EQUITY			
Share capital	26	324,295	324,295
Treasury stock	27	(671,507)	(671,507)
Other reserves	27	1,057,714	1,057,714
Accumulated losses		(30,339)	(60,671)
Total equity		<u>680,163</u>	<u>649,831</u>
LIABILITIES			
Current liabilities			
Redemption liabilities	30	679,986	720,861
Other payables	31	58,791	8,737
Total current liabilities		<u>738,777</u>	<u>729,598</u>
Total liabilities		<u>738,777</u>	<u>729,598</u>
Total equity and liabilities		<u><u>1,418,940</u></u>	<u><u>1,379,429</u></u>

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	<i>Note</i>	Share capital	Treasury stock	Other reserves	Retained earnings	Total equity
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Balance at 1 January 2019		–	–	(57,502)	278,705	221,203
Profit for the year		–	–	–	51,909	51,909
Other comprehensive income:						
– Fair value changes of equity investment at fair value through other comprehensive income		–	–	138	–	138
Total comprehensive income		–	–	138	51,909	52,047
Transactions with owners in their capacity as owners:						
– Deemed distributions	27(a)	–	–	(60,985)	–	(60,985)
– Deemed contributions	27(a)	–	–	19,604	–	19,604
Total transactions with owners in their capacity as owners		–	–	(41,381)	–	(41,381)
Balance at 31 December 2019		–	–	(98,745)	330,614	231,869
Balance at 1 January 2020		–	–	(98,745)	330,614	231,869
Profit for the year		–	–	–	68,772	68,772
Other comprehensive income:						
– Fair value changes of equity investment at fair value through other comprehensive income	27	–	–	427	–	427
– Transfer of gain on disposal of equity investment at fair value through other comprehensive income to retained earnings	27	–	–	(979)	979	–
Total comprehensive income		–	–	(552)	69,751	69,199
Transactions with owners in their capacity as owners:						
– Deemed distributions	27(a)	–	–	(777,645)	–	(777,645)
– Deemed contributions	27(a)	–	–	730,176	–	730,176
Total transactions with owners in their capacity as owners		–	–	(47,469)	–	(47,469)
Balance at 31 December 2020		–	–	(146,766)	400,365	253,599

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	<i>Note</i>	<u>Share capital</u>	<u>Treasury stock</u>	<u>Other reserves</u>	<u>Retained earnings</u>	<u>Total equity</u>
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Balance at 1 January 2021		–	–	(146,766)	400,365	253,599
Profit for the year		–	–	–	58,697	58,697
Total comprehensive income		–	–	–	58,697	58,697
Transactions with owners in their capacity as owners:						
– Issuance of shares to Lepu Medical Technology (Beijing) Co., Ltd. (“Lepu Medical”)	26(a)	277,200	–	(277,200)	–	–
– Issuance of shares to Beijing Target Medical Technologies Co., Ltd. (“Target Medical”)	26(a)	2,800	–	4,409	–	7,209
– Issuance of shares to Ningbo Jiacheng Enterprise Management Partnership (Limited Partnership) (“Ningbo Jiacheng”) and Ningbo Jiadu Enterprise Management Partnership (Limited Partnership) (“Ningbo Jiadu”)		14,737	–	36,547	–	51,284
– Issuance of shares to [REDACTED]		29,558	–	580,182	–	609,740
– Deemed distributions	27(a)	–	–	(72,167)	–	(72,167)
– Deemed contributions	27(a)	–	–	446,079	–	446,079
– Recognition of redemption liabilities	30	–	(671,507)	–	–	(671,507)
– Share-based payments – deemed contribution from Lepu Medical	28	–	–	22,257	–	22,257
– Dividends to shareholder	37	–	–	–	(320,000)	(320,000)
Total transactions with owners in their capacity as owners		324,295	(671,507)	740,107	(320,000)	72,895
Balance at 31 December 2021		<u>324,295</u>	<u>(671,507)</u>	<u>593,341</u>	<u>139,062</u>	<u>385,191</u>
Balance at 1 January 2022		324,295	(671,507)	593,341	139,062	385,191
Profit for the period		–	–	–	24,255	24,255
Total comprehensive income		–	–	–	24,255	24,255
Transactions with owners in their capacity as owners:						
– Share-based payments – deemed contribution from Lepu Medical	28	–	–	7,801	–	7,801
Total transactions with owners in their capacity as owners		–	–	7,801	–	7,801
Balance at 30 June 2022		<u>324,295</u>	<u>(671,507)</u>	<u>601,142</u>	<u>163,317</u>	<u>417,247</u>

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	<i>Note</i>	<u>Share capital</u>	<u>Treasury stock</u>	<u>Other reserves</u>	<u>Retained earnings</u>	<u>Total equity</u>
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Unaudited						
Balance at 1 January 2021		–	–	(146,766)	400,365	253,599
Profit for the period		–	–	–	41,767	41,767
Total comprehensive income		–	–	–	41,767	41,767
Transactions with owners in their capacity as owners:						
– Issuance of shares to Lepu Medical	27	277,200	–	(277,200)	–	–
– Issuance of shares to Target Medical	27	2,800	–	4,409	–	7,209
– Issuance of shares to Ningbo Jiacheng and Ningbo Jiadu		14,737	–	36,547	–	51,284
– Issuance of shares to [REDACTED]		29,558	–	580,182	–	609,740
– Deemed distributions	27(a)	–	–	(72,167)	–	(72,167)
– Deemed contributions	27(a)	–	–	446,079	–	446,079
– Recognition of redemption liabilities	30	–	(671,507)	–	–	(671,507)
– Share-based payments – deemed contribution from Lepu Medical	28	–	–	3,952	–	3,952
– Dividends to shareholder	37	–	–	–	(320,000)	(320,000)
Total transactions with owners in their capacity as owners		324,295	(671,507)	721,802	(320,000)	54,590
Balance at 30 June 2021		324,295	(671,507)	575,036	122,132	349,956

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	Note	Year ended 31 December			Six months ended 30 June	
		2019	2020	2021	2021	2022
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
						(Unaudited)
Cash flows from operating activities						
Cash generated from operations	33(a)	60,836	73,056	104,609	70,996	53,541
Interest received		151	149	1,185	221	1,645
Income tax paid		(6,512)	(14,108)	(516)	(9,464)	(2,521)
Net cash from operating activities		54,475	59,097	105,278	61,753	52,665
Cash flows from investing activities						
Purchases of property, plant and equipment		(3,267)	(2,525)	(22,452)	(6,055)	(9,461)
Purchases of intangible assets		(943)	(1,036)	-	-	(515)
Payments of internal development costs capitalised as intangible assets		(11,817)	(12,104)	(69,388)	(25,896)	(26,598)
Proceeds from sale of property, plant and equipment		-	106	-	-	-
Proceeds from sale of investment properties		2,953	6,056	-	-	-
Proceeds from sale of financial assets at fair value through other comprehensive income		-	1,040	-	-	-
Purchases of wealth management products		-	-	(3,275,000)	-	(2,740,000)
Proceeds from disposal of wealth management products (including investment income)		-	-	3,281,669	-	2,743,809
Placement of bank deposit with initial term of over three months		-	-	-	-	(70,000)
Net cash used in investing activities		(13,074)	(8,463)	(85,171)	(31,951)	(102,765)
Cash flows from financing activities						
Deemed contributions	27(a)	19,604	730,176	446,079	446,079	-
Deemed distributions	27(a)	(60,985)	(777,645)	(72,167)	(72,167)	-
Dividends paid to shareholder	37	-	-	(320,000)	(320,000)	-
Settlements to related parties		-	-	(45,858)	(45,389)	-
Capital contribution from Target Medical	26(a)	-	-	7,209	7,209	-
Capital contribution from Ningbo Jiacheng and Ningbo Jiadu	26(b)	-	-	51,284	51,284	-
Capital contribution from the [REDACTED]	26(c)	-	-	609,740	609,740	-
Payments for [REDACTED] expenses		-	-	(1,683)	(2,815)	(1,886)
Payments for lease liabilities		(483)	(492)	(2,378)	(666)	(342)
Net cash (used in)/from financing activities		(41,864)	(47,961)	672,226	673,275	(2,228)
Net (decrease)/increase 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	25	16,119	18,792	713,480	724,781	664,534

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II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1 GENERAL INFORMATION, REORGANISATION AND BASIS OF PRESENTATION

1.1 General information

LEPU ScienTech Medical Technology (Shanghai) Co., Ltd. (the “Company”, 樂普心泰醫療科技(上海)股份有限公司) was incorporated as a joint stock limited liability company in the People’s Republic of China (the “PRC” or “China”) on 29 January 2021. The address of its registered office is Room 201, Building 41, No. 258, Xinzhuan Road, Songjiang District, Shanghai, the PRC.

The Company is an investment holding company. The Company and its subsidiary (together referred as to the “Group”) are principally engaged in manufacturing and sales of interventional treatment series occluders for defective congenital heart disease (缺損性先天性心臟病介入治療系列封堵器) and the research and development of biological valve (生物瓣膜) for heart disease (the “[REDACTED] Business”).

Upon incorporation of the Company in January 2021, the Company had a registered capital of RMB280,000,000 and was owned by Lepu Medical Technology (Beijing) Co., Ltd. (樂普(北京)醫療器械股份有限公司) (“Lepu Medical”) and Beijing Target Medical Technologies Co., Ltd. (北京天地和協科技有限公司) (“Target Medical”), as to 99.05% and 0.95%, respectively.

Lepu Medical was incorporated in the PRC on 11 June 1999 whose shares are listed on the Shenzhen Stock Exchange (stock code: 300003) and Target Medical was incorporated in the PRC on 18 November 1999 which is a wholly-owned subsidiary of Lepu Medical.

On 22 February 2021, Ningbo Jiadu Enterprise Management Partnership (Limited Partnership) (“Ningbo Jiadu”) and Ningbo Jiacheng Enterprise Management Partnership (Limited Partnership) (“Ningbo Jiacheng”) (collectively referred to as the “Vehicles”) were incorporated in the PRC under the Company Law of the PRC as vehicles companies to hold the ordinary shares of the Company for the employees under the Employee Share Ownership Plan of 2021 (the “ESOP”). Ningbo Jiadu was designated as ESOP platform of the Group’s employees, and Ningbo Jiacheng was designated as ESOP platform of the Lepu Medical’s employees. As the Group does not have power to govern the relevant activities of the Vehicles nor having the repurchase or settlement obligations to acquire any shares granted under the ESOP, the directors of the Company consider that it is appropriate not to consolidate the Vehicles.

On 28 May 2021, the Company and Vivo Capital Fund IX, L.P (“Vivo Capital Fund IX”), SCC Growth VI Holdco AF, Ltd. (“SCC Growth”), Shanghai Biomedical Industry Equity Investment Fund Partnership (Limited Partnership) (“Shanghai Biomedical”, 上海生物醫藥產業股權投資基金合夥企業(有限合夥)), Huaihua Haozhi Enterprise Management Partnership (Limited Partnership) (“Huaihua Haozhi”, 懷化皓智企業管理合夥企業(有限合夥)) and CDH Supermatrix D Limited (“CDH Supermatrix”) (collectively as the “[REDACTED]”) entered into a capital increase agreement (the “[REDACTED] Shareholders Agreement”), pursuant to which each of the “[REDACTED]” agreed to “[REDACTED]” in the Company by subscription of the increased registered capital of the Company. The cash as injected by the “[REDACTED]” for the subscription of the aforesaid shares of the Company amounted to approximately RMB609,740,000 were fully paid in June 2021.

As of the date of this Historical Financial Information, Lepu Medical, together with its wholly-owned subsidiary, Target Medical, held 86.34% equity interest in the Company (with Lepu Medical and Target Medical directly hold 85.48% and 0.86% equity interests in the Company respectively). Dr. Pu Zhongjie is the actual controller of Lepu Medical. Lepu Medical, Dr. Pu Zhongjie and Target Medical are considered as a group of controlling shareholders of the Company.

In 2021, the Coronavirus Disease 2019 (“COVID-19”) pandemic in China has been effectively contained by the prompt and effective governmental control measures. Benefited from this, the Group’s business volume, financial performance (not considering the impact of non-recurring “[REDACTED]” expenses as incurred) and net cash inflows from its operations are all positively improved in 2021. However, the outbreak of the Omicron and other variants and quarantine measures taken in Shanghai and other cities in the PRC in 2022 had posted impact on the Group’s businesses to certain extent. To cope with the temporary city lock down measures as implemented by the government in the Shanghai city, the Group’s production and sales activities have also been partially suspended from April 2022 and resumed in June 2022. Therefore, the business growth of the Group for the six months ended 30 June 2022 has been temporarily impacted. Considering the uncertainty of the development of COVID-19 pandemic, management of

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the Company will continue to pay close attention on the development of COVID-19 pandemic and dedicate resources to take any necessary measures on a timely manner to minimise the unfavorable impact on the Group’s businesses and operations in subsequent periods (if any).

1.2 Reorganisation

Prior to the incorporation of the Company and the completion of the reorganisation as described below, the [REDACTED] Business was carried out by Shanghai Shape Memory Alloy Co., Ltd. (“Shanghai Shape Memory Alloy”), a then wholly-owned subsidiary of Lepu Medical, and the biological valve division within Lepu Medical.

Shanghai Shape Memory Alloy was established in the PRC on 25 February 1994 by Shanghai Shiliupu Material (Group) Company (上海十六鋪物資(集團)公司, “Shiliupu”), an independent third party. Lepu Medical acquired Shanghai Shape Memory Alloy in October 2008 to be its wholly-owned subsidiary and subsequently made additional contribution to Shanghai Shape Memory Alloy.

For the purpose of introduction of domestic and overseas [REDACTED] and preparation for the [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (“HKEx”), the Group underwent a group reorganisation (the “Reorganisation”) to establish the Company as the holding company of the [REDACTED] Business. The Reorganisation mainly involved the following:

- (i) On 24 December 2020, Shanghai Shape Memory Alloy disposed of its entire equity interest in Ningbo Bingkun Medical Devices Co., Ltd. (“Ningbo Bingkun”) to Lepu Medical. Ningbo Bingkun (through its subsidiaries) is principally engaged in the research, development, production and sales of surgical matching device and minimally invasive surgical-related products for use in open surgeries and laparoscopic surgeries which are unrelated to the [REDACTED] Business.
- (ii) On 5 January 2021, Shanghai Shape Memory Alloy acquired the heart valve businesses relating to research and development of biological valve from Lepu Medical. In connection with the above transaction, core research and development scientists and contracts related to biological valve are also transferred to Shanghai Shape Memory Alloy. The transaction was closed on 14 April 2021.

Up to the date of this Historical Financial Information, the key research and development work of certain heart valve products were registered under the name of, and conducted by, Lepu Medical. The Group entered into a framework agreement with Lepu Medical and entrusted Lepu Medical to develop certain heart valve products under the Group’s instruction due to regulatory restrictions and commercial reasons, notwithstanding the fact that Shanghai Shape Memory Alloy became the legal owner of all intellectual properties of the related heart valve businesses.

- (iii) On 29 January 2021, the Company was incorporated as a joint stock limited liability company by Lepu Medical and Target Medical in the PRC, with a registered capital of RMB280 million.
- (iv) On 22 February 2021, Ningbo Jiadu and Ningbo Jiacheng which were established as the shareholding platforms for certain employees of the Group, Lepu Medical and its subsidiaries (excluding the Group). Ningbo Jiadu and Ningbo Jiacheng contributed RMB31,796,000 and RMB19,488,000 to subscribe 9,137,000 and 5,600,000 shares in the Company, respectively in June 2021.
- (v) On 5 March 2021, Lepu Medical injected its entire 100% equity interest in Shanghai Shape Memory Alloy to the Company in exchange for 277,200,000 shares of the Company.

The Group’s cash payments/receipts in connection with Shanghai Shape Memory Alloy’s investment in Ningbo Bingkun, Lepu Medical’s cash injection for the development of the abovementioned heart valve business and also the Group’s payment for the subsequent acquisition of the heart valve business prior to the completion of the Reorganisation have been accounted for as deemed distribution to/contribution from Lepu Medical during the Track Record Period. More details of which have been set out in Note 27(a).

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Upon completion of the Reorganisation and as of the date of this Historical Financial Information, the Company has direct interests in the following subsidiary:

Company name	Country of incorporation	Paid-up capital <i>RMB’000</i>	Attributable equity interest of the Group					Principal activities/ place of operation	Note
			As at 31 December			As at 30 June			
			2019	2020	2021	2022	As at the date of this report		
Directly owned:									
Shanghai Shape Memory Alloy	The PRC	100,000	100%	100%	100%	100%	100%	Manufacturing and sales of interventional treatment series occluders for defective congenital heart disease and the research and development of biological valve for heart disease/The PRC	(1)

- (1) The statutory financial statements for the years ended 31 December 2019 and 2020 were audited by BDO China Shu Lun Pan CPAs and as of the date of the Historical Financial Information, the financial statements for the year ended 31 December 2021 has not yet been audited.
- (2) The English name of the subsidiary referred herein represent the Directors’ best effort at translating the Chinese name of the subsidiary as no English name has been registered.

1.3 Basis of presentation

The Historical Financial Information have been prepared by including the historical financial information of the company/division engaged in the [REDACTED] Business and excluding the historical financial information of Ningbo Bingkun, which are under the common control of Lepu Medical immediately before and after the Reorganisation and now comprising the Group as if the current Group structure had been in existence throughout the periods presented, or since the date when the consolidating company/division first came under the control of Lepu Medical, whichever is a shorter period.

The net assets of the consolidating company/division were consolidated using the existing book values from Lepu Medical’s perspective. No amount is recognised in consideration for goodwill or excess of acquirer’s interest in the acquiree’s fair value of identifiable assets, liabilities and contingent liabilities over cost at the time of business combination under common control, to the extent of the continuation of the controlling party’s interest.

As required by the relevant PRC rules and regulations with respect to the Reorganisation and the incorporation of the Company, the equity interest of Shanghai Shape Memory Alloy contributed from Lepu Medical are stated at revaluation cost by reference to a valuation report.

Inter-company transactions, balances and unrealised gains/losses on transactions between the Company and its subsidiary are eliminated on consolidation.

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2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

This note provides a list of the significant accounting policies adopted in the preparation of the Historical Financial Information. These policies have been consistently applied throughout the Track Record Period, unless otherwise stated.

2.1 Basis of preparation

(i) *Compliance with International Financial Reporting Standards (“IFRSs”)*

The Historical Financial Information of the Company has been prepared in accordance with all applicable IFRSs issued by International Accounting Standards Board (“IASB”).

All effective standards, amendments to standards and interpretations, which are mandatory for the financial year beginning on or after 1 January 2022, are consistently applied to the Group throughout the Track Record Period.

The preparation of the financial information in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Group’s accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the Historical Financial Information, are disclosed in Note 4.

(ii) *Historical cost convention*

The Historical Financial Information has been prepared under the historical cost convention, as modified by the revaluation of financial assets at fair value (either through other comprehensive income (“OCI”) or through profit or loss), which were carried at fair value.

(iii) *New or amended standards issued but not yet adopted*

The following new or amended standards have been published (which may be applicable to the Group) but not mandatory for the reporting periods ended 30 June 2022 and have not been early adopted by the Group:

		<u>Effective date</u>
IFRS 17	Insurance contracts	1 January 2023
Amendments to IAS 1	Classification of liabilities as current or non-current	1 January 2023
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of accounting policies	1 January 2023
Amendments to IAS 8	Definition of accounting estimates	1 January 2023
Amendments to IAS 12	Deferred tax relate to assets and liabilities arising from a single transaction	1 January 2023

Management of the Company has assessed and concluded that the abovementioned new or amended standards did not have any significant impact on the amounts recognised in prior years and are not expected to significantly affect the current or future periods.

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2.2 Principles of consolidation

Subsidiaries are all entities (including controlled entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

Intercompany transactions, balances and unrealised gains on transactions between group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Non-controlling interests in the results and equity of subsidiaries (if applicable) are shown separately in the consolidated statement of profit or loss and other comprehensive income, statement of changes in equity and balance sheet respectively.

2.3 Business combinations

The acquisition method of accounting is used to account for all business combinations (excluding those involving the entities under common control), regardless of whether equity instruments or other assets are acquired. The consideration transferred for the acquisition of a subsidiary comprises (if applicable):

- fair values of the assets transferred;
- liabilities incurred to the former owners of the acquired business;
- equity interests issued by the Group;
- fair value of any asset or liability resulting from a contingent consideration arrangement; or
- fair value of any pre-existing equity interest in the subsidiary.

Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are, with limited exceptions, measured initially at their fair values at the acquisition date. The Group recognises any non-controlling interest in the acquired entity on an acquisition-by-acquisition basis either at fair value or at the non-controlling interest’s proportionate share of the acquired entity’s net identifiable assets.

Acquisition-related costs are expensed as incurred.

The excess of the

- consideration transferred;
- amount of any non-controlling interest in the acquired entity; and
- acquisition-date fair value of any previous equity interest in the acquired entity

over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts are less than the fair value of the net identifiable assets of the business acquired, the difference is recognised directly in profit or loss as a bargain purchase.

Contingent consideration is classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognised in profit or loss.

If the business combination is achieved in stages, the acquisition date carrying value of the acquirer’s previously held equity interest in the acquiree is remeasured to fair value at the acquisition date. Any gains or losses arising from such remeasurement are recognised in profit or loss.

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2.4 Separate financial statements

Investments in subsidiaries are accounted for at cost less impairment. Cost includes direct attributable costs of investment. The results of subsidiaries are accounted for by the Company on the basis of dividends received and receivable.

Impairment testing of the investments in subsidiaries is required upon receiving a dividend from these investments if the dividend exceeds the total comprehensive income of the subsidiary in the period the dividend is declared or if the carrying amount of the investment in the separate financial statements exceeds the carrying amount in the consolidated financial statements of the investee’s net assets including goodwill.

2.5 Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker (“CODM”). The CODM, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as executive directors of the Company.

2.6 Foreign currency translation

(i) *Functional and presentation currency*

Items included in the financial statements of each of the group entities are measured using the currency of the primary economic environment in which the entity operates (the “functional currency”). The Historical Financial Information are presented in RMB, which is the Company’s functional and presentation currency and also the functional currency of the subsidiary.

(ii) *Transactions and balances*

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognised in profit or loss.

All foreign exchange gains and losses are presented in the consolidated statement of profit or loss and other comprehensive income on a net basis within “Other income and gains/(losses) – net”.

2.7 Property, plant and equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation and accumulated impairment (if any). Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset’s carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognised when replaced. All other repairs and maintenance are charged to profit or loss during the reporting period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate their costs, net of their residual values, over their estimated useful lives as follows:

• Buildings	25-40 years
• Electronic equipment	3 years
• Machinery	5-10 years
• Vehicles	3-12 years
• Others	3-10 years

The assets’ residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset’s carrying amount is written down immediately to its recoverable amount if the asset’s carrying amount is greater than its estimated recoverable amount (Note 2.11).

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Gains and losses on disposals are determined by comparing proceeds with carrying amount are recognised in profit or loss and presented as “Other income and gains/(losses) – net” in the consolidated statement of profit or loss and other comprehensive income.

2.8 Investment properties

Investment properties comprise buildings, held for long-term rental yields or for capital appreciation or both and not occupied by the Group, and is measured initially at its cost, including related transaction costs. After initial recognition, the Group chooses the cost model to measure all of its investment properties, which are stated at historical costs less accumulated depreciation and accumulated impairment losses (if any). Depreciation of investment properties is calculated using the straight-line method to allocate their costs to their residual values over their estimated useful lives of 30-40 years.

An investment property’s carrying amount is written down immediately to its recoverable amount if the investment property’s carrying amount is greater than its estimated recoverable amount. Gains and losses on disposals are determined by comparing proceeds with carrying amount and are recognised in profit and loss.

2.9 Intangible assets

(i) Patents and licences

Patents and licences acquired in a business combination are recognised at fair value at the acquisition date. Patents and licences which have finite useful lives are carried at cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate their costs over their estimated useful lives of 3-10 years (representing the remaining lives of the registered patent period and licenses period as approved by administrative authorities or the period after considering the expected administrative extension of the related licenses) from the point at which the asset is ready for use.

(ii) Purchased software

Purchased software licenses are capitalised on the basis of the costs incurred to acquire and bring the specific software into usage. These costs are amortised using the straight-line method over their estimated useful lives of 10 years. Costs associated with maintaining computer software programs are recognised as expense as incurred.

(iii) Research and development

Research and development cost comprise all costs that are directly attributable to research and development activities (relating to the design and testing of new or improved high end medical instruments) or that can be allocated on a reasonable basis to such activities. Research and development costs are recognised as intangible assets when the following criteria are met:

- it is technically feasible to complete the medical instruments so that it will be available for use or sale;
- management intends to complete the medical instruments and use or sell it;
- there is an ability to use or sell the medical instruments;
- it can be demonstrated how the medical instruments will generate probable future economic benefits;
- adequate technical, financial and other resources to complete the development and the ability to use or sell the medical instruments are available; and
- the expenditure attributable to the medical instruments during its development phase can be reliably measured.

Other development expenditures that do not meet these criteria are charged to expense as incurred. Development costs previously recognised as an expense are not recognised as an asset in a subsequent period.

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2.10 Goodwill

Goodwill is measured as described in Note 2.3. Goodwill is not amortised, but it is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it might be impaired, and is carried at cost less accumulated impairment losses (if any). Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold.

Goodwill is allocated to cash-generating units for the purpose of impairment testing. The allocation is made to those cash-generating units or groups of cash-generating units that are expected to benefit from the business combination in which the goodwill arose. The units or groups of units are identified at the lowest level at which goodwill is monitored for internal management purposes, being the operating segments (Note 5).

2.11 Impairment of non-financial assets

Goodwill and intangible assets that have an indefinite useful life or not available for use are not subject to amortisation and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

2.12 Investments and other financial assets

(i) *Classification*

The Group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through OCI or through profit or loss), and
- those to be measured at amortised cost.

The classification depends on the entity's business model for managing the financial assets and the contractual terms of the cash flows.

For assets measured at fair value, gains and losses will either be recorded in profit or loss or OCI. For investments in equity instruments that are not held for trading, this will depend on whether the Group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income (FVOCI).

The Group reclassifies debt investments when and only when its business model for managing those assets changes.

(ii) *Recognition and derecognition*

Regular way purchases and sales of financial assets are recognised on trade-date, the date on which the Group commits to purchase or sell the asset. Financial assets are derecognised when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

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(iii) *Measurement*

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss (FVPL), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss.

Debt instruments

Subsequent measurement of debt instruments depends on the Group’s business model for managing the asset and the cash flow characteristics of the asset. There are three measurement categories into which the Group classifies its debt instruments:

- **Amortised cost:** Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortised cost. Interest income from these financial assets is included in finance income using the effective interest rate method. Any gain or loss arising on derecognition is recognised directly in profit or loss and presented in “Other income and gains/(losses) – net” together with foreign exchange gains and losses. Impairment losses are presented as separate line item in the consolidated statement of profit or loss and other comprehensive income.
- **FVOCI:** Assets that are held for collection of contractual cash flows and for selling the financial assets, where the assets’ cash flows represent solely payments of principal and interest, are measured at FVOCI. Movements in the carrying amount are taken through OCI, except for the recognition of impairment gains or losses, interest income and foreign exchange gains and losses which are recognised in profit or loss. When the financial asset is derecognised, the cumulative gain or loss previously recognised in OCI is reclassified from equity to profit or loss and recognised in other gains/(losses). Interest income from these financial assets is included in finance income using the effective interest rate method. Foreign exchange gains and losses are presented in “Other income and gains/(losses) – net” and impairment expenses are presented as separate line item in the consolidated statement of profit or loss and other comprehensive income.
- **FVPL:** Assets that do not meet the criteria for amortised cost or FVOCI are measured at FVPL. A gain or loss on a debt investment that is subsequently measured at FVPL is recognised in profit or loss and presented net within “Other income and gains/(losses) – net” in the period in which it arises.

Equity instruments

The Group subsequently measures all equity investments at fair value. Where the Group’s management has elected to present fair value gains and losses on equity investments in OCI, there is no subsequent reclassification of fair value gains and losses to profit or loss following the derecognition of the investment. Dividends from such investments continue to be recognised in profit or loss as other income when the Group’s right to receive payments is established.

Changes in the fair value of financial assets at FVPL are recognised in “Other income and gains/(losses) – net” in the consolidated statement of profit or loss and other comprehensive income as applicable. Impairment losses (and reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value.

(iv) *Impairment*

The Group assesses on a forward-looking basis the expected credit loss associated with its debt instruments carried at amortised cost and FVOCI. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

For trade receivables, the Group applies the simplified approach permitted by IFRS 9, which requires expected lifetime losses to be recognised from initial recognition of the receivables, see Notes 3.1(b) and 23 for further details.

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2.13 Offsetting financial instruments

Financial assets and liabilities are offset and the net amount is reported in the consolidated balance sheets where the Group currently has a legally enforceable right to offset the recognised amounts and there is an intention to settle on a net basis or realise the asset and settle the liability simultaneously. The legally enforceable right must not be contingent on future events and must be enforceable in the normal course of business and in the event of default, insolvency or bankruptcy of the Group or the counterparty.

2.14 Inventories

Raw materials, work in progress and finished goods are stated at the lower of cost and net realisable value. Cost comprises direct materials, direct labour and an appropriate proportion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Costs are assigned to individual items of inventory based on weighted average costs. Costs of purchased inventory are determined after deducting rebates and discounts. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

2.15 Trade receivables

Trade receivables are amounts due from customers for goods sold in the ordinary course of business. They are generally due for settlement within one year and therefore all classified as current.

Trade receivables are recognised initially at the amount of consideration that is unconditional unless they contain significant financing components, when they are recognised at fair value. The Group holds the trade receivables with the objective of collecting the contractual cash flows and therefore measures them subsequently at amortised cost using the effective interest method. See Note 23 for further information about the Group’s accounting for trade receivables and Note 3.1(b) for a description of the Group’s impairment policies.

2.16 Cash and cash equivalents

For the purpose of presentation in the statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with banks and other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

2.17 Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of equity instruments are shown in equity as a deduction, net of tax, from the proceeds.

Treasury stock is recorded to reflect the carrying amount of the redemption liabilities when it is initially reclassified from equity, and will be reversed when the redemption liabilities are derecognised upon when the Group’s obligations in connection with those redemption liabilities are discharged, cancelled or have expired which will then be reclassified back to equity (Note 2.23).

2.18 Trade and other payables

Trade and other payables mainly represent the obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognised initially at their fair value and subsequently measured at amortised cost using the effective interest method.

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2.19 Current and deferred income tax

The income tax expense or credit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred income tax assets and liabilities attributable to temporary differences and to unused tax losses.

(a) *Current income tax*

The current income tax charge is calculated on the basis of the tax laws enacted at the end of the reporting period in the countries where the Group operates and generates taxable income.

Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

(b) *Deferred income tax*

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. However, deferred income tax liabilities are not recognised if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realised or the deferred income tax liability is settled.

Deferred income tax assets are recognised only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

Deferred income tax liabilities and assets are not recognised for temporary differences between the carrying amount and tax bases of investments in foreign operations where the Group is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred income tax assets and liabilities are offset where there is a legally enforceable right to offset current income tax assets and liabilities and where the deferred income tax balances relate to the same taxation authority. Current income tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

Current and deferred income tax is recognised in profit or loss, except to the extent that it relates to items recognised in other comprehensive income or directly in equity. In this case, the tax is also recognised in other comprehensive income or directly in equity, respectively.

2.20 Employee benefits

(a) *Short-term obligations*

Liabilities for wages and salaries, including non-monetary benefits and accumulating sick leave that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognised in respect of employees' services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the balance sheet.

(b) *Pension, housing funds, medical insurances and other social insurances obligations*

Employees of the Group are covered by various government-sponsored defined-contribution pension plans in the PRC under which the employees are entitled to a monthly pension based on certain formulas. The relevant government agencies are responsible for the pension liability to these employees when they retire. The Group contributes on a monthly basis to these pension plans for the employees which are determined at a certain percentage of their salaries. Under these plans, the Group has no obligation for post-retirement benefits beyond the contribution made. Contributions to these plans are expensed as incurred and contributions paid to the defined contribution pension plans for a staff are not available to reduce the Group's future obligations to such defined-contribution pension plans even if the staff leaves the Group.

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2.21 Share-based payments

The fair value of awarded shares granted to employees under the ESOP less amount paid by employees is recognised as an employee benefits expense over the relevant service period, being the vesting period of the shares, and the credit is recognised in equity in the share-based payment reserves. The fair value of the shares is measured at the grant date. The number of shares expected to vest is estimated based on the non-market vesting conditions. The estimates are revised at the end of each reporting period and adjustments are recognised in profit or loss and the share-based payment reserves. Where shares are forfeited due to a failure by the employee to satisfy the service conditions, any expenses previously recognised in relation to such shares are reversed effective at the date of the forfeiture.

2.22 Provisions

Provisions are recognised when the Group has a present legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation and the amount can be reliably estimated. Provisions are not recognised for future operating losses.

Where there are a number of similar obligations, the likelihood that an outflow will be required in settlement is determined by considering the class of obligations as a whole. A provision is recognised even if the likelihood of an outflow with respect to any one item included in the same class of obligations may be small.

Provisions are measured at the present value of management’s best estimate of the expenditure required to settle the present obligation at the end of the reporting period. The discount rate used to determine the present value is a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The increase in the provision due to the passage of time is recognised as interest expense.

2.23 Redemption liabilities

A contract that contains an obligation to purchase the Company’s equity instruments for cash or another financial asset gives rise to a financial liability for the present value of the redemption amount, even if the Company’s obligations to purchase is conditional on the counterparty exercising a right to redeem. The Company undertakes such redemption obligations as certain preferred rights are granted to investors in the Company’s financing process. The related redemption liabilities are recognised as financial liabilities initially at fair value (representing the present value of the estimated redemption amount) and reclassified from equity. Subsequently, the redemption liabilities are measured at amortized cost with interest charged in finance costs.

The Group derecognises the redemption liabilities when, and only when, the Group’s obligations are discharged, cancelled or have expired. When the preferred rights are waived by investors, the carrying amount of redemption liability is reclassified back to equity.

2.24 Revenue recognition

Revenue is recognised as and when the Group’s obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Group expects to receive in exchange for transferring products or services to a customer (the “transaction price”).

A performance obligation represents a good and service (or a bundle of goods or services) that is distinct or a series of distinct goods or services that are substantially the same.

Depending on the terms of the contract and the laws applicable, control of the goods and services may be transferred over time or at a point in time.

A contract asset represents the Group’s right to consideration in exchange for goods or services that the Group has transferred to a customer that is not yet unconditional. It is assessed for impairment in accordance with using the same approach as for trade receivables. In contrast, a receivable represents the Group’s unconditional right to consideration, i.e. only the passage of time is required before payment of that consideration is due. There is normally no significant cost to obtain contract.

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A contract liability represents the Group's obligation to transfer goods or services to a customer for which the Group has received consideration (or an amount of consideration is due) from the customer.

The following is a description of the accounting policy for the principal revenue stream of the Group.

(a) Sale of goods

Sales are recognised when control of the products has transferred, being when the products are delivered to the customers or consumed by hospitals for direct sales to hospitals, and there is no unfulfilled obligation that could affect the customer's acceptance of the products. Delivery occurs when the products have been transferred to the customer, the risks of obsolescence and loss have been transferred to the customer, and either the customer has accepted the products in accordance with the sales contract, the acceptance provisions have lapsed, or the Group has objective evidence that all criteria for acceptance have been satisfied.

The products are often sold to major customers with retrospective volume rebates based on aggregate sales over a 12-month period. In addition, the Group has also contracted with certain major customers for granting them with the rights to claim for the Group's delivery of additional units of products (capped at a pre-determined ratio to the customer's purchases of the Group's products over a 12-month period) under certain pre-agreed circumstances which are irrelevant to the quality and functionality of the Group's products (the "claims for additional units"). Revenue from these sales is recognised based on the price specified in the respective contracts, net of the estimated volume rebates and the estimated claims for additional units. Accumulated experience is used to estimate and provide for the discounts and claims, using the expected value method, and revenue is only recognised to the extent that it is highly probable that a significant reversal will not occur.

Revenue is recognised net of value-added taxes and volume rebates and claims for additional units as mentioned above (if applicable). Revenue is measured at the fair value of the consideration received or receivable.

As receivable is recognised when the goods are delivered as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

2.25 Earnings per share

To calculate earnings per share, after the period when the establishment of the Company.

(a) Basic earnings per share

Basic earnings per share is calculated by dividing:

- The profit attributable to owners of the Company, excluding any costs of servicing equity other than ordinary shares
- By the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year and excluding treasury shares.

(b) Diluted earnings per share

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account:

- The after-income tax effect of interest and other financing costs associated with dilutive potential ordinary shares, and
- The weighted average number of additional ordinary shares that would have been outstanding assuming the [REDACTED] of all dilutive potential ordinary shares.

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2.26 Leases as lessee

The Group leases properties in the PRC as lessee. Rental contracts are typically made for fixed periods of 2-5 years. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants, but leased assets may not be used as security for borrowing purposes.

Leases are recognised as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Each lease payment is allocated between the principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments (if applicable):

- fixed payments (including in-substance fixed payments), less any lease incentives receivable;
- variable lease payment that are based on an index or a rate, initially measured using the index or rate as at the commencement date;
- amounts expected to be payable by the lessee under residual value guarantees;
- the exercise price of a purchase option if the lessee is reasonably certain to exercise that option; and
- payments of penalties for terminating the lease, if the lease term reflects the Group exercising that option.

The lease payments are discounted using the interest rate implied in the lease, if that rate can be determined, or the respective incremental borrowing rate.

Right-of-use assets are measured at cost comprising the following (if applicable):

- the amount of the initial measurement of lease liability;
- any lease payments made at or before the commencement date less any lease incentives received;
- any initial direct costs; and
- restoration costs.

2.27 Dividend distribution

Provision is made for the amount of any dividend declared, being appropriately authorised and no longer at the discretion of the entity, on or before the end of the reporting period but not distributed at the end of the reporting period.

2.28 Government grants

Grants from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received, and the Group will comply with all attached conditions.

Government grants relating to costs are deferred and recognised in the profit or loss over the period necessary to match them with the costs that they are intended to compensate.

Government grants relating to the purchase of property, plant and equipment are included in non-current liabilities as deferred income and are credited to profit or loss on a straight-line basis over the expected lives of the related assets.

3 FINANCIAL RISK MANAGEMENT

The Group’s activities expose it to a variety of financial risks: market risk (including foreign exchange risk), credit risk and liquidity risk. The Group’s overall risk management programme focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the Group’s financial performance. Risk management is carried out by the management of the Group. The Group currently does not use any derivative financial instruments to hedge certain risk exposure.

3.1 Financial risk factors

(a) Foreign exchange risk

Foreign exchange risk arises when future commercial transactions or recognised assets and liabilities are denominated in a currency that is not the functional currency of respective group entities. RMB is the functional currency of both the Company and its subsidiary.

Foreign exchange risk arises from future commercial transactions and recognised assets and liabilities denominated in a currency other than RMB. Certain trade payables, redemption liabilities, trade receivables and cash and cash equivalents are denominated in foreign currencies other than RMB and hence exposed the Group to foreign currency risk. The Group will constantly review the economic situation and its foreign exchange risk profile, and will consider appropriate hedging measures in the future, as may be necessary.

Most foreign exchange transactions were denominated in USD for the group entities that have functional currency in RMB. As at 31 December 2019, 2020 and 2021 and 30 June 2022, if the USD strengthened/weakened by 5% against the RMB, with all other variables held constant, net profit for the year/period would have been approximately RMB24,000 lower/higher, RMB104,000 lower/higher, RMB19,002,000 lower/higher and RMB19,880,000 lower/higher, respectively.

(b) Credit risk

Credit risk mainly arises from bank deposit with initial term of over three months, cash and cash equivalents, trade receivables and other receivables. The maximum exposure to credit risk is represented by the carrying amount of each financial asset in consolidated balance sheets.

The Group expects that there is no significant credit risk associated with bank deposit with initial term of over three months and cash and cash equivalents since they are deposited at state-owned banks or reputable commercial banks which are high-credit-quality financial institutions. Management does not expect that there will be any significant losses from non-performance by these counterparties.

The Group has the following types of financial assets subject to expected credit loss model:

- trade receivables
- other receivables

(i) Credit risk of trade receivables

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables.

To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due.

The expected loss rates are based on the historical credit losses and adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables. The Group has identified the Gross Domestic Product and the Producer Price Index in China (the prime location where it sells its goods) to be the most relevant factors, and accordingly adjusts the historical loss rates based on expected changes in these factors.

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On that basis, the loss allowance as at 31 December 2019, 2020 and 2021 and 30 June 2022 were determined as follows for trade receivables:

	No more than 3 months	3-6 months	6-12 months	More than 1 year	Total
At 31 December 2019					
Expected loss rate (%)	2%	3%	4%	43%	16%
Gross carrying amount – trade receivables (RMB'000)	12,630	10,557	13,426	17,219	53,832
Loss allowance (RMB'000)	(245)	(278)	(505)	(7,473)	(8,501)
	No more than 3 months	3-6 months	6-12 months	More than 1 year	Total
At 31 December 2020					
Expected loss rate (%)	3%	5%	7%	54%	16%
Gross carrying amount – trade receivables (RMB'000)	11,563	10,900	12,802	10,401	45,666
Loss allowance (RMB'000)	(379)	(498)	(883)	(5,589)	(7,349)
	No more than 3 months	3-6 months	6-12 months	More than 1 year	Total
At 31 December 2021					
Expected loss rate (%)	5%	8%	12%	90%	26%
Gross carrying amount – trade receivables (RMB'000)	8,140	8,412	8,780	6,825	32,157
Loss allowance (RMB'000)	(447)	(662)	(1,038)	(6,141)	(8,288)
	No more than 3 months	3-6 months	6-12 months	More than 1 year	Total
At 30 June 2022					
Expected loss rate (%)	5%	9%	18%	73%	27%
Gross carrying amount – trade receivables (RMB'000)	15,649	7,957	9,205	11,981	44,792
Loss allowance (RMB'000)	(779)	(727)	(1,691)	(8,712)	(11,909)

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Trade receivables are written off where there is no reasonable expectation of recovery. Impairment losses on trade receivables are presented as net impairment losses within operating profit. Subsequent recoveries of amounts previously written off are credited against the same line item. Movements in the loss allowance for trade receivables during the respective year/period are as follows:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(Unaudited)	
At beginning of the year/period	(6,879)	(8,501)	(7,349)	(7,349)	(8,288)
(Provision for)/reversal of impairment of trade receivables	(1,622)	1,152	(939)	(1,040)	(3,621)
At end of the year/period	<u>(8,501)</u>	<u>(7,349)</u>	<u>(8,288)</u>	<u>(8,389)</u>	<u>(11,909)</u>

(ii) *Credit risk of other receivables*

For other receivables, management makes periodic assessments as well as individual assessment on the recoverability based on historical settlement records, experience and forward-looking information on macroeconomic factors affecting the ability of the counterparties to settle the receivables. Movements in the loss allowance for other receivables during the respective year/period are as follows:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(Unaudited)	
At beginning of the year/period	(1,014)	(1,180)	(1,660)	(1,660)	(188)
(Provision for)/reversal of impairment of other receivables	(166)	(480)	1,472	1,504	(548)
At end of the year/period	<u>(1,180)</u>	<u>(1,660)</u>	<u>(188)</u>	<u>(156)</u>	<u>(736)</u>

(c) *Liquidity risk*

The Group aims to maintain sufficient cash and cash equivalents. Due to the dynamic nature of the underlying businesses, the policy of the Group is to regularly monitor the Group’s liquidity risk and to maintain adequate cash and cash equivalents to meet the Group’s liquidity requirements.

The table below analyses the Group’s non-derivative financial liabilities that will be settled into relevant maturity grouping based on the remaining period at each balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows. Balances due within 12 months equal their carrying balances as the impact of discounting is not significant.

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The following table presents the Group’s contractual maturities of financial liabilities as at 31 December 2019, 2020 and 2021 and 30 June 2022:

	Less than 1 year	Between 1-2 years	More than 2 years	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
As at 31 December 2019				
Trade and other payables (excluded other taxes payable and employee benefit payables)	48,893	–	–	48,893
Lease liabilities	426	–	–	426
	<u>49,319</u>	<u>–</u>	<u>–</u>	<u>49,319</u>
As at 31 December 2020				
Trade and other payables (excluded other taxes payable and employee benefit payables)	51,623	–	–	51,623
Lease liabilities	119	–	–	119
	<u>51,742</u>	<u>–</u>	<u>–</u>	<u>51,742</u>
As at 31 December 2021				
Trade and other payables (excluded other taxes payable and employee benefit payables)	13,994	–	–	13,994
Lease liabilities	2,247	2,089	3,071	7,407
	<u>16,241</u>	<u>2,089</u>	<u>3,071</u>	<u>21,401</u>
As at 30 June 2022				
Trade and other payables (excluded other taxes payable and employee benefit payables)	40,072	–	–	40,072
Lease liabilities	2,155	2,131	2,475	6,761
	<u>42,227</u>	<u>2,131</u>	<u>2,475</u>	<u>46,833</u>

The redemption liabilities with carrying amounts of approximately RMB679,986,000 (estimated undiscounted cash flow amounts of RMB701,066,000) and RMB720,861,000 (estimated undiscounted cash flow amounts of RMB732,072,000) as at 31 December 2021 and 30 June 2022 respectively (Note 30) have not been included in the analysis above as it is not managed by maturity date by the management of the Company.

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3.2 Capital risk management

The Group’s objectives when managing capital are to safeguard the Group’s ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

In order to maintain or adjust the capital structure, the Group may issue new shares or sell assets to reduce debt. The Group monitors capital (including share capital and other reserves) by regularly reviewing the capital structure. As a part of this review, the Company considers the cost of capital and the risks associated with the issued share capital. In the opinion of the directors of the Company, the Group’s capital risk is low as it does not have any external borrowings as of the respective balance sheet dates.

3.3 Fair value estimation

(a) Financial assets and liabilities

(i) Fair value hierarchy

This section explains the judgements and estimates made in determining the fair values of the financial instruments that are recognised and measured at fair value in the Historical Financial Information. To provide an indication about the reliability of the inputs used in determining fair value, the Group has classified its financial instruments into the three levels prescribed under the accounting standards.

The fair values of the financial assets and liabilities measured at amortised cost approximate their carrying amounts as at 31 December 2019, 2020 and 2021 and 30 June 2022.

There are no financial liabilities that were measured at fair value as at 31 December 2019, 2020 and 2021 and 30 June 2022 and there are no financial assets that were measured at fair value as at 31 December 2020 and 2021.

The following table presents the Group’s financial assets that were measured at fair value at 31 December 2019 and 30 June 2022:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
At 31 December 2019				
Financial assets at FVOCI	–	–	849	849
At 30 June 2022				
Financial assets at FVPL	–	–	1,004	1,004

The Group’s policy is to recognise transfers into and transfers out of fair value hierarchy levels as at the end of the reporting year.

Level 1: The fair value of financial instruments traded in active markets is based on quoted market prices at each of the reporting dates. A market is regarded as active if quoted prices are readily and regularly available from an exchange, dealer, broker, industry group, pricing service, or regulatory agency, and those prices represent actual and regularly occurring market transactions on an arm’s length basis. The quoted market price used for financial assets held by the Group is the current bid price. These instruments are included in level 1.

Level 2: The fair value of financial instruments that are not traded in an active market (for example, over-the-counter derivatives) is determined using valuation techniques which maximise the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for unlisted equity securities.

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(ii) Valuation techniques used to determine fair values

Specific valuation techniques used to value financial instruments include:

- Quoted market prices or dealer quotes for similar instruments; and
- Other techniques, such as discounted cash flow analysis, are used to determine fair value for the remaining financial instruments.

For unlisted equity securities where the fair values have been determined based on present values and the discount rates used were adjusted for the counterparty own credit risk. The directors of the Company have not identified that a reasonable change in any of the inputs that could cause the significant change of fair value. Accordingly, the directors of the Company have concluded not to disclose the details on the qualitative and quantitative sensitivity of changes in unobservable inputs.

(iii) Valuation processes

The finance department of the Group performs the valuations of non-property items required for financial reporting purposes, including level 3 fair values, and report directly to the chief financial officer ("CFO"). Discussions of valuation processes and results are held between the CFO and the finance personnels responsible for valuations on a periodical basis, in line with the Group's reporting periods.

The main level 3 inputs used by the Group are derived and evaluated as follows:

- Discount rates for financial assets were determined using a capital asset pricing model to calculate discount rate that reflects current market assessments of the time value of money and the risk specific to the asset.
- Credit risk factors specific to the Group (including assumptions about credit default rates) are derived from credit risk gradings determined by the Group's internal credit risk management group.
- Expected revenue growth and profit margins factors for unlisted equity securities are estimated based on market information of comparable companies with similar business.

There were no changes in valuation techniques during the Track Record Period. There were no transfers between levels 1, 2 and 3 for recurring fair value measurements during the Track Record Period.

(iv) Fair value measurements using significant unobservable inputs (level 3)

During the Track Record Period, the valuation of level 3 instruments mainly included investment in wealth management products issued by banks. As these instruments are not traded in an active market, their fair values have been determined by income approach to use a discounted cash flow analysis with an expected rate of return.

All the wealth management products were mature within one year with variable return rates indexed to the performance of underlying assets. The fair values were determined based on discounted cash flow assuming the expected return will be obtained upon maturity.

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The following table presents the changes in level 3 items for the year ended 31 December 2021 and the six months ended 30 June 2022:

	FVPL
	<i>RMB'000</i>
Opening balance as at 1 January 2021	–
Acquisitions	3,275,000
Disposals	(3,281,669)
Gains recognised in other income (<i>Note 10</i>)	6,669
	<hr/>
Closing balance as at 31 December 2021	–
	<hr/> <hr/>
Opening balance as at 1 January 2022	–
Acquisitions	2,740,000
Disposals	(2,743,809)
Gains recognised in other income (<i>Note 10</i>)	4,813*
	<hr/>
Closing balance as at 30 June 2022	1,004
	<hr/> <hr/>
* Includes unrealised gains recognised in profit or loss attributable to balances held as at 30 June 2022	4
	<hr/> <hr/>

The following table summarises the quantitative information about the significant unobservable inputs used in level 3 fair value measurements for the year ended 31 December 2021 and the six months ended 30 June 2022:

		Range of inputs		
		For the year ended 31 December 2021	For the six months ended 30 June 2022	
Significant unobservable inputs	Expected	Relationship of unobservable inputs to fair values		
Investment in wealth management products issued by banks	Expected return rate	2.09% to 3.00%	2.04%	The higher the expected return rate, the higher the fair value

For investment in wealth management products issued by banks, the directors of the Company have not identified that a reasonable change in any of the inputs that could cause the significant change of fair value. Accordingly, the directors of the Company have concluded not to disclose the details on the quantitative sensitivity of changes in unobservable inputs.

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4 CRITICAL ESTIMATES AND JUDGEMENTS

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgement in applying the Group’s accounting policies.

Estimates and judgements are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

(i) Estimated impairment of goodwill and intangible assets not subject to amortisation

The Group tests whether goodwill and intangible assets not subject to amortisation has suffered any impairment on an annual basis. The recoverable amount of a cash generating unit (“CGU”) is determined based on the higher of fair value less costs of disposal or value-in-use calculations which involved significant management’s judgement and estimates. The calculations use cash flow projections based on financial budgets approved by management covering a five-year period or a longer period where applicable. Cash flows beyond the periods as covered by the management approved budget are extrapolated using the estimated growth rates. Details of impairment assessment, the key assumptions adopted and management’s judgment applied in the assessment are disclosed in Notes 17 and 18.

(ii) Capitalisation of development costs

As of the 31 December 2019, 2020 and 2021 and 30 June 2022, the carrying amount of the Group’s development costs as capitalised as intangible assets amounted to approximately RMB53,401,000, RMB41,927,000, RMB92,025,000 and RMB103,346,000, respectively.

The determination of the capitalisation amounts involved management’s judgement in assessing of whether technical and commercial feasibility of each project had been achieved. Technical feasibility is evaluated based on testing results of products and commercial feasibility are evaluated based on forecast with assumptions on revenue to be generated, budget costs to be incurred and relevant market analysis of the relevant products.

(iii) Estimated useful lives and residual values of property, plant and equipment and technologies

The Group’s management determines the estimated useful lives, residual values and related depreciation and amortisation charges for the Group’s property, plant and equipment and patents for technologies with reference to the estimated periods that the Group intends to derive future economic benefits from the use of these assets. Management will revise the depreciation and amortisation charges where useful lives are different to that of previously estimated, or it will write-off or write-down technically obsolete or non-strategic assets that have been abandoned or sold. Actual economic lives may differ from estimated useful lives and actual residual values may differ from estimated residual values. Periodic review could result in a change in depreciable lives and residual values and therefore changing the depreciation and amortisation charges in future periods.

(iv) Provision of expected credit loss (“ECL”) for trade receivables

The Group uses provision matrix to calculate ECL for the trade receivables. The provision rates are based on internal credit ratings as groupings of various debtors that have similar loss patterns. The provision matrix is based on the Group’s historical default rates taking into consideration both quantitative and qualitative information that is reasonable and supportable including forward-looking information that is available without undue costs or effort. At every reporting date, the historical observed default rates are reassessed and changes in the forward-looking information are considered. In addition, trade receivables with credit impaired are assessed for ECL individually.

The provision of ECL is sensitive to changes in estimates. The information about the ECL and the Group’s trade receivables are disclosed in Notes 3.1(b) and 23.

(v) Allocation of transaction price to performance obligations

Revenue arrangements with distinct performance obligation are divided into separate units of accounting and the transaction price is allocated based on relative stand-alone selling prices.

Significant assumptions and estimates have been made in estimating the number of units to be claimed for each of distinct performance obligation, and changes in judgments on these assumptions and estimates could materially impact the timing of revenue recognition.

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(vi) Fair value of restricted share granted and share-based payment recognised under the ESOP

The Group has adopted the ESOP for the Group’s certain employees in 2021. The fair value of the restricted shares granted to employees is determined by using the discounted cash flow method to determine the underlying equity fair value of the Company and equity allocation based on Option Pricing model (“OPM model”) to determine the fair value of common shares. Significant estimates on assumptions, such as risk-free interest rate, volatility, dividend yield and lack of marketability discount are made based on management’s best estimates. Further details are included in Note 28.

The Group has to estimate the expected forfeiture rate at the end of vesting periods (the “Forfeiture Rate”) of the restricted shares granted in order to determine the amount of share-based payment expenses charged to the profit or loss for each year/period. As at 31 December 2021 and 30 June 2022, management of the Company has assessed and concluded that the expected Forfeiture Rate of the restricted shares awarded of the Group are to be nil and 12.7%, respectively.

5 SEGMENT INFORMATION

Description of segments and principal activities

The Group’s business activities, for which discrete financial information is available, are regularly reviewed and evaluated by the CODM. The CODM, who is responsible for allocating resource and assessing performance of the operating segments, has been identified as the executive directors of the Company that make strategic decisions.

The CODM assessed the performance of the reportable operating segments mainly based on segment revenue, cost of sales, research and development expenses of each reportable operating segment. Thus, segment result would present revenue, cost of sales, research and development expenses and gross profit for each reportable operating segment, which is in line with CODM’s performance review.

The Group’s reportable operating segments are as follows:

Occluder Business

Occluder Business is primarily operated by Shanghai Shape Memory Alloy, which is engaged in the business of research, development and sales of interventional treatment series occluders for defective congenital heart disease.

Heart Valve Business

Heart Valve Business is primarily operated by the Beijing Branch of Shanghai Shape Memory Alloy, which is currently engaged in the business of research and development of heart valve medical devices.

There were no separate segment assets and segment liabilities information provided to the CODM, as CODM does not use this information to allocate resources to or evaluate the performance of the operating segments.

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The segment information provided to the Group’s CODM for reportable segments for the respective years/periods is as follows:

	Year ended 31 December 2019		
	Occluder Business	Heart Valve Business	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Revenue	116,451	–	116,451
Cost of sales	(13,619)	–	(13,619)
Gross profit	102,832	–	102,832
Research and development expenses	(8,020)	(17,810)	(25,830)
Segment profit/(loss)	<u>94,812</u>	<u>(17,810)</u>	<u>77,002</u>
Unallocated items			
– Distribution expenses			(21,760)
– General and administrative expenses			(8,981)
– Net provision for impairment losses on financial assets			(1,788)
– Other income and gains – net			15,746
– Finance income – net			127
Profit before income tax			<u>60,346</u>

	Year ended 31 December 2020		
	Occluder Business	Heart Valve Business	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Revenue	148,247	–	148,247
Cost of sales	(15,134)	–	(15,134)
Gross profit	133,113	–	133,113
Research and development expenses	(11,234)	(27,723)	(38,957)
Segment profit/(loss)	<u>121,879</u>	<u>(27,723)</u>	<u>94,156</u>
Unallocated items			
– Distribution expenses			(23,146)
– General and administrative expenses			(8,383)
– Net reversal of impairment losses on financial assets			672
– Other income and gains – net			13,238
– Finance income – net			142
Profit before income tax			<u>76,679</u>

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	Year ended 31 December 2021		
	Occluder Business	Heart Valve Business	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Revenue	222,583	–	222,583
Cost of sales	(25,038)	–	(25,038)
Gross profit	197,545	–	197,545
Research and development expenses	(18,561)	(22,826)	(41,387)
Segment profit/(loss)	178,984	(22,826)	156,158
Unallocated items			
– Distribution expenses			(43,072)
– General and administrative expenses			(59,874)
– Net reversal of impairment losses on financial assets			533
– Other income and gains – net			22,642
– Finance costs – net			(10,360)
Profit before income tax			66,027

	Six months ended 30 June 2021 (Unaudited)		
	Occluder Business	Heart Valve Business	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Revenue	110,968	–	110,968
Cost of sales	(11,884)	–	(11,884)
Gross profit	99,084	–	99,084
Research and development expenses	(5,823)	(10,623)	(16,446)
Segment profit/(loss)	93,261	(10,623)	82,638
Unallocated items			
– Distribution expenses			(17,383)
– General and administrative expenses			(24,457)
– Net reversal of impairment losses on financial assets			464
– Other income and gains – net			4,401
– Finance costs – net			(693)
Profit before income tax			44,970

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	Six months ended 30 June 2022		
	Occluder Business	Heart Valve Business	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Revenue	124,804	–	124,804
Cost of sales	(15,322)	–	(15,322)
Gross profit	109,482	–	109,482
Research and development expenses	(7,490)	(12,147)	(19,637)
Segment profit/(loss)	101,992	(12,147)	89,845
Unallocated items			
– Distribution expenses			(16,626)
– General and administrative expenses			(16,402)
– Net provision for impairment losses on financial assets			(4,169)
– Other income and gains/(losses) – net			(18,289)
– Finance costs – net			(9,053)
Profit before income tax			25,306

Note:

During the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022, the research and development expenses capitalised as intangible assets and not included in the segment information above amounted to approximately RMB12,236,000, RMB12,411,000, RMB74,996,000, RMB26,684,000 and RMB28,055,000, respectively.

The major customers which contributed more than 10% of the Group’s total revenue for the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022 are listed as below:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
Percentage of revenue from the major customers to the Group’s total revenue					
Customer A (Occluder Business)	*	19%	*	*	*

(Unaudited)

* The amount of aggregate revenue from the customer (which is a related company) is less than 10% of the Group’s total revenue for the respective years/periods.

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Analysis of revenue

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>	
Derived:					
– In the PRC	116,451	148,247	210,259	109,887	105,555
– Outside the PRC	–	–	12,324	1,081	19,249
	<u>116,451</u>	<u>148,247</u>	<u>222,583</u>	<u>110,968</u>	<u>124,804</u>

Revenue is attributed to countries based on the customers’ locations.

6 REVENUE

An analysis of the Group’s revenue by category for the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022 was as follows:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>	
Revenue from contracts with customers recognised at a point in time					
– Revenue from sales of medical occluders	<u>116,451</u>	<u>148,247</u>	<u>222,583</u>	<u>110,968</u>	<u>124,804</u>

Revenues from external customers are derived from the sales of medical occluders both directly to hospitals and network of distributors. The Group has recognised revenue-related contract liabilities as set forth in Note 32.

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7 EXPENSES BY NATURE

The details of cost of sales, distribution expenses, general and administrative expenses and research and development expense are as follows:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(Unaudited)	
Employee benefit expense (Note 8)	31,259	32,363	58,546	18,773	31,148
Products testing, pre-clinical trial and animals studies fees	2,606	11,739	11,254	5,535	2,807
Changes in inventories of finished goods and work in progress	(315)	(3,541)	(12,505)	(3,199)	(2,814)
Raw materials and consumables used for					
– products production	5,935	9,394	22,804	8,963	8,533
– research and development	4,129	6,834	9,536	4,817	5,704
	10,064	16,228	32,340	13,780	14,237
Consulting services fees	6,016	7,201	7,845	3,538	1,748
Amortisation of intangible assets (Note 18)	250	1,511	4,182	1,365	3,458
Depreciation of					
– property, plant and equipment (Note 14)	2,978	3,028	2,882	1,466	1,685
– right-of-use assets (Note 15)	459	470	1,673	558	1,190
– investment properties (Note 16)	1,030	1,105	1,070	535	451
	4,467	4,603	5,625	2,559	3,326
Travelling expenses	5,120	3,714	7,020	2,979	1,637
Utilities and office expenses	2,270	3,531	3,349	788	948
Taxes and surcharges	2,412	2,427	5,836	2,406	1,693
Marketing expenses	2,448	2,168	7,134	1,848	3,046
Transportation costs	868	784	1,374	474	555
[REDACTED] expenses	–	–	32,690	17,219	5,124
Others	2,725	2,892	4,681	2,105	1,074
Total	70,190	85,620	169,371	70,170	67,987

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8 EMPLOYEE BENEFIT EXPENSE

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				<i>(Unaudited)</i>	
Wages, salaries and bonuses	30,593	33,246	41,529	18,235	23,042
Social security costs and housing benefits	6,119	4,782	8,091	2,817	5,693
Other employee welfares	821	511	687	384	170
Share-based payment expenses	–	–	22,257	3,952	7,801
	37,533	38,539	72,564	25,388	36,706
Less: amounts capitalised as intangible assets	(6,274)	(6,176)	(14,018)	(6,615)	(5,558)
Amount charged to profit or loss	31,259	32,363	58,546	18,773	31,148
Representing amounts charged to:					
– cost of sales	4,716	4,794	7,224	3,061	4,667
– distribution expenses	6,254	7,867	18,699	6,664	9,208
– general and administrative expenses	4,237	3,889	17,141	4,523	9,045
– research and development expenses	16,052	15,813	15,482	4,525	8,228
	31,259	32,363	58,546	18,773	31,148

(a) The employees of the Group in the PRC have participated in state-managed pension scheme operated by the PRC Government. The Group is required to contribute a specified percentage of payroll costs as determined by local government authority to the pension obligations to fund the benefits. The only obligation of the Group with respect to the retirement benefits scheme is to make the specified contribution under the scheme.

(b) Five highest paid individuals

The five individuals whose emoluments were the highest in the Group for the years/periods include 2, 2, 2, 2 and 2 directors for the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022, respectively. The emoluments payable to the remaining 3, 3, 3 and 3 highest paid individuals for the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022 respectively are as below:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				<i>(Unaudited)</i>	
Wages, salaries and bonuses	1,560	1,958	2,096	1,032	933
Social security costs and housing benefits	334	182	325	164	135
Share-based payments	–	–	1,821	357	1,247
	1,894	2,140	4,242	1,553	2,315

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The emoluments of the non-director highest paid individuals fell within the following bands:

Emolument bands (in HK dollar)	Number of individuals				
	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
				<i>(Unaudited)</i>	
HK\$1 – HK\$500,000	–	–	–	2	–
HK\$500,001 – HK\$1,000,000	3	3	–	1	2
HK\$1,000,001 – HK\$1,500,000	–	–	1	–	1
HK\$1,500,001 – HK\$2,000,000	–	–	1	–	–
HK\$2,000,001 – HK\$2,500,000	–	–	1	–	–
	<u>3</u>	<u>3</u>	<u>3</u>	<u>3</u>	<u>3</u>

9 NET PROVISION FOR/(REVERSAL OF) IMPAIRMENT LOSSES ON FINANCIAL ASSETS

Net provision for/(reversal of) loss allowance on:	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>	
– trade receivables	1,622	(1,152)	939	1,040	3,621
– other receivables	166	480	(1,472)	(1,504)	548
	<u>1,788</u>	<u>(672)</u>	<u>(533)</u>	<u>(464)</u>	<u>4,169</u>

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10 OTHER INCOME AND GAINS/(LOSSES) – NET

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(Unaudited)	
Government grants	8,998	5,630	7,743	4,476	2,574
Commission income from related party (Note 21(a))	–	–	–	–	734
Rental income from investment properties (Note 16(a))	3,027	2,454	2,564	1,253	215
Investment income on wealth management products	–	–	6,669	–	4,809
Others	1,234	249	414	378	40
Other income	13,259	8,333	17,390	6,107	8,372
Gains on disposal of investment properties	2,436	5,111	–	–	–
Fair value gains on financial assets at FVPL	–	–	–	–	4
Net loss on disposal of financial assets at FVOCI	–	(139)	–	–	–
Net loss on disposal/write-off of property, plant and equipment	(9)	(19)	(1)	(1)	(1)
Net foreign exchange gains/(losses)	–	–	5,192	(1,766)	(26,864)
Others	60	(48)	61	61	200
Other gains/(losses) – net	2,487	4,905	5,252	(1,706)	(26,661)
Other income and gains/(losses) – net	15,746	13,238	22,642	4,401	(18,289)

11 FINANCE INCOME/(COSTS) – NET

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(Unaudited)	
Finance income:					
Bank interest income	151	149	1,185	221	1,645
Finance costs:					
Interest expense on lease liabilities	(24)	(7)	(229)	(66)	(175)
Interest expense on redemption liabilities	–	–	(11,316)	(848)	(10,523)
	(24)	(7)	(11,545)	(914)	(10,698)
Finance income/(costs) – net	127	142	(10,360)	(693)	(9,053)

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12 INCOME TAX EXPENSE

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				<i>(Unaudited)</i>	
Current income tax charge	11,238	4,273	12,429	7,882	8,557
Deferred income tax (credit)/charge	(2,801)	3,634	(5,099)	(4,679)	(7,506)
Income tax expense	8,437	7,907	7,330	3,203	1,051

Shanghai Shape Memory Alloy is qualified as a “High and New Technology Enterprise (“HNTE”)” under the relevant PRC laws and regulations on 23 October 2017 (status renewed on 18 November 2020). Accordingly, it was entitled to a preferential income tax rate of 15% on its estimated assessable profits for the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022. Shanghai Shape Memory Alloy is subject to the requirement for re-applying for the renewal of this HNTEs status every three years.

According to the relevant laws and regulations promulgated by the State Administration of Taxation of the PRC that has been effective from 2018 to 2020, enterprise engaging in research and development activities are entitled to claim 175% (raised to 200% from 2021 onwards) of their research and development expenses incurred as tax deductible expenses when determining their assessable profits for that year (the “super deduction”).

Reconciliation of income tax expense

A reconciliation of the expected income tax calculated at the applicable tax rate and profit before income tax, with the actual income tax is as follows:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				<i>(Unaudited)</i>	
Profit before income tax	60,346	76,679	66,027	44,970	25,306
Tax calculated at the PRC statutory income tax rate (25%)	15,087	19,170	16,507	11,243	6,327
Tax effect of:					
Preferential tax rate	(6,035)	(7,669)	(10,207)	(6,476)	(6,220)
Expenses not deductible for tax purpose	253	301	6,726	857	4,012
Super deduction for research and development expenses	(868)	(3,895)	(5,696)	(2,421)	(3,068)
	8,437	7,907	7,330	3,203	1,051

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13 EARNINGS PER SHARE

(a) Basic earnings per share

Basic earnings per share is calculated by dividing the profit attributable to owners of the Company by the weighted average number of ordinary shares in issue during each year/period. The basic earnings per share for the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022 is calculated on the profit attributable to owners of the Company and on the assumption that 277.2 million shares issued upon the incorporation of the Company in connection with the Reorganisation were deemed to have been in issue since 1 January 2019.

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
				<i>(Unaudited)</i>	
Profit attributable to owners of the Company for the years/periods (RMB’000)	51,909	68,772	58,697	41,767	24,255
Weighted average number of ordinary shares in issue (in thousands) <i>(note)</i>	277,200	277,200	303,883	283,134	324,295
Basic earnings per share (in RMB per share)	<u>0.19</u>	<u>0.25</u>	<u>0.19</u>	<u>0.15</u>	<u>0.07</u>

Note:

The 29,558,155 shares subscribed by the [REDACTED] (Note 26(c)) are treated as ordinary shares for the purpose to calculate earnings per share as they are recognised in equity and have no preferred right as to dividends compared with ordinary shares. Movement in the number of fully paid ordinary shares outstanding for the reported periods are shown in Note 26.

(b) Diluted earnings per share

Diluted earnings per share is the same as basic earnings per share as there were no potential dilutive ordinary shares outstanding during the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022.

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14 PROPERTY, PLANT AND EQUIPMENT

	Buildings	Electronic equipment	Machinery	Vehicles	Others	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2019						
Cost	80,110	956	13,449	2,263	1,290	98,068
Accumulated depreciation	(7,846)	(839)	(7,203)	(484)	(1,033)	(17,405)
Net book amount	72,264	117	6,246	1,779	257	80,663
Year ended 31 December 2019						
Opening net book amount	72,264	117	6,246	1,779	257	80,663
Additions	–	123	2,497	–	53	2,673
Net transfer to investment properties	(11,613)	–	–	–	–	(11,613)
Write-off	–	(1)	(8)	–	–	(9)
Depreciation charge	(1,926)	(45)	(894)	(266)	(124)	(3,255)
Closing net book amount	58,725	194	7,841	1,513	186	68,459
At 31 December 2019						
Cost	69,716	1,055	15,892	2,263	1,344	90,270
Accumulated depreciation	(10,991)	(861)	(8,051)	(750)	(1,158)	(21,811)
Net book amount	58,725	194	7,841	1,513	186	68,459
Year ended 31 December 2020						
Opening net book amount	58,725	194	7,841	1,513	186	68,459
Additions	–	146	1,592	407	12	2,157
Disposals/write-off	–	(1)	(1)	(123)	–	(125)
Depreciation charge	(1,731)	(79)	(1,149)	(262)	(74)	(3,295)
Closing net book amount	56,994	260	8,283	1,535	124	67,196
At 31 December 2020						
Cost	69,716	1,189	17,477	2,334	1,356	92,072
Accumulated depreciation	(12,722)	(929)	(9,194)	(799)	(1,232)	(24,876)
Net book amount	56,994	260	8,283	1,535	124	67,196
Year ended 31 December 2021						
Opening net book amount	56,994	260	8,283	1,535	124	67,196
Additions	–	983	10,606	–	1,106	12,695
Write-off	–	(1)	–	–	–	(1)
Depreciation charge	(1,622)	(442)	(1,240)	(271)	(54)	(3,629)
Closing net book amount	55,372	800	17,649	1,264	1,176	76,261
At 31 December 2021						
Cost	69,716	2,141	28,083	2,334	2,462	104,736
Accumulated depreciation	(14,344)	(1,341)	(10,434)	(1,070)	(1,286)	(28,475)
Net book amount	55,372	800	17,649	1,264	1,176	76,261

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	Buildings	Electronic equipment	Machinery	Vehicles	Others	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Six months ended 30 June 2022						
Opening net book amount	55,372	800	17,649	1,264	1,176	76,261
Additions	974	62	7,192	–	211	8,439
Write-off	–	(1)	–	–	–	(1)
Depreciation charge	(877)	(147)	(1,053)	(136)	(40)	(2,253)
Closing net book amount	55,469	714	23,788	1,128	1,347	82,446
At 30 June 2022						
Cost	70,690	1,841	35,275	2,334	2,673	112,813
Accumulated depreciation	(15,221)	(1,127)	(11,487)	(1,206)	(1,326)	(30,367)
Net book amount	55,469	714	23,788	1,128	1,347	82,446

Depreciation of property, plant, and equipment charged to profit and loss and the amounts of depreciation being capitalised are analysed as follows:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Depreciation for the year/period	3,255	3,295	3,629	1,742	2,253
Less: amounts capitalised as intangible assets	(277)	(267)	(747)	(276)	(568)
Amount charged to profit or loss (Note 7)	2,978	3,028	2,882	1,466	1,685
Representing amounts charged to:					
– cost of sales	805	803	839	405	528
– distribution expenses	16	24	50	20	34
– general and administrative expenses	1,539	1,294	1,100	550	717
– research and development expenses	618	907	893	491	406
	2,978	3,028	2,882	1,466	1,685

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15 RIGHT-OF-USE ASSETS

(a) Amounts recognised in the consolidated balance sheets

	As at 31 December			As at
	2019	2020	2021	30 June
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>2022</i>
Right-of-use-assets				<i>RMB'000</i>
– Leased buildings	454	216	6,763	5,841

The Group leases various warehouses, staff dormitories and areas for research and development activities. Rental contracts are typically made for fixed periods of 2-5 years without extension option or residual value guarantee.

Information about leases for which the Group is a lessee is presented below:

	<u>Leased buildings</u>
	<i>RMB'000</i>
At 1 January 2019	
Cost	804
Accumulated depreciation	(613)
Net book amount	<u>191</u>
Year ended 31 December 2019	
Opening net book amount	191
Additions	722
Depreciation charge	(459)
Closing net book amount	<u>454</u>
At 31 December 2019	
Cost	1,526
Accumulated depreciation	(1,072)
Net book amount	<u>454</u>
Year ended 31 December 2020	
Opening net book amount	454
Additions	232
Depreciation charge	(470)
Closing net book amount	<u>216</u>
At 31 December 2020	
Cost	1,758
Accumulated depreciation	(1,542)
Net book amount	<u>216</u>
Year ended 31 December 2021	
Opening net book amount	216
Additions	8,220
Depreciation charge	(1,673)
Closing net book amount	<u>6,763</u>

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	<u>Leased buildings</u>
	<i>RMB'000</i>
At 31 December 2021	
Cost	8,452
Accumulated depreciation	(1,689)
Net book amount	<u>6,763</u>
Six months ended 30 June 2022	
Opening net book amount	6,763
Additions	268
Depreciation charge	(1,190)
Closing net book amount	<u>5,841</u>
At 30 June 2022	
Cost	8,552
Accumulated depreciation	(2,711)
Net book amount	<u>5,841</u>

(b) Lease liabilities recognised in the consolidated balance sheets as follows:

	<u>As at 31 December</u>			<u>As at</u>
	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>30 June</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<u>2022</u>
				<i>RMB'000</i>
Lease liabilities – current	369	116	2,143	1,994
Lease liabilities – non-current	–	–	4,044	4,294
	<u>369</u>	<u>116</u>	<u>6,187</u>	<u>6,288</u>

(c) Amounts recognised in profit or loss as follows:

	<u>Year ended 31 December</u>			<u>Six months ended 30 June</u>	
	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>2021</u>	<u>2022</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>	
Depreciation charge of right-of-use assets (<i>Note 7</i>)	459	470	1,673	558	1,190
Interest expense (<i>Note 11</i>)	24	7	229	66	175
	<u>483</u>	<u>477</u>	<u>1,902</u>	<u>624</u>	<u>1,365</u>

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16 INVESTMENT PROPERTIES

	Buildings
	<i>RMB'000</i>
At 1 January 2019	
Cost	37,159
Accumulated depreciation	(4,552)
Net book value	32,607
Year ended 31 December 2019	
Opening net book value	32,607
Disposals	(517)
Net transfer from property, plant and equipment (<i>Note 14</i>)	11,613
Depreciation charge (<i>Note 7</i>)	(1,030)
Closing net book value	42,673
At 31 December 2019	
Cost	46,709
Accumulated depreciation	(4,036)
Net book value	42,673
Year ended 31 December 2020	
Opening net book value	42,673
Disposals	(945)
Depreciation charge (<i>Note 7</i>)	(1,105)
Closing net book value	40,623
At 31 December 2020	
Cost	45,081
Accumulated depreciation	(4,458)
Net book value	40,623
Year ended 31 December 2021	
Opening net book value	40,623
Depreciation charge (<i>Note 7</i>)	(1,070)
Closing net book value	39,553
At 31 December 2021	
Cost	45,081
Accumulated depreciation	(5,528)
Net book value	39,553
Six months ended 30 June 2022	
Opening net book value	39,553
Depreciation charge (<i>Note 7</i>)	(451)
Closing net book value	39,102
At 30 June 2022	
Cost	45,081
Accumulated depreciation	(5,979)
Net book value	39,102

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- (a) As at 31 December 2019, 2020 and 2021 and 30 June 2022, the fair values of the investment properties of the Group as determined by an independent professional valuation firm amounted to approximately RMB55,600,000, RMB47,300,000 and RMB47,300,000 and RMB47,300,000, respectively.

The amounts recognised in profit and loss for investment properties are as follows:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>	
Rental income (<i>Note 10</i>)	3,027	2,454	2,564	1,253	215
Direct operating expenses from properties that generated rental income	(1,030)	(1,105)	(1,070)	(535)	(451)

Depreciation of investment properties for the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022 of RMB1,030,000, RMB1,105,000, RMB1,070,000, RMB535,000 and RMB451,000, respectively have been charged to “general and administrative expenses”.

(b) Leasing arrangements

The investment properties are leased to tenants under operating leases with rentals payable quarterly. There are no variable lease payments that depend on an index or rate.

Minimum lease payments receivable on leases of investment properties are as follows:

	As at 31 December			As at
	2019	2020	2021	30 June
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Within 1 year	2,454	2,482	2,497	507
Between 1 and 2 years	2,482	2,497	2,418	401
Between 2 and 3 years	2,497	2,418	1,239	–
Between 3 and 4 years	2,418	1,239	–	–
Between 4 and 5 years	1,239	–	–	–
	<u>11,090</u>	<u>8,636</u>	<u>6,154</u>	<u>908</u>

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17 GOODWILL

	As at 31 December			As at
	2019	2020	2021	30 June
	RMB'000	RMB'000	RMB'000	2022
				RMB'000
Goodwill on acquisition of Shanghai Shape Memory Alloy	48,282	48,282	48,282	48,282

As mentioned in Note 1, Lepu Medical acquired 100% of the equity interest in Shanghai Shape Memory Alloy in October 2008 from an independent third party. The goodwill of approximately RMB48,282,000 as recognised represents the excess of the purchase consideration over the fair value of the net identifiable assets acquired, which is attributable to the core technology and synergy effects expected from the Occluder Business of Shanghai Shape Memory Alloy.

As part of the Reorganization, Lepu Medical has injected its 100% equity interest in Shanghai Shape Memory Alloy to the Company in exchange for 277,200,000 ordinary shares of the Company. As described in Note 1.3, the Historical Financial Information have been prepared by including the historical financial information of the company/division engaged in the [REDACTED] Business, including Shanghai Shape Memory Alloy, which are under common control of Lepu Medical immediately before and after the Reorganisation and now comprising the Group as if the current group structure had been in existence throughout the periods presented, or since the date when the consolidating company/division first came under the control of Lepu Medical, whichever is a shorter period. Hence, the goodwill from the acquisition of Shanghai Shape Memory Alloy as previously recognised by Lepu Medical has been consolidated by the Group as if it has been consolidated from the earliest date presented in the Historical Financial Information. None of the goodwill recognised is expected to be deductible for income tax purposes.

For the purpose of impairment review for goodwill and intangible assets not subject to amortisation (i.e. capitalised development costs in Note 18 refers) which are attributable to the CGU of Occluder Business, the recoverable amount of the CGU is determined based on value-in-use calculations. These calculations use pre-tax cash flow projections based on financial budgets prepared by management covering a five-year period. Cash flows beyond the five-year period are extrapolated using the estimated terminal growth rates stated below.

The key assumptions used for value-in-use calculations are as follows:

	Gross profit margin	Growth rate of revenue	Terminal growth rate	Pre-tax discount rate
As at 31 December 2019	88.68%-91.15%	1.00%-5.00%	1.00%	14.86%
As at 31 December 2020	88.39%-90.59%	1.00%-5.00%	1.00%	14.75%
As at 31 December 2021	85.93%-88.35%	1.00%-4.00%	0.00%	15.73%

The growth rate for the first 5 years and budgeted gross profit margin were determined by the management based on past performance and its expectation for market and product development. The terminal growth rate used does not exceed the industry growth forecast for the market in which the Group operates. The discount rate used is pre-tax and reflects market assessments of the time value and the specific risks relating to the industry.

The result of the impairment testing reveals that the estimated recoverable amount of the CGU of Occluder Business far exceeded its carrying amount with sufficient headroom amounted to approximately RMB196,352,000, RMB240,173,000 and RMB484,252,000 as at 31 December 2019, 2020 and 2021, respectively.

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Management of the Company performs the sensitivity analysis based on the assumptions that budgeted gross profit margin, growth rate of revenue, terminal growth rate or the pre-tax discount rate used in the value-in-use calculation for the CGU of Occluder Business have been changed, with all other variables held constant, the headroom would be changed as below:

	Headroom amount		
	As at 31 December		
	2019	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Gross profit margin decreases			
by 10%	98,386	137,504	398,664
Growth rate of revenue decreases			
by 1%	168,761	201,099	465,126
Terminal growth rate decreases			
by 1%	191,711	235,160	455,062
Pre-tax discount rate increases			
by 1%	191,490	234,553	436,852

The directors of the Company have not identified that a reasonable possible change in any of the key assumptions that could cause the carrying amount of goodwill and intangible assets not subject to amortisation (attributable to the CGU of Occluder Business) to exceed their recoverable amount. Accordingly, the directors of the Company have concluded that no provision for impairment is required to be recognised as of the respective balance sheet dates.

As there were no indicators for impairment of the CGU of Occluder Business at 30 June 2022, management has not updated any of the impairment calculations since 31 December 2021 and the directors of the Company have concluded that no provision for impairment of the CGU of Occluder Business is required to be recognised as of 30 June 2022.

18 INTANGIBLE ASSETS

	Patents and licences	Purchased software	Development costs	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2019				
Cost	397	108	41,165	41,670
Accumulated amortisation	(158)	(25)	–	(183)
Net book value	239	83	41,165	41,487
Year ended 31 December 2019				
Opening net book value	239	83	41,165	41,487
Costs for internal development	–	–	12,236	12,236
Additions	943	–	–	943
Amortisation charge	(396)	(11)	–	(407)
Closing net book value	786	72	53,401	54,259
At 31 December 2019				
Cost	943	108	53,401	54,452
Accumulated amortisation	(157)	(36)	–	(193)
Net book value	786	72	53,401	54,259

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	<u>Patents and licences</u>	<u>Purchased software</u>	<u>Development costs</u>	<u>Total</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Year ended 31 December 2020				
Opening net book value	786	72	53,401	54,259
Costs for internal development	–	–	12,411	12,411
Additions	1,036	–	–	1,036
Transfer (<i>note</i>)	23,885	–	(23,885)	–
Amortisation charge	(1,736)	(11)	–	(1,747)
Closing net book value	23,971	61	41,927	65,959
At 31 December 2020				
Cost	25,864	108	41,927	67,899
Accumulated amortisation	(1,893)	(47)	–	(1,940)
Net book value	23,971	61	41,927	65,959
Year ended 31 December 2021				
Opening net book value	23,971	61	41,927	65,959
Costs for internal development	–	–	74,996	74,996
Additions	–	19	–	19
Transfer (<i>note</i>)	24,898	–	(24,898)	–
Amortisation charge	(4,404)	(13)	–	(4,417)
Closing net book value	44,465	67	92,025	136,557
At 31 December 2021				
Cost	50,762	127	92,025	142,914
Accumulated amortisation	(6,297)	(60)	–	(6,357)
Net book value	44,465	67	92,025	136,557
Six months ended 30 June 2022				
Opening net book value	44,465	67	92,025	136,557
Costs for internal development	–	–	28,055	28,055
Additions	–	515	–	515
Transfer (<i>note</i>)	16,734	–	(16,734)	–
Amortisation charge	(3,462)	(16)	–	(3,478)
Closing net book value	57,737	566	103,346	161,649
At 30 June 2022				
Cost	67,496	642	103,346	171,484
Accumulated amortisation	(9,759)	(76)	–	(9,835)
Net book value	57,737	566	103,346	161,649

Note:

During the years ended 31 December 2020 and 2021 and the six months ended 30 June 2022, Shanghai Shape Memory Alloy obtained two, two and one Medical Device Registration Certificates related to new occluder products, respectively. The carrying amounts of the related development costs as previously capitalised were therefore transferred to patents and licences with amortisation commenced then accordingly.

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The Group’s development costs represented capitalised development expenditures which are not subject to amortisation during the development stage but are subject to an annual impairment testing. Prior to 31 December 2020, all the capitalised development costs are attributable to the CGU of Occluder Business. For the year ended 31 December 2021 and the six months ended 30 June 2022, part of the eligible development costs attributable to the CGU of Heart Valve Business of approximately RMB41,477,000 and RMB21,073,000 have been capitalised, respectively.

Development costs which are attributable to the CGU of Occluder Business and more details of the impairment test as conducted by management and the result of which have been set out in Note 17.

Development costs which are attributable to the CGU of Heart Valve Business are not available for use and are tested for impairment on an annual basis at 31 December for each year, or more frequently if events or changes in circumstances indicate that they might be impaired in accordance with International Accounting Standard 36 “Impairment of Assets”. The recoverable amount is determined based on fair value less cost of disposal.

The management has involved an independent qualified valuer to perform impairment assessment to assess the fair value less cost of disposal of the development costs which are attributable to the CGU of Heart Valve Business as at 31 December 2021 by using the discounted cash flow approach. For the discounted cash flows, the estimated revenue was based on the management’s expected timing of the product candidates’ commercialisation, productivity and sales volume. Management estimated the product candidates’ sales volume based on market conditions and the state of technology development. Management then adjusted the estimated revenue to profit contributed from the development costs which are attributable to the CGU of Heart Valve Business by considering a percentage of costs and operating expenses to the revenue (“cost component ratio”), which was determined by reference to the current operating margin levels of comparable companies, with adjustments made based on management’s industry experience as well as the research and development plans. Finally, management estimated the discount rate based on the uncertain success rate of commercialisation for the applicable product candidates.

Considering the development stage and expected market conditions, management expected that the first commercialisation year of related heart valve product candidates will be in 2025. Based on the related heart valve product candidates’ life cycle and industry practice, the management expected that the estimated useful life of related heart valve products is at least 10 years. The cash flow projections for the first five years from 2026 to 2030 are based on financial budgets prepared by management with reference to market conditions. The cash flow projections for the subsequent years from 2031 to 2035 are extrapolated based on the forecasts using a steady growth rate of revenue of 2%, which does not exceed the long term industry growth forecast for the market in which the Group operates. The key assumptions used in the fair value less cost of disposal calculation for the CGU of Heart Valve Business are as follows:

	<u>Gross profit margin</u>	<u>Growth rate of revenue</u>		<u>Cost component ratio</u>	<u>Post-tax discount rate</u>
		<u>2026-2030</u>	<u>2031-2035</u>		
As at 31 December 2021	70%~85%	24.4%- 188.4%	2%	54.3%- 68.3%	17.90%

Based on the result of impairment assessment, the recoverable amount of the CGU of the Heart Valve Business is estimated to be exceeded its carrying amount as at 31 December 2021 by approximately RMB21,322,000.

The recoverable amount of the CGU of the Heart Valve Business would equal its carrying amount, if each of the key assumptions were to change as follows, with all other variables held constant and the management believe that the key assumptions would not likely to change as such:

	<u>As at 31 December 2021</u>
Gross profit margin	-12.54%
Growth rate of revenue	-7.68%
Cost component ratio	+8.40%
Post-tax discount rate	+3.57%

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The directors of the Company have not identified that a reasonable possible change in any of the key assumptions that could cause the carrying amount of CGU of the Heart Valve Business to exceed its recoverable amount. The directors of the Company have concluded that no provision for impairment of the CGU of Heart Valve Business is required to be recognised as at 31 December 2021.

As there were no indicators for impairment of the CGU of the Heart Valve Business at 30 June 2022, management has not updated any of the impairment calculations since 31 December 2021 and the directors of the Company have concluded that no provision for impairment of the CGU of the Heart Valve Business is required to be recognised as of 30 June 2022.

Amortisation of intangible assets has been charged to profit or loss or capitalised as follows:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(Unaudited)	
Amortisation for the year	407	1,747	4,417	1,509	3,478
Less: amounts capitalised as development costs	(157)	(236)	(235)	(144)	(20)
Amount charged to profit or loss (Note 7)	<u>250</u>	<u>1,511</u>	<u>4,182</u>	<u>1,365</u>	<u>3,458</u>
Representing amounts charged to:					
– cost of sales	239	1,500	4,168	1,360	3,344
– general and administrative expenses	11	11	11	5	15
– research and development expenses	–	–	3	–	99
	<u>250</u>	<u>1,511</u>	<u>4,182</u>	<u>1,365</u>	<u>3,458</u>

19 FINANCIAL INSTRUMENTS BY CATEGORY

The Group holds the following financial instruments:

	As at 31 December			As at 30 June
	2019	2020	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000
Assets as per consolidated balance sheets				
Financial assets at amortised cost				
– trade receivables	45,331	38,317	23,869	32,883
– other receivables	8,581	10,681	1,816	18,924
– bank deposit with initial term of over three months and cash and cash equivalents	16,119	18,792	713,480	734,534
Financial assets at FVPL	–	–	–	1,004
Financial assets at FVOCI	849	–	–	–
	<u>70,880</u>	<u>67,790</u>	<u>739,165</u>	<u>787,345</u>

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	As at 31 December			As at
	2019	2020	2021	30 June
	RMB'000	RMB'000	RMB'000	2022
				RMB'000
Liabilities as per consolidated balance sheets				
Financial liabilities at amortised cost				
– trade and other payables (excluding employee benefits payables and other tax payables)	48,893	51,623	13,994	40,072
– lease liabilities	369	116	6,187	6,288
– redemption liabilities	–	–	679,986	720,861
	<u>49,262</u>	<u>51,739</u>	<u>700,167</u>	<u>767,221</u>

The Group’s exposure to various risks associated with the financial instruments has been set out in Note 3. The maximum exposure to credit risk at each balance sheet date is the carrying amount of each class of financial assets as mentioned above.

20 DEFERRED INCOME TAX

Group

The analysis of deferred income tax assets/(liabilities), prior to any offset pursuant to net-off provisions, is as follows:

	As at 31 December			As at
	2019	2020	2021	30 June
	RMB'000	RMB'000	RMB'000	2022
				RMB'000
Deferred income tax assets				
– to be recovered within 12 months	5,654	2,121	3,326	4,110
– to be recovered after 12 months	1,452	1,351	6,259	12,844
	<u>7,106</u>	<u>3,472</u>	<u>9,585</u>	<u>16,954</u>
Deferred income tax liabilities				
– to be settled within 12 months	–	–	(349)	(335)
– to be settled after 12 months	(97)	–	(665)	(542)
	<u>(97)</u>	<u>–</u>	<u>(1,014)</u>	<u>(877)</u>
	<u>7,009</u>	<u>3,472</u>	<u>8,571</u>	<u>16,077</u>

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current income tax assets against current income tax liabilities and when the deferred income tax related to the same tax authority.

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The movement in deferred income tax assets and liabilities during the Track Record Period, without taking into consideration the offsetting of balance within the same tax jurisdiction, are as follows:

Deferred income tax assets

	Research and development expenses	Allowances for receivables	Contract liabilities	Tax losses	Lease liabilities	Others	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
As at 1 January 2019	1,514	1,184	1,300	–	–	307	4,305
Credited/(charged) to profit or loss	2,671	268	14	–	–	(152)	2,801
As at 31 December 2019	4,185	1,452	1,314	–	–	155	7,106
(Charged)/credited to profit or loss	(4,185)	(101)	414	–	–	238	(3,634)
As at 31 December 2020	–	1,351	1,728	–	–	393	3,472
(Charged)/credited to profit or loss	–	(80)	5	5,652	929	(393)	6,113
As at 31 December 2021	–	1,271	1,733	5,652	929	–	9,585
Credited to profit or loss	–	626	180	6,549	14	–	7,369
As at 30 June 2022	–	1,897	1,913	12,201	943	–	16,954

Deferred income tax liabilities

	Fair value changes of financial assets	Right-of-use assets	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
As at 1 January 2019	(73)	–	(73)
Charged to other comprehensive income	(24)	–	(24)
As at 31 December 2019	(97)	–	(97)
Credited to other comprehensive income	97	–	97
As at 31 December 2020	–	–	–
Charged to profit or loss	–	(1,014)	(1,014)
As at 31 December 2021	–	(1,014)	(1,014)
(Charged)/credit to profit or loss	(1)	138	137
As at 30 June 2022	(1)	(876)	(877)

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Deferred income tax assets

	<u>Tax losses</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>
As at 29 January 2021 (date of incorporation of the Company)	–	–
Credited to profit or loss	<u>5,652</u>	<u>5,652</u>
As at 31 December 2021	<u>5,652</u>	<u>5,652</u>
As at 1 January 2022	5,652	5,652
Credited to profit or loss	<u>6,549</u>	<u>6,549</u>
As at 30 June 2022	<u>12,201</u>	<u>12,201</u>

Deferred income tax liabilities

	<u>Fair value changes of financial assets</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>
As at 1 January 2022	–	–
Charged to profit or loss	<u>(1)</u>	<u>(1)</u>
As at 30 June 2022	<u>(1)</u>	<u>(1)</u>

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21 PREPAYMENTS AND OTHER RECEIVABLES

Group

	As at 31 December			As at
	2019	2020	2021	30 June
	RMB'000	RMB'000	RMB'000	2022
				RMB'000
Receivables due from related parties (Note 35(c))	6,788	8,034	–	–
Payment of expenses on behalf of an investee company	1,800	1,800	–	–
Proceeds receivables from disposal of an investment property	–	1,351	–	–
Deposits	776	676	1,348	1,634
Staff advance	176	285	397	633
Receivables from sales on behalf of a related party (note a)	–	–	–	17,098
Others	221	195	259	295
	9,761	12,341	2,004	19,660
Less: provision for impairment of other receivables	(1,180)	(1,660)	(188)	(736)
Other receivables – net	8,581	10,681	1,816	18,924
Prepayment to related parties (Note 35(c))	–	303	58	1,234
Prepayment for raw materials	1,828	5,266	9,948	20,235
Prepayment for products testing and clinical trial fee	2,871	3,021	3,547	5,405
Prepayment for purchases of property, plant and equipment	632	1,000	11,187	12,304
[REDACTED] expenses prepaid or to be capitalised	–	–	3,474	3,540
Prepayment for consulting service fees	138	691	522	357
Value-added tax recoverable	–	–	1,705	912
Others	24	220	695	1,200
	5,493	10,501	31,136	45,187
Total prepayments and other receivables	14,074	21,182	32,952	64,111
Less: non-current portion	(632)	(1,000)	(11,187)	(12,304)
Current portion	13,442	20,182	21,765	51,807

Notes:

- (a) During the six months ended 30 June 2022, the Group has provided COVID-19 antigen testing related products distribution services (as an agent) to a subsidiary of Lepu Medical (the “Fellow Subsidiary”). Under the distribution arrangement, the Group purchased the related products from the Fellow Subsidiary and sold them to the end customers following the instructions from the Fellow Subsidiary. The Group merely acted as an agent to sell the related products to the end customers on behalf of the Fellow Subsidiary. Except for the commission income of approximately RMB734,000 as recognised by the Group from the provision of such distribution services on net basis, no other revenue or income has been recognised by the Group under the distribution arrangement. The sale proceeds receivable from the end customers and the amounts payable to the Fellow Subsidiary in connection with the sales and purchases of the related COVID-19 antigen testing products have been recognised as the Group’s other receivables and other payables, respectively.

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- (b) Other receivables due from related parties were denominated in RMB, unsecured, interest-free and had no fixed terms of repayment.

Company

	As at 31 December	As at 30 June
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments and other receivables		
– Other receivables due from subsidiary	–	21,290
– [REDACTED] expenses prepaid or to be capitalised	3,474	3,540
– Value-added tax recoverable	1,092	912
– Others	–	216
	<u>4,566</u>	<u>25,958</u>

The Company’s other receivables from subsidiary are denominated in RMB, unsecured, interest-free and repayable on demand.

22 INVENTORIES

	As at 31 December			As at 30 June
	2019	2020	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	4,962	13,688	11,266	15,319
Work in progress	1,794	4,440	8,734	11,427
Finished goods	4,296	5,191	13,402	13,523
	<u>11,052</u>	<u>23,319</u>	<u>33,402</u>	<u>40,269</u>

During the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022, inventories recognised in profit and loss amounted to approximately RMB9,749,000, RMB12,687,000, RMB19,835,000, RMB10,581,000 and RMB11,423,000, respectively. These costs are charged to profit or loss as follows:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	<i>(Unaudited)</i>				
Cost of inventories sold or consumed charged to:					
– cost of sales	5,620	5,853	10,299	5,764	5,719
– research and development expenses	4,129	6,834	9,536	4,817	5,704
	<u>9,749</u>	<u>12,687</u>	<u>19,835</u>	<u>10,581</u>	<u>11,423</u>

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23 TRADE RECEIVABLES

	As at 31 December			As at
	2019	2020	2021	30 June
	RMB'000	RMB'000	RMB'000	2022
				RMB'000
Trade receivables from contracts with customers				
– third parties	34,882	35,588	31,887	43,086
– related parties (Note 35(c))	18,950	10,078	270	1,706
	53,832	45,666	32,157	44,792
Less: allowance for impairment	(8,501)	(7,349)	(8,288)	(11,909)
	45,331	38,317	23,869	32,883

The Group generally does not offer any official contractual credit terms to its customers and will closely monitor the settlement pattern of respective customers. For certain individual customers with long-term relationship with the Group and have good credit history in the past, the Group may allow them to settle the related receivable balances within a discretionary period ranging from 30 days to 180 days. The aging analysis of the gross trade receivable as at 31 December 2019, 2020 and 2021 and 30 June 2022, based on invoice date, are as follows:

	As at 31 December			As at
	2019	2020	2021	30 June
	RMB'000	RMB'000	RMB'000	2022
				RMB'000
Within 1 year	36,613	35,265	25,332	32,811
Between 1 year and 2 years	12,886	6,483	1,992	6,916
Over 2 years	4,333	3,918	4,833	5,065
	53,832	45,666	32,157	44,792

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for trade receivables. Details of the allowance for impairment and the movement in the allowance balance has been set out in Note 3.1(b).

The carrying amounts of trade receivables are denominated in the following currencies:

	As at 31 December			As at
	2019	2020	2021	30 June
	RMB'000	RMB'000	RMB'000	2022
				RMB'000
RMB	53,832	45,666	30,840	37,484
USD	–	–	1,141	6,839
EUR	–	–	176	469
	53,832	45,666	32,157	44,792

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24 FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

Group and Company

	<u>As at 30 June</u>
	<u>2022</u>
	<i>RMB’000</i>
Investment in wealth management products issued by banks	<u>1,004</u>

The financial assets at fair value through profit or loss as of 30 June 2022 represent investments in wealth management products denominated in RMB, with expected rates of return of 2.04% per annum. The returns of the investments are not guaranteed, hence the contractual cash flows do not qualify for solely payments of principal and interest. Therefore, the investments have been accounted for as financial assets at fair value through profit or loss. None of these investments are past due.

(i) Amounts recognised in profit or loss

The carrying amount of the financial assets was a reasonable approximation of their fair value due to the short-term investment period and stable yield rate. Investment income of RMB4,809,000 and unrealised fair value gains of RMB4,000 have been recognised as other income and gain for the six months ended 30 June 2022 (Note 10).

(ii) Risk exposure and fair value measurements

Information about the methods and assumptions used in determining fair value has been set out in Note 3.3.

25 BANK DEPOSIT WITH INITIAL TERM OF OVER THREE MONTHS AND CASH AND CASH EQUIVALENTS

Group

	<u>As at 31 December</u>			<u>As at</u>
	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>30 June</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cash and cash equivalents:				
– Cash at bank and in hand	<u>16,119</u>	<u>18,792</u>	<u>713,480</u>	<u>664,534</u>
Cash and cash equivalents are denominated in:				
– RMB	16,119	18,792	648,410	590,191
– USD	–	–	63,094	71,482
– EUR	–	–	1,976	2,861
	<u>16,119</u>	<u>18,792</u>	<u>713,480</u>	<u>664,534</u>
Bank deposit with initial term of over three months denominated in:				
– RMB	<u>–</u>	<u>–</u>	<u>–</u>	<u>70,000</u>

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Company

	As at 31 December	As at 30 June
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Cash and cash equivalents:		
– Cash at bank and in hand	694,946	556,491
Cash and cash equivalents are denominated in:		
– RMB	639,821	499,404
– USD	55,125	57,087
	694,946	556,491
Bank deposit with initial term of over three months denominated in:		
– RMB	–	70,000

26 SHARE CAPITAL

Group and Company

	Number of ordinary shares	Nominal value of shares	Share capital	Total
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Issued and fully paid				
As at 29 January 2021 (date of incorporation of the Company)	–	–	–	–
Issuance of ordinary shares	324,294,997	324,295	324,295	324,295
As at 31 December 2021 and 30 June 2022	324,294,997	324,295	324,295	324,295

On 29 January 2021, the Company was incorporated as a joint stock limited liability company in the PRC by Lepu Medical and Target Medical, with a registered capital of RMB280,000,000. The shares as issued by the Company during the period from 29 January 2021 (date of incorporation) to 30 June 2022 are summarised as below:

- (a) On 5 March 2021, Lepu Medical injected the 100% equity interest of Shanghai Shape Memory Alloy to the Company in exchange for 277,200,000 ordinary shares of the Company. Upon completion of the capital injection, capital reserve of approximately RMB713,776,000, which represented the fair value of 100% equity interest of Shanghai Shape Memory Alloy at the date of capital injection, was transferred to the Company’s share capital and share premium accounts for the amounts of approximately RMB277,200,000 and RMB436,576,000, respectively.

Target Medical has also subscribed 2,800,000 shares of the Company on 23 March 2021, with cash consideration of RMB7,209,000. The difference of par value of the shares issued and total consideration of approximately RMB4,409,000 was recorded as share premium.

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- (b) On 26 April 2021, the Company entered into investment agreement with Ningbo Jiacheng and Ningbo Jiadu, pursuant to which Ningbo Jiacheng and Ningbo Jiadu subscribed 5,600,000 and 9,137,000 shares of the Company at the consideration of RMB19,488,000 and RMB31,796,000, respectively and these shares were issued in June 2021. The difference of par value of the shares issued and total consideration of approximately RMB36,547,000 was recorded as share premium.

- (c) Pursuant to the [REDACTED] Shareholders Agreement as mentioned in Note 1.1, the [REDACTED] have subscribed 29,558,155 shares of the Company at a total cash consideration of approximately RMB609,740,000 (out of which, capital injection amounts of approximately RMB512,560,000 are denominated in USD (representing USD80 million as injected by 3 of the [REDACTED])) and these shares have been issued by the Company in June 2021. The difference of par value of the shares issued and total consideration of approximately RMB580,182,000 was recorded as share premium.

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27 TREASURY STOCK AND OTHER RESERVES

Group	Other reserves					Total
	Treasury stock	Share premium	Capital reserve	Capital reserve-share-based payments	Other reserves	
	RMB'000 (note b)	RMB'000	RMB'000	RMB'000	RMB'000	
As at 1 January 2019	–	–	(57,916)	–	414	(57,502)
Fair value changes of equity investment at FVOCI	–	–	–	–	138	138
Deemed distributions (note a)	–	–	(60,985)	–	–	(60,985)
Deemed contributions (note a)	–	–	19,604	–	–	19,604
As at 31 December 2019	–	–	(99,297)	–	552	(98,745)
As at 1 January 2020	–	–	(99,297)	–	552	(98,745)
Fair value changes of equity investment at FVOCI	–	–	–	–	427	427
Disposal of equity investment at fair value through other comprehensive income	–	–	–	–	(979)	(979)
Deemed distributions (note a)	–	–	(777,645)	–	–	(777,645)
Deemed contributions (note a)	–	–	730,176	–	–	730,176
As at 31 December 2020	–	–	(146,766)	–	–	(146,766)
As at 1 January 2021	–	–	(146,766)	–	–	(146,766)
Issuance of shares to Lepu Medical (Note 26(a))	–	436,576	(713,776)	–	–	(277,200)
Issuance of shares to Target Medical (Note 26(a))	–	4,409	–	–	–	4,409
Issuance of shares to Ningbo Jiacheng and Ningbo Jiadu (Note 26(b))	–	36,547	–	–	–	36,547
Issuance of shares to [REDACTED] (Note 26(c))	–	580,182	–	–	–	580,182
Deemed distributions (note a)	–	–	(72,167)	–	–	(72,167)
Deemed contributions (note a)	–	–	446,079	–	–	446,079
Recognition of redemption liabilities (Note 30)	(671,507)	–	–	–	–	–
Share-based payments – deemed contribution from Lepu Medical (Note 28(a))	–	–	–	22,257	–	22,257
As at 31 December 2021	(671,507)	1,057,714	(486,630)	22,257	–	593,341

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	Other reserves					Total
	Treasury stock	Share premium	Capital reserve	Capital reserve-share-based payments	Other reserves	
	RMB’000 (note b)	RMB’000	RMB’000	RMB’000	RMB’000	
As at 1 January 2022	(671,507)	1,057,714	(486,630)	22,257	–	593,341
Share-based payments – deemed contribution from Lepu Medical (Note 28(a))	–	–	–	7,801	–	7,801
As at 30 June 2022	<u>(671,507)</u>	<u>1,057,714</u>	<u>(486,630)</u>	<u>30,058</u>	<u>–</u>	<u>601,142</u>

(a) Deemed distributions and contributions

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000
Deemed distributions					
– Cash payments in relation to the Shanghai Shape Memory Alloy’s investment in Ningbo Bingkun (note i)	(60,985)	(777,645)	–	–	–
– Cash distribution to shareholder during the Reorganisation (note ii)	–	–	(72,167)	(72,167)	–
	<u>(60,985)</u>	<u>(777,645)</u>	<u>(72,167)</u>	<u>(72,167)</u>	<u>–</u>
Deemed contributions					
– Cash receipt from Lepu Medical for the Shanghai Shape Memory Alloy’s transfer out of investment in Ningbo Bingkun (note i)	–	658,800	439,200	439,200	–
– Dividend received from Ningbo Bingkun (note i)	–	37,830	–	–	–
– Injection of Heart Valve Business (note ii)	19,604	33,546	6,879	6,879	–
	<u>19,604</u>	<u>730,176</u>	<u>446,079</u>	<u>446,079</u>	<u>–</u>

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Notes:

- (i) Shanghai Shape Memory Alloy has acquired 63.05% equity interests in Ningbo Bingkun from a third party in September 2015 and its equity interests in Ningbo Bingkun are further increased to 98.05% in December 2018. Shanghai Shape Memory Alloy has been designated by Lepu Medical as the shareholding entity to hold this investment on its behalf. Shanghai Shape Memory Alloy’s investments costs in Ningbo Bingkun were primarily financed by Lepu Medical, with the remaining portion being financed by the cash as accumulated from Shanghai Shape Memory Alloy’s own business operations in prior years.

Ningbo Bingkun is principally engaged in the research, development, production and sales of surgical matching devices and minimally invasive surgical-related products for use in open surgeries and laparoscopic surgeries which are unrelated to the [REDACTED] Business. Considering Ningbo Bingkun is not a company engaged in the [REDACTED] Business, its financial information (together with Shanghai Shape Memory Alloy’s investments costs in Ningbo Bingkun and any payable balances arisen from the investments (the “Payable Balances”) as reflected in the Shanghai Shape Memory Alloy’s standalone financial statements) have not been included in this Historical Financial Information in accordance with the basis of presentation as set out in Note 1.3.

During the years ended 31 December 2019 and 2020, the aggregated total of Shanghai Shape Memory Alloy’s cash payments for further investments in Ningbo Bingkun (regardless of the funding source) and settlement of the Payable Balances amounted to approximately RMB60,985,000 and RMB777,645,000, respectively and these cash payments have been accounted for as deemed distributions to Lepu Medical during the respective years.

The dividend income as received by Shanghai Shape Memory Alloy from Ningbo Bingkun of RMB37,830,000 during the year ended 31 December 2020 has been accounted for as deemed contribution from Lepu Medical.

As mentioned in Note 1.2, Shanghai Shape Memory Alloy has disposed of its entire equity interest in Ningbo Bingkun to Lepu Medical at a consideration of RMB1,098,000,000 in December 2020. Part of the disposal consideration of RMB658,800,000 was received by Shanghai Shape Memory Alloy in December 2020 and the remaining consideration of RMB439,200,000 was received by the Company in January 2021. The cash receipts of these disposal consideration have been accounted for as deemed contribution from Lepu Medical.

- (ii) As part of the Reorganisation mentioned in Note 1.2, Shanghai Shape Memory Alloy has acquired the Heart Valve Business from Lepu Medical at an aggregate consideration of approximately RMB72,167,000 which was treated as a deemed distribution to the shareholder of the Group. The net assets and financial results attributable to the Heart Valve Business have been included in this Historical Financial Information based on basis of presentation as set out in Note 1.3. During the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021, the cash as injected by Lepu Medical for the development of the Heart Valve Business of RMB19,604,000, RMB33,546,000, RMB6,879,000 and RMB6,879,000, respectively have been accounted for as deemed contribution from Lepu Medical.

(b) Treasury stock

Treasury stock is recorded to reflect the carrying amount of the redemption liabilities when it is initially reclassified from equity, and will be reversed when the redemption liabilities are derecognised upon when the Group’s obligations in connection with those redemption liabilities are discharged, cancelled or have expired which will then be reclassified back to equity. Details of the redemption liabilities have been set out in Note 30.

Company

As at 31 December 2021 and 30 June 2022, the Company’s other reserves represent the share premium as arisen from the issuance of the Company’s shares of RMB1,057,714,000.

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28 SHARE-BASED PAYMENTS

As mentioned in Note 1.2, both Ningbo Jiadu and Ningbo Jiacheng are not controlled by the Group under the ESOP.

In June 2021, Ningbo Jiadu (with the authorisation from the Board of Directors of Lepu Medical) has granted 9,136,842 shares of the Company to 49 employees of the Group (the “Grantees”) at a consideration of RMB3.48 per share under the ESOP which are vested when Grantees complete a contractual terms of services with the aim to motivate the Grantees to continue serving the Group in future. The Grantees’ interests in these granted shares are held through their proportionate partnership interests in Ningbo Jiadu as limited partners.

Pursuant to the limited partnership agreement of Ningbo Jiadu, the employees with equity incentive are restricted from selling, transferring or disposing of their respective partnership interest for the first 12 months from the date of the Company’s shares are [REDACTED] on a recognised stock exchange (the “[REDACTED]”). On the first [REDACTED] after each of the first and second anniversary of the [REDACTED], 15% of the interest owned by each of the employees with equity incentive will be vested and released. On the first [REDACTED] after the third anniversary of the [REDACTED], the remaining 70% of the interest owned by each of the employees with equity incentive will be vested and released.

If the Company fails to complete a successful [REDACTED] of its shares on a recognised stock exchange within 24 months from the dates when the Grantees owned their respective partnership interests in Ningbo Jiadu (the “partnership joining date”), on each of the third and fourth anniversary of the partnership joining date, 15% of the interests owned by each of the employees with equity incentive will be vested and released. On the fifth anniversary of the partnership joining date, the remaining 70% of the interest owned by each of the employees with equity incentive will be vested and released.

Set out below are the movement in the number of awarded restricted shares under the ESOP:

	<u>Number of shares</u>
At 1 January 2021	–
Granted	9,136,842
Vested	–
Forfeited	–
	<hr/>
At 31 December 2021 and 30 June 2022	9,136,842
	<hr/> <hr/>

The fair value of the restricted shares granted to employees is determined by using the discounted cash flow method to determine the underlying equity fair value of the Company and equity allocation based on OPM model to determine the fair value of common shares. Significant estimates on key assumptions, such as risk-free interest rate, volatility, dividend yield and lack of marketability discount are made based on management’s best estimates.

Details of these key assumptions at the date of grant are summarised as below:

	<u>Key assumptions/ inputs</u>
Risk-free interest rate	2.61%
Volatility	42.7%
Dividend yield	0%
Lack of marketability discount	12%

As at 31 December 2021 and 30 June 2022, management of the Company has assessed and estimated that the expected Forfeiture Rate for each of the vesting period of the restricted shares granted to be nil and 12.7%. Due to the change in the expected Forfeiture Rate, a reversal of share-based payment expenses of approximately RMB6,381,000 has been recognised and net with the share-based payment expenses for the six months ended 30 June 2022.

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(a) *Expenses arising from share-based payment transactions*

	Year ended	Six months ended 30 June	
	31 December	2021	2022
	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Share-based payment expenses, net	22,257	3,952	7,801
Less: amounts capitalised as intangible assets	(4,457)	(1,128)	(704)
Amount charged to profit or loss	<u>17,800</u>	<u>2,824</u>	<u>7,097</u>
Representing amounts charged to:			
– distribution expenses	2,836	504	415
– general and administrative expenses	9,200	1,630	4,890
– research and development expenses	5,764	690	1,792
	<u>17,800</u>	<u>2,824</u>	<u>7,097</u>

Considering the abovementioned shares were granted to the Grantees for securing their continuous services to the Group, the Group has recognised the related share-based payment expenses during the year ended 31 December 2021 and the six months ended 30 June 2022. The shares as granted by Ningbo Jiadu under the approval from Lepu Medical (the parent of the Company) are those shares as subscribed and fully paid by Ningbo Jiadu in April 2021 (Note 26(b)). Therefore, the grant of the shares by Ningbo Jiadu to the Grantees without any recharge to the Group has also been accounted for as deemed contribution from shareholders in equity.

29 DEFERRED INCOME

	As at 31 December			As at
	2019	2020	2021	30 June
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Deferred government grants	<u>2,148</u>	<u>1,315</u>	<u>482</u>	<u>152</u>

Deferred government grants primarily comprise of assets related government grants, which is deferred and recognised in profit or loss on a straight-line basis over the residual expected useful lives of the related assets.

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30 REDEMPTION LIABILITIES

Group and Company

	As at 31 December	As at 30 June
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Redemption liabilities, at amortised cost	679,986	720,861

On 28 May 2021, the Company and the [REDACTED] as mentioned in Note 1.1 (i.e. Vivo Capital Fund IX, SCC Growth, Shanghai Biomedical, Huaihua Haozhi and CDH Supermatrix), entered into [REDACTED] Shareholders Agreement, pursuant to which each of the [REDACTED] agreed to [REDACTED] in the Company by subscription of the increased registered capital of the Company. The cash as injected by the [REDACTED] for the subscription of the Company’s shares as allotted pursuant to the [REDACTED] Shareholder Agreement amounted to approximately RMB609,740,000 (Note 26(c)).

Pursuant to the [REDACTED] Shareholders Agreement, the preferred rights are expected to be granted to the [REDACTED] or become effective when any of the following circumstance occurs or the date comes, whichever is the earliest (collectively the “Triggering Events and Effective Dates”):

- (i) The Company’s application for [REDACTED] (the “[REDACTED]”) has not been approved by the relevant regulatory authority or stock exchange since submitting within twelve months;
- (ii) The Company voluntarily withdraws the [REDACTED] application or the [REDACTED] sponsor of the Company withdraws its recommendation letter;
- (iii) The application of [REDACTED] was rejected or rebutted by the relevant regulatory authority or stock exchange;
- (iv) The Company fails to qualify its shares [REDACTED] on a recognised stock exchange prior to 31 December 2022.

These preferred rights are summarised as follows:

(a) Liquidation preferences

In the event of any liquidation, dissolution or winding up of the Company, either voluntarily or involuntarily, the [REDACTED] shall be entitled to receive the liquidation preference amount, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the other holders of ordinary shares.

The liquidation preference amount for the [REDACTED] is calculated whichever higher of: (i) the distributable assets of the Company for the [REDACTED] based on their shareholding ratio; (ii) the original investment principals from the [REDACTED], plus an annual simple rate of 10% of the original investment principals for a period of time commencing from the delivery date to the actual payments date of the settlement (calculated as 360 days in a calendar year) and any declared but unpaid dividends or profits thereon up to the date of the settlement, meanwhile, minus any dividends or profits already distributed. If the amount of distributable assets is not enough to cover the amount calculated based on the method described in (ii) above, the difference should be paid by Lepu Medical.

A liquidation event means (i) any sale, disposition or conveyance by the Company of all or substantially all of its assets (including the exclusive licensing of all or substantially all the intellectual property assets of the Company); (ii) any merger, consolidation or other transactions resulting in the Company acquired by other entity or after which change the substantial control of the Company; (iii) any liquidation, dissolution or winding up, either voluntarily or involuntarily, of the Company.

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(b) Anti-dilution right

If the Company increases its share capital at a price lower than the price paid by the [REDACTED] on a per share capital basis (the “New Low Financing”), the [REDACTED] have a right to require : (i) the Company to issue new share capital for nominal price (or lowest price allowed by the law) to the [REDACTED]; (ii) the Controlling Shareholder to transfer the equity interests of the Company to the [REDACTED] at nominal price or the lowest price allowed by the law; (iii) the Controlling Shareholder to settle the difference in cash, so that the total amount paid by the [REDACTED] divided by the total amount of share capital obtained is equal to the price per share capital in the new issuance.

(c) Redemption right

The [REDACTED] have a right to require the Lepu Medical to redeem their investments if (i) the Company failed to qualify its shares list on a recognised stock exchange before 31 December 2022; (ii) during the period from the issuance date to before the Company’s share qualified list on a recognised stock exchange, the Company and its ultimate controlling shareholder or other existing shareholders has committed a major criminal violation; (iii) the ultimate controlling shareholder of Lepu Medical was changed.

The redemption amount for the [REDACTED] is the original investment principals from the [REDACTED], and any declared but unpaid dividends or profits thereon up to the date of the settlement, meanwhile, minus any dividends or profits distributed to the [REDACTED].

The liquidation preferences granted to the [REDACTED] constitute possible obligations for the Company to repurchase its own equity instruments. These obligations were recognised as redemption liabilities which are initially measured at fair value (representing the present value of the expected cash flows for settling the related obligations if these rights are exercised by the investors) and subsequently measured at amortised cost. The Company applied a redemption discount rate of 3.10% to determine the initial recognition amount of the redemption liabilities. As mentioned above, Lepu Medical is solely responsible for any settlement to the [REDACTED] if they exercise their redemption rights. The anti-dilution right is a derivative financial instrument measured at fair value through profit or loss, of which the fair value was considered close to nil as the directors of Company expected the New Low Financing would never occur before the Company’s successful [REDACTED].

Pursuant to the [REDACTED] Shareholders Agreement, the preferred rights granted to the [REDACTED] will lapse upon the completion of the [REDACTED], the redemption liabilities will then be transferred to the Group’s equity accordingly.

Recognition and measurement of redemption liabilities

The redemption liabilities are arisen from the share capital of the Company with preferred rights as held by the [REDACTED]. The Group recognised the redemption liabilities as financial liabilities due to that all triggering events of key preferred rights to the [REDACTED], are out of control of the Company and they do not meet the definition of equity for the Company. The financial liabilities are initially measured at fair value (representing the present value of the estimated redemption liabilities) and subsequently measured at amortised cost. The present value is the amount expected to be paid to the [REDACTED] upon liquidation which is assumed to be at the dates of issuance of the Company’s shares with preferred rights. Interests from the financial instruments are charged in finance cost.

In June 2021, the Company issued share capital of approximately RMB29,558,000 to the [REDACTED]. The difference between capital contribution received from the [REDACTED] and share capital issued of approximately RMB580,182,000 was credited as the Company’s share premium. The Company further recognised the redemption liabilities of approximately of RMB671,507,000 which is the present value of the estimated redemption liabilities as of the date of issuance of the Company’s shares with preferred rights to the [REDACTED]. The Company applied a redemption discount rate of 3.10%, to determine the present value of the redemption liabilities.

Considering the Triggering Events and Effective Dates as mentioned above, management of the Company has classified the entire redemption liabilities as current liabilities as at 31 December 2021 and 30 June 2022.

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The movements of redemption liabilities are set out below:

Group and Company

	Redemption liabilities	
	<u>RMB'000</u>	
As at 1 January 2021		–
Initial recognition		671,507
Exchange gain		(2,837)
Interest expense (<i>Note 11</i>)		<u>11,316</u>
As at 31 December 2021		<u><u>679,986</u></u>
As at 1 January 2022		679,986
Exchange losses		30,352
Interest expense (<i>Note 11</i>)		<u>10,523</u>
As at 30 June 2022		<u><u>720,861</u></u>
	As at	As at
	31 December	30 June
	<u>2021</u>	<u>2022</u>
	<i>RMB'000</i>	<i>RMB'000</i>
Denominated in:		
USD	571,165	610,379
RMB	<u>108,821</u>	<u>110,482</u>
	<u><u>679,986</u></u>	<u><u>720,861</u></u>

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31 TRADE AND OTHER PAYABLES

Group

	As at 31 December			As at
	2019	2020	2021	30 June
	RMB'000	RMB'000	RMB'000	2022
				RMB'000
Trade payables				
– related parties (<i>Note 35(c)</i>)	1,243	2,019	–	147
– third parties	3,221	2,401	6,680	5,536
	4,464	4,420	6,680	5,683
Other payables to related parties (<i>Note 35(c)</i>)	42,866	45,754	–	25,629
Employee benefits payable	4,379	6,988	7,139	6,172
Other taxes payable	4,014	3,526	5,167	8,183
Deposits received from customers	651	608	326	271
Accrual of [REDACTED] expenses	–	–	5,535	7,045
Payables for equipment acquisition	–	–	430	95
Others	912	841	1,023	1,349
	<u>57,286</u>	<u>62,137</u>	<u>26,300</u>	<u>54,427</u>

Note:

As at 31 December 2019 and 2020, other payables due to related parties primarily represented balances due to Lepu Medical (*Note 35(c)*) as arisen from Lepu Medical’s settlement of certain employee benefit expenses and operating costs on behalf of the Group.

The abovementioned operating costs as paid by Lepu Medical on behalf of the Group represents the settlement of sales proceeds as collected on behalf of an independent overseas supplier for its sales of certain surgical dressing products in the China market which the Group had provided the related distribution services (as an agent). The aforesaid distribution arrangement was terminated in the second half of 2019. For the year ended 31 December 2019, the income from the provision of such distribution services and other services to the supplier amounted to approximately RMB1,261,000.

As at 31 December 2019, 2020, 2021 and 30 June 2022, the expenses and operating costs as settled by Lepu Medical on behalf of the Group but not yet settled by the Group amounted to approximately RMB42,866,000, RMB45,754,000, nil and nil, respectively.

As at 30 June 2022, other payables due to related parties represent the balances payable to the Fellow Subsidiary as arisen from the distribution arrangement as mentioned in *Note 21(a)*.

Other payables due to related parties are denominated in RMB, unsecured, interest-free and repayable on demand.

The carrying amounts of trade and other payables are considered to be the same as their fair values, due to their short-term nature.

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The credit period granted by suppliers to the Group ranged from 30 days to 120 days. Aging analysis of the trade payables at each balance sheet date are as follows:

	As at 31 December			As at
	2019	2020	2021	30 June
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Within 1 year	4,132	3,179	6,533	5,536
Between 1 year and 2 years	186	1,002	–	–
Over 2 years	146	239	147	147
	<u>4,464</u>	<u>4,420</u>	<u>6,680</u>	<u>5,683</u>

The carrying amounts of trade and other payables are denominated in the following currencies:

	As at 31 December			As at
	2019	2020	2021	30 June
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
RMB	56,506	61,289	25,407	53,575
EUR	–	–	–	49
USD	780	848	893	803
	<u>57,286</u>	<u>62,137</u>	<u>26,300</u>	<u>54,427</u>

Company

	As at	As at
	31 December	30 June
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Other payables		
– Payable to subsidiary	50,500	–
– Accrual of [REDACTED] expenses	5,535	7,045
– Other taxes payable	2,039	1,213
– Employee benefits payable	717	479
	<u>58,791</u>	<u>8,737</u>

The Company’s other payable to the subsidiary was denominated in RMB, unsecured, interest-free and had no fixed terms of repayment.

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32 CONTRACT LIABILITIES

	As at 1 January	As at 31 December			As at 30 June
	2019	2019	2020	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Contract liabilities					
– receipts in advance from customers	3,108	3,448	3,826	3,229	1,668
– rebates to customers (<i>note</i>)	3,161	4,200	4,672	3,589	2,932
– customers’ rights to claim for additional units of products (<i>note</i>)	5,504	4,558	6,845	7,965	9,826
	<u>11,773</u>	<u>12,206</u>	<u>15,343</u>	<u>14,783</u>	<u>14,426</u>

Note:

The Group has contracted with certain customers to offer them with volume rebates if their purchases of the Group’s products (i.e. occluders) have exceeded certain pre-determined level and these volume rebates are to be settled by way of the delivery of additional units of the Group’s products to these customers with no cash alternative settlement. In addition, the Group has also contracted with certain customers for granting them with the rights to claim for the Group’s delivery of additional units of its products (capped at a pre-determined ratio to the respective customer’s total quantities of products as purchased in a financial year) under certain pre-agreed circumstances which are irrelevant to the quality and functionality of the Group’s products (the “claims of additional units”). The sale transaction prices as allocated to the Group’s unsatisfied performance obligations in delivering additional units of its products as settlement for the aforesaid volume rebates and the claims of additional units have been deferred and accounted for as contract liabilities of the Group.

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Revenue recognised that was included in the contract liabilities balance at the beginning of the year/period	<u>11,773</u>	<u>12,206</u>	<u>15,343</u>	<u>15,343</u>	<u>14,783</u>

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33 CASH FLOW INFORMATION

(a) Reconciliation of profit before income tax to cash generated from operations

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(Unaudited)	
Profit before income tax	60,346	76,679	66,027	44,970	25,306
Adjustments for:					
– depreciation and amortisation	4,717	6,114	9,807	3,924	6,784
– amortisation of deferred income related to government grants	(833)	(833)	(833)	(416)	(330)
– net loss on disposal/write-off of property, plant and equipment	9	19	1	1	1
– net gains on disposal of investment properties	(2,436)	(5,111)	–	–	–
– net loss on disposal of financial assets at FVOCI	–	139	–	–	–
– net provisions for/(reversal of) impairment losses on financial assets	1,788	(672)	(533)	(464)	4,169
– share-based compensation expenses	–	–	17,800	2,824	7,097
– fair value gains on financial assets at fair value through profit or loss	–	–	–	–	(4)
– investment income on financial assets at fair value through profit or loss	–	–	(6,669)	–	(4,809)
– finance (income)/costs – net	(127)	(142)	10,360	693	9,053
– net foreign exchange (gains)/losses	–	–	(5,192)	1,766	26,864
	<u>63,464</u>	<u>76,193</u>	<u>90,768</u>	<u>53,298</u>	<u>74,131</u>
Change in working capital:					
– inventories	(1,426)	(12,267)	(10,083)	2,876	(6,867)
– prepayments and other receivables	(5,241)	(7,024)	1,725	4,288	(27,669)
– trade receivables	(15,870)	8,166	13,509	5,985	(12,529)
– trade and other payables	19,576	4,851	9,250	4,149	26,832
– contract liabilities	433	3,137	(560)	400	(357)
– deferred income	(100)	–	–	–	–
	<u>(1,426)</u>	<u>(12,267)</u>	<u>(10,083)</u>	<u>2,876</u>	<u>(6,867)</u>
Cash generated from operations	<u>60,836</u>	<u>73,056</u>	<u>104,609</u>	<u>70,996</u>	<u>53,541</u>

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(b) Changes in liabilities from financing activities

	Lease liabilities	Redemption liabilities	Other payable to related parties
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2019	106	–	26,727
Cash flows	(483)	–	–
New leases	722	–	–
Additions	–	–	16,139
Interest expense (<i>Note 11</i>)	24	–	–
At 31 December 2019	<u>369</u>	<u>–</u>	<u>42,866</u>
At 1 January 2020	369	–	42,866
Cash flows	(492)	–	–
New leases	232	–	–
Additions	–	–	2,888
Interest expense (<i>Note 11</i>)	7	–	–
At 31 December 2020	<u>116</u>	<u>–</u>	<u>45,754</u>
At 1 January 2021	116	–	45,754
Cash flows	(2,378)	–	(45,858)
New leases	8,220	–	–
Additions	–	–	104
Initial recognition of redemption liabilities (<i>Note 30</i>)	–	671,507	–
Interest expense (<i>Notes 11 and 30</i>)	229	11,316	–
Foreign exchange adjustment (<i>Note 30</i>)	–	(2,837)	–
At 31 December 2021	<u>6,187</u>	<u>679,986</u>	<u>–</u>
At 1 January 2022	6,187	679,986	–
Cash flows	(342)	–	–
New leases	268	–	–
Interest expense (<i>Notes 11 and 30</i>)	175	10,523	–
Foreign exchange adjustments (<i>Note 30</i>)	–	30,352	–
At 30 June 2022	<u>6,288</u>	<u>720,861</u>	<u>–</u>
(Unaudited)			
At 1 January 2021	116	–	45,754
Cash flows	(666)	–	(45,389)
New leases	3,636	–	–
Initial recognition of redemption liabilities (<i>Note 30</i>)	–	671,507	–
Interest expense (<i>Note 11</i>)	66	848	–
Foreign exchange adjustments (<i>Note 30</i>)	–	4,678	–
At 30 June 2021	<u>3,152</u>	<u>677,033</u>	<u>365</u>

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(c) Major non-cash transactions

	Year ended 31 December
	2021
	<i>RMB’000</i>
Issue of shares to Lepu Medical in exchange of its entire 100% equity interest in Shanghai Shape Memory Alloy (<i>Notes 1.2(v) and 26(a)</i>)	713,776

34 COMMITMENTS

The Group capital commitments as of 31 December 2019, 2020 and 2021 and 30 June 2022 are as follows:

	As at 31 December			As at 30 June
	2019	2020	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Property, plant and equipment	–	–	10,776	6,491

35 RELATED PARTY TRANSACTIONS

Parties are considered to be related if one party has the ability, directly or indirectly, to control the other party or exercise significant influence over the other party in making financial and operation decisions. Parties are also considered to be related if they are subject to common control.

The following is a summary of the significant transactions carried out between the Group and its related parties in the ordinary course of the Group’s business during the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2022, and balances arising from related party transactions as at 31 December 2019, 2020 and 2021 and 30 June 2022.

(a) Name and relationship with related parties

Names of the major related parties	Nature of relationship
Lepu Medical Technology (Beijing) Co., Ltd. (“Lepu Medical”), (樂普(北京)醫療器械股份有限公司)	Parent of the Company
Jiangsu Bolangsensi Medical Equipment Co., Ltd. (江蘇博朗森思醫療器械有限公司)	A subsidiary of Lepu Medical
Lepu (Shanghai) Medical Equipment Co., Ltd. (樂普(上海)醫療器械有限公司)	A subsidiary of Lepu Medical
Xi’an Qinming Medical Instrument Co., Ltd. (西安秦明醫學儀器有限公司)	A subsidiary of Lepu Medical
Anhui Magete Medical Technology Co., Ltd. (安徽省瑪格特醫療科技有限公司)	A subsidiary of Lepu Medical
Lepu International Holdings (Shenzhen) Co., Ltd. (樂普國際控股(深圳)有限公司)	A subsidiary of Lepu Medical
Hefei High-tech Cardiovascular Hospital (合肥高新心血管病醫院)	A subsidiary of Lepu Medical
Beijing Ruixiang Taikang Technology Co., Ltd. (北京瑞祥泰康科技有限公司)	A subsidiary of Lepu Medical
Beijing Target Medical Technologies Co., Ltd. (北京天地和協科技有限公司)	A subsidiary of Lepu Medical

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Names of the major related parties	Nature of relationship
Lepu Biopharma Co., Ltd. (樂普生物科技股份有限公司)	A joint venture of Lepu Medical
Lepu Hangjia (Shanghai) Business Incubator Management Co., Ltd. (樂普航嘉(上海)創業孵化器管理有限公司)	A subsidiary of joint venture of Lepu Medical
LepuCare (India) Vascular Solutions Pvt. Ltd.	A subsidiary of Lepu Medical
Beijing Lepu Precision Medical Technology Co., Ltd. (北京樂普精密醫療科技有限公司)	A subsidiary of Lepu Medical
Jiangsu Shangzhi Medical Instrument Co., Ltd. (江蘇上智醫療器械有限公司)	A subsidiary of Lepu Medical
Beijing Lepu Medical Technology Co., Ltd. (北京樂普診斷科技股份有限公司)	A subsidiary of Lepu Medical

(b) Transactions with related parties

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>	
Sale of goods					
– Lepu Medical	7,815	27,970	9,712	8,520	–
– Subsidiaries of Lepu Medical	2,397	3,069	6,384	2,951	2,560
	<u>10,212</u>	<u>31,039</u>	<u>16,096</u>	<u>11,471</u>	<u>2,560</u>
Rental income					
– Subsidiaries of Lepu Medical	608	519	471	211	215
– Joint venture of Lepu Medical	378	479	522	260	–
– Subsidiary of joint venture of Lepu Medical	1,256	939	1,041	517	–
	<u>2,242</u>	<u>1,937</u>	<u>2,034</u>	<u>988</u>	<u>215</u>
Commission income					
– Subsidiary of Lepu Medical (<i>Note 21(a)</i>)	–	–	–	–	734
	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>	<u>734</u>
Purchases of raw materials and services					
– Lepu Medical (<i>note</i>)	399	740	29,258	18,175	16,111
– Subsidiaries of Lepu Medical	417	330	3,036	874	622
	<u>816</u>	<u>1,070</u>	<u>32,294</u>	<u>19,049</u>	<u>16,733</u>

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	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>	
Addition of right-of-use assets (leased buildings)					
– Lepu Medical	–	–	2,901	–	–
Payment of lease liabilities					
– Lepu Medical	–	–	596	–	–

Note: Up to the date of this Historical Financial Information, the key research and development work of certain heart valve products were registered under the name of, and conducted by, Lepu Medical. In May 2021, the Group entered into a framework agreement with Lepu Medical and entrusted Lepu Medical to development of certain heart valve products under the Group’s instruction due to regulatory restrictions and commercial reasons (the “Entrusted Development Services”). For the year ended 31 December 2021 and the six months ended 30 June 2021 and 2022, the service fee paid/payable to Lepu Medical in respect of these Entrusted Development Services amounted to approximately RMB28,715,000, Nil and RMB16,111,000, respectively.

On top of the transactions with related parties as disclosed above, the Group also has the following transactions with related parties as disclosed in other notes:

- (i) the Group has issued certain of its shares to Lepu Medical for the 100% equity interest in Shanghai Shape Memory Alloy (Note 26(a));
- (ii) the Group has certain deemed contributions from or distributions to Lepu Medical during the Track Record Period (Notes 27(a) and 28(a)); and
- (iii) the Group has purchased certain COVID-19 antigen testing related products with carrying amounts of approximately RMB22,681,000 from a subsidiary of Lepu Medical and sold them to end customers on behalf of that subsidiary of Lepu Medical under a distribution arrangement as described in (Note 21(a)).

(c) Balances with related parties

	As at 31 December			As at
	2019	2020	2021	30 June
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Receivables from related parties				
Trade receivables				
– Lepu Medical	12,246	–	–	–
– Subsidiaries of Lepu Medical	6,704	10,078	270	1,706
	18,950	10,078	270	1,706

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	As at 31 December			As at
	2019	2020	2021	30 June
	RMB'000	RMB'000	RMB'000	2022
				RMB'000
Other receivables				
– Lepu Medical	–	68	–	–
– Subsidiaries of Lepu Medical	4,731	4,627	–	–
– Joint venture of Lepu Medical	480	161	–	–
– Subsidiary of joint venture of Lepu Medical	1,577	3,178	–	–
	<u>6,788</u>	<u>8,034</u>	<u>–</u>	<u>–</u>
Prepayments				
– Subsidiaries of Lepu Medical	–	303	58	1,234
	<u>–</u>	<u>303</u>	<u>58</u>	<u>1,234</u>
Payables to related parties				
Trade payables				
– Lepu Medical	1,243	2,019	–	147
	<u>1,243</u>	<u>2,019</u>	<u>–</u>	<u>147</u>
Other payables				
– Lepu Medical	42,866	45,750	–	–
– Subsidiaries of Lepu Medical	–	4	–	25,629
	<u>42,866</u>	<u>45,754</u>	<u>–</u>	<u>25,629</u>
Lease liabilities				
– Lepu Medical	–	–	2,157	2,218
	<u>–</u>	<u>–</u>	<u>2,157</u>	<u>2,218</u>

All the trade receivables/payable, lease liabilities and prepayment balances with related parties are trade in nature. As at 30 June 2022, other payable to a subsidiary of Lepu Medical represented the balances as arisen from the distribution arrangement as detailed in Note 21(a), which is also trade in nature. All other receivables from related parties and other payable to related parties (excluding aforementioned balances) are non-trade in nature, and these balances have been fully settled up to the date of this Historical Financial Information.

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(d) Key management personnel compensation

Key management includes directors (executive and non-executive) and respective department heads. The compensation paid or payable to key management for employee services is shown below:

	Year ended 31 December			Six months ended 30 June	
	2019	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
				(Unaudited)	
Salaries, other short-term employee benefits and share-based payment					
– Directors and supervisors	1,982	2,004	8,147	1,850	4,410
– Other key management	749	881	4,388	1,131	1,400
	<u>2,731</u>	<u>2,885</u>	<u>12,535</u>	<u>2,981</u>	<u>5,810</u>

(e) Directors’ emoluments

The remuneration of every director and the chief executive officer for the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022, were set out below:

	Wages, salaries and bonuses	Social security costs and housing benefits	Total
	RMB'000	RMB'000	RMB'000
For the year ended 31 December 2019			
Executive directors			
Ms. Chen Juan (note a)	577	100	677
Ms. Zhang Yuxin (note b)	605	127	732
Non-executive directors			
Mr. Fu Shan (note e)	–	–	–
Mr. Zheng Guorui (note e)	–	–	–
Mr. Leung Waifung (note c)	–	–	–
Mr. Zheng Yufeng (note e)	–	–	–
Mr. Liu Daozhi (note e)	–	–	–
	<u>1,182</u>	<u>227</u>	<u>1,409</u>

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	<u>Wages, salaries and bonuses</u>	<u>Social security costs and housing benefits</u>	<u>Total</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
For the year ended 31 December 2020			
Executive directors			
Ms. Chen Juan (<i>note a</i>)	620	64	684
Ms. Zhang Yuxin (<i>note b</i>)	660	111	771
Non-executive directors			
Mr. Fu Shan (<i>note e</i>)	–	–	–
Mr. Zheng Guorui (<i>note e</i>)	–	–	–
Mr. Leung Waifung (<i>note c</i>)	–	–	–
Mr. Zheng Yufeng (<i>note e</i>)	–	–	–
Mr. Liu Daozhi (<i>note e</i>)	–	–	–
	<u>1,280</u>	<u>175</u>	<u>1,455</u>

	<u>Wages, salaries and bonuses</u>	<u>Social security costs and housing benefits</u>	<u>Share-based payments</u>	<u>Total</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
For the year ended 31 December 2021				
Executive directors				
Ms. Chen Juan (<i>note a</i>)	1,411	131	2,276	3,818
Ms. Zhang Yuxin (<i>note b</i>)	949	131	1,973	3,053
Non-executive directors				
Mr. Fu Shan (<i>note e</i>)	–	–	–	–
Mr. Zheng Guorui (<i>note e</i>)	–	–	–	–
Mr. Leung Waifung (<i>note c</i>)	133	–	–	133
Mr. Zheng Yufeng (<i>note e</i>)	117	–	–	117
Mr. Liu Daozhi (<i>note e</i>)	117	–	–	117
Ms. Chan Ka Lai Vanessa (<i>note d</i>)	67	–	–	67
	<u>2,794</u>	<u>262</u>	<u>4,249</u>	<u>7,305</u>

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	Wages, salaries and bonuses	Social security costs and housing benefits	Share-based payments	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
For the six months ended 30 June 2021 (Unaudited)				
Executive directors				
Ms. Chen Juan (<i>note a</i>)	810	66	382	1,258
Ms. Zhang Yuxin (<i>note b</i>)	570	66	331	967
Non-executive directors				
Mr. Fu Shan (<i>note e</i>)	–	–	–	–
Mr. Zheng Guorui (<i>note e</i>)	–	–	–	–
Mr. Leung Waifung (<i>note c</i>)	100	–	–	100
Mr. Zheng Yufeng (<i>note e</i>)	17	–	–	17
Mr. Liu Daozhi (<i>note e</i>)	17	–	–	17
	<u>1,514</u>	<u>132</u>	<u>713</u>	<u>2,359</u>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
For the six months ended 30 June 2022				
Executive directors				
Ms. Chen Juan (<i>note a</i>)	796	64	1,247	2,107
Ms. Zhang Yuxin (<i>note b</i>)	611	66	1,080	1,757
Non-executive directors				
Mr. Fu Shan (<i>note e</i>)	–	–	–	–
Mr. Zheng Guorui (<i>note e</i>)	–	–	–	–
Mr. Zheng Yufeng (<i>note e</i>)	100	–	–	100
Mr. Liu Daozhi (<i>note e</i>)	100	–	–	100
Ms. Chan Ka Lai Vanessa (<i>note d</i>)	100	–	–	100
	<u>1,707</u>	<u>130</u>	<u>2,327</u>	<u>4,164</u>

Notes:

- (a) Ms. Chen Juan was appointed as the chief executive officer and director of the Company on 29 January 2021. The amounts presented above represent the wages, salaries and bonuses and other benefits paid/payable to her during the Track Record Period.
- (b) Ms. Zhang Yuxin was appointed as a director of the Company on 29 January 2021. The amounts presented above represent the wages, salaries and bonuses and other benefits paid/payable to her during the Track Record Period.
- (c) Mr. Leung Waifung was appointed as a non-executive director of the Company on 29 January 2021 and resigned on 2 September 2021.
- (d) Ms. Chan Ka Lai Vanessa was appointed as a non-executive director of the Company on 2 September 2021.
- (e) Mr. Fu Shan, Mr. Zheng Guorui, Mr. Zheng Yufeng and Mr. Liu Daozhi were appointed as non-executive directors of the Company on 9 June 2021.

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ACCOUNTANT’S REPORT

(f) Directors’ retirement benefits

There were no retirement benefits paid/payable to any director during the Track Record Period.

(g) Directors’ termination benefits

There were no termination benefits paid/payable to any director during the Track Record Period.

(h) Consideration provided to or receivable by third parties for making available directors’ Services

No consideration was provided to or receivable by third parties for making available directors’ services during the Track Record Period.

(i) Information about loans, quasi-loans, controlled corporate bodies, connected entities and other dealings in favor of directors

No loans, quasi-loans, controlled corporate bodies, connected entities and other dealings were entered into between the Group and the directors in favor of the directors, during the Track Record Period.

(j) Directors’ material interests in transactions, arrangements or contracts

No significant transactions, arrangements and contracts in relation to the Group’s business to which the Company was a party and in which a director of the Company had a material interest, whether directly or indirectly, subsisted at the end of the years/period or at any time during the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2021 and 2022.

36 CONTINGENCIES

The Group did not have any material contingent liabilities as of 31 December 2019, 2020 and 2021 and 30 June 2022.

37 DIVIDEND

Pursuant to the resolution of the shareholders’ meeting of Shanghai Shape Memory Alloy held on 20 January 2021, it is resolved that Shanghai Shape Memory Alloy distributed dividend of RMB320,000,000 to Lepu Medical. No other dividend has been declared by the Company or the companies now comprising the Group during each of the years ended 31 December 2019, 2020 and 2021 and the six months ended 30 June 2022.

38 EVENTS OCCURRING AFTER THE REPORTING PERIOD

[There were no significant events after the end of the Track Record Period that require additional disclosures or adjustments.]

III. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared for the Company or any of the companies now comprising the Group in respect of any period subsequent to 30 June 2022 and up to the date of this report. Save as disclosed in Note 37 and elsewhere in the Historical Financial Information, no other dividend or distribution have been declared, made or paid by the Company or any of the companies now comprising the Group in respect of any period subsequent to 30 June 2022.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

APPENDIX III

PROPERTY VALUATION REPORT

The following is the text of a letter and valuation certificate prepared for the purpose of incorporation in this document received from Jones Lang LaSalle Corporate Appraisal and Advisory Limited, an independent valuer, in connection with its valuation as at 31 July 2022 of the properties held by the Group.



仲量聯行

Jones Lang LaSalle Corporate Appraisal and Advisory Limited
7th Floor, One Taikoo Place
979 King's Road, Hong Kong
tel +852 2846 5000 fax +852 2169 6001
Company Licence No.: C-030171

[Date]

The Board of Directors

LEPU ScienTech Medical Technology (Shanghai) Co., Ltd.*

1/F, 5/F

Building 41

No. 258, Xinzhuan Road

Songjiang District

Shanghai

The People's Republic of China

Dear Sirs,

In accordance with your instructions to value the property interests held by LEPU ScienTech Medical Technology (Shanghai) Co., Ltd.* (the “Company”) and its subsidiaries (hereinafter together referred to as the “Group”) in the People's Republic of China (the “PRC”), we confirm that we have carried out inspections, made relevant enquiries and searches and obtained such further information as we consider necessary for the purpose of providing you with our opinion of the market values of the property interests as at 31 July 2022 (the “valuation date”).

Our valuation is carried out on a market value basis. Market value is defined as “the estimated amount for which an asset or liability should exchange on the valuation date between a willing buyer and a willing seller in an arm's-length transaction, after proper marketing and where the parties had each acted knowledgeably, prudently and without compulsion.”

We have valued the property interest in Group I which is held for investment by the Group and property interests in Group II which are held for self-occupation by the Group by the income approach by taking into account the rental income of the properties derived from the existing leases and/or achievable in the existing market with due allowance for the reversionary income potential of the leases, which have been then capitalized to determine the market value at an appropriate capitalization rate.

APPENDIX III

PROPERTY VALUATION REPORT

Our valuation has been made on the assumption that the seller sells the property interests in the market without the benefit of a deferred term contract, leaseback, joint venture, management agreement or any similar arrangement, which could serve to affect the values of the property interests.

No allowance has been made in our report for any charge, mortgage or amount owing on any of the property interests valued nor for any expense or taxation which may be incurred in effecting a sale. Unless otherwise stated, it is assumed that the properties are free from encumbrances, restrictions and outgoings of an onerous nature, which could affect their values.

In valuing the property interests, we have complied with all requirements contained in Chapter 5 and Practice Note 12 of the Rules Governing the Listing of Securities issued by the Stock Exchange of Hong Kong Limited; the RICS Valuation — Global Standards published by the Royal Institution of Chartered Surveyors; the HKIS Valuation Standards published by the Hong Kong Institute of Surveyors, and the International Valuation Standards issued by the International Valuation Standards Council.

We have relied to a very considerable extent on the information given by the Group and have accepted advice given to us on such matters as tenure, planning approvals, statutory notices, easements, particulars of occupancy, lettings, and all other relevant matters.

We have been shown copies of Real Estate Title Certificates relating to the property interests and have made relevant enquiries. Where possible, we have examined the original documents to verify the existing title to the property interests in the PRC and any material encumbrance that might be attached to the property interests or any tenancy amendment. We have relied considerably on the advice given by the Company’s PRC legal advisors — Haiwen & Partners, concerning the validity of the property interests in the PRC.

We have not carried out detailed measurements to verify the correctness of the areas in respect of the properties but have assumed that the areas shown on the title documents and official site plans handed to us are correct. All documents and contracts have been used as reference only and all dimensions, measurements and areas are approximations. No on-site measurement has been taken.

We have inspected the exterior and, where possible, the interior of the properties. However, we have not carried out investigation to determine the suitability of the ground conditions and services for any development thereon. Our valuation has been prepared on the assumption that these aspects are satisfactory. Moreover, no structural survey has been made, but in the course of our inspection, we did not note any serious defect. We are not, however, able to report whether the properties are free of rot, infestation or any other structural defect. No tests were carried out on any of the services.

Inspection of the properties was carried out in February 2021 and subsequent re-inspection of the properties was carried out in October 2022 by Ms. Peiling Cai who has obtained a master degree with subjects in Real Estate and has 3 years’ experience in the valuation of properties in the PRC.

APPENDIX III

PROPERTY VALUATION REPORT

We have had no reason to doubt the truth and accuracy of the information provided to us by the Group. We have also sought confirmation from the Group that no material factors have been omitted from the information supplied. We consider that we have been provided with sufficient information to arrive an informed view, and we have no reason to suspect that any material information has been withheld.

We are instructed to provide our opinion of value as per the valuation date only. It is based on economic, market and other conditions as they exist on, and information made available to us as of, the valuation date and we assume no obligation to update or otherwise revise these materials for events in the time since then. In particular, the outbreak of the Novel Coronavirus (COVID-19) since declared Global Pandemic on 11 March 2020 has caused much disruption to economic activities around the world. As of the report date, China’s economy has recovered and most business activities have been back to normal. We also note that market activity and market sentiment in this particular market sector remain stable. However, we remain cautious due to uncertainty for the pace of global economic recovery in the midst of the outbreak which may have future impact on the real estate market. Therefore, we recommend that you keep the valuation of these properties under frequent review.

Unless otherwise stated, all monetary figures stated in this report are in Renminbi (RMB).

Our summary of values and valuation certificates are attached below for your attention.

Yours faithfully,
For and on behalf of
Jones Lang LaSalle Corporate Appraisal and Advisory Limited
Eddie T. W. Yiu
MRICS MHKIS RPS (GP)
Senior Director

Note: Eddie T.W. Yiu is a Chartered Surveyor who has 28 years’ experience in the valuation of properties in Hong Kong and the PRC as well as relevant experience in the Asia-Pacific region.

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SUMMARY OF VALUES

Abbreviation:

Group I: Property held for investment by the Group in the PRC
 Group II: Properties held for self-occupation by the Group in the PRC
 “—”: Not applicable

No.	Property	Market value in	Market value in	The total market
		existing state as at	existing state as at	value in existing
		31 July 2022	31 July 2022	state as at
		RMB	RMB	31 July 2022
		Group I:	Group II:	RMB
1.	Building No. 41 No. 258 Xinzhuan Road Caohejing Hi-Tech Park Xinqiao Town Songjiang District Shanghai The PRC (上海•漕河涇新興產業園)	47,300,000	48,400,000	95,700,000
2.	Unit 701 and 702 of Building No. 2 No. 518 Xinzhuan Road Caohejing Development Zone Xinqiao Town Songjiang District Shanghai The PRC (上海•漕河涇開發區)	—	13,100,000	13,100,000
Total				108,800,000

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VALUATION CERTIFICATE

No.	Property	Description and tenure	Particulars of occupancy	Market value in existing state as at 31 July 2022 <i>RMB</i>
1.	Building No. 41, No. 258 Xinzhuan Road Caohejing Hi-Tech Park Xinqiao Town Songjiang District Shanghai The PRC (上海•漕河涇新興產業園)	<p>Caohejing Hi-Tech Park is located at No. 258 Xinzhuan Road. The locality is a well-developed industrial area served by adequate facilities with mature public infrastructures.</p> <p>Caohejing Hi-Tech Park occupies a parcel of land with a site area of approximately 97,847.6 sq.m. (including the land use rights of the property) which had been developed into a business park. The property comprises a 5-storey industrial building completed in 2013 and was partially held for investment and partially held and occupied by the Group as at the valuation date.</p> <p>The property has a gross floor area of approximately 9,048.65 sq.m. which is an industrial building for production, laboratory and office uses. Each floor of the building comprises two units.</p> <p>The land use rights of the property have been granted for a term expiring on 30 May 2060 for industrial use.</p>	<p>As at the valuation date, except for Unit 302 of the property with a gross floor area of approximately 950.05 sq.m. which was rented to a connected party for production, laboratory and office uses, and Level 1 and Level 5 of the property were occupied by the Group for production, laboratory and office purposes, the remaining portions of the property were vacant.</p>	95,700,000

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Notes:

- Pursuant to a Real Estate Title Certificate — Hu Fang Di Song Zi (2014) Di No. 021308, the property with a gross floor area of approximately 9,048.65 sq.m is owned by Shanghai Shape Memory Alloy Co., Ltd.* (上海形状记忆合金材料有限公司, “Shanghai Shape Memory Alloy,” a wholly-owned subsidiary of the Company) and the corresponding land use rights have been granted to Shanghai Shape Memory Alloy for a term expiring on 30 May 2060 for industrial use.

- According to the Real Estate Title Certificate, the gross floor area of the property is set out as below:

<u>Group</u>	<u>Unit</u>	<u>Usage</u>	<u>Gross Floor Area</u> <i>(sq.m.)</i>
Group I — Property held for investment by the Group			
	201	Factory	872.11
	202	Factory	950.05
	301	Factory	872.11
	302	Factory	950.05
	401	Factory	872.11
		Sub-total	<u>4,516.43</u>
Group II — Properties held for self-occupation by the Group			
	101	Factory	863.32
	102	Factory	896.69
	402	Factory	950.05
	501	Factory	872.11
	502	Factory	950.05
		Sub-total	<u>4,532.22</u>
		Total	<u><u>9,048.65</u></u>

- As at the valuation date, pursuant to a Tenancy Agreement entered into between Shanghai Shape Memory Alloy and a connected party, Unit 302 of the property with a gross floor area of approximately 950.05 sq.m. was leased out for production, laboratory and office purposes with the expiry date on 31 July 2024. The annual passing rental as at the valuation date was RMB532,000 exclusive of management fees, water and electricity charges.
- For the purpose of this report, Level 2, Unit 301, Unit 302 and Unit 401 of the property are classified into the group as “Group I — Property held for investment in the PRC” according to the purpose for which it is held.
- Our valuation has been made on the following basis and analysis:
 - In undertaking our valuation, we have considered the actual rent in the existing tenancy agreement and also compared with similar developments which are located in the similar areas as the industrial buildings of the subject property, for the calculation of market rent in considering the reversionary rental income after the expiry of the existing lease for occupied area, and the rental income of vacant area;
 - The unit rent of these comparable industrial units is from RMB1.8 to RMB2.0 per sq.m. per day; and
 - Based on our research on industrial market in the surrounding area of the property, the stabilized market yield ranged from 4% to 5% as at the valuation date. Considering the location, risks and characteristics of the property, we have applied a market yield of 4.75% for the property as the capitalization rate in the valuation.

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6. We have been provided with a legal opinion regarding the property interests by the Company’s PRC legal advisors, which contains, inter alia, the following:

Shanghai Shape Memory Alloy is legally and validly in possession of the property. Shanghai Shape Memory Alloy has the rights to occupy, use, lease, transfer or otherwise dispose of the property.

7. For the purpose of this report, the property is classified into the following groups according to the purpose for which it is held, we are of the opinion that the market value of each group as at the valuation date in its existing state is set out as below:

Group	Market value in existing state as at the valuation date
	<i>(RMB)</i>
Group I — Property held for investment by the Group	47,300,000
Group II — Properties held for self-occupation by the Group	48,400,000
Total:	95,700,000

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VALUATION CERTIFICATE

No.	Property	Description and tenure	Particulars of occupancy	Market value in existing state as at 31 July 2022 <i>RMB</i>
2.	Unit 701 and 702 of Building No. 2, No. 518 Xinzhuan Road Caohejing Development Zone Xinqiao Town Songjiang District Shanghai The PRC (上海漕河泾開發區)	<p>Caohejing Development Zone is located at No. 518 Xinzhuan Road. The locality is a well-developed industrial area served by adequate facilities with mature public infrastructures.</p> <p>Caohejing Development Zone occupies a parcel of land with a site area of approximately 56,127 sq.m. (including the land use rights of the property) which had been developed into a business park. The property comprises two units on Level 7 of an 8-storey industrial building completed in 2009 and was held for self-occupation by the Group as at the valuation date.</p> <p>The property has a gross floor area of approximately 1,247.54 sq.m. which are industrial units for production, laboratory and office uses.</p> <p>The land use rights of the property have been granted for a term expiring on 2 November 2056 for industrial use.</p>	As at the valuation date, the property was vacant.	13,100,000

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Notes:

1. Pursuant to a Real Estate Title Certificate — Hu Fang Di Song Zi (2010) Di No. 005662, the property with a gross floor area of approximately 1,247.54 sq.m is owned by Shanghai Shape Memory Alloy and the corresponding land use rights have been granted to Shanghai Shape Memory Alloy for a term expiring on 2 November 2056 for industrial use.
2. According to the Real Estate Title Certificate, the gross floor area of the property is set out as below:

<u>Group</u>	<u>Unit</u>	<u>Usage</u>	<u>Gross Floor Area</u> (sq.m.)
Group II — Properties held for self-occupation by the Group	701	Factory	531.00
	702	Factory	716.54
		Total	1,247.54

3. Our valuation has been made on the following basis and analysis:
 - a. In undertaking our valuation, we have compared with similar developments which are located in the similar areas as the industrial buildings of the subject property, for the calculation of market rent of the property;
 - b. The unit rent of these comparable industrial units is from RMB1.8 to RMB2.0 per sq.m. per day; and
 - c. Based on our research on industrial market in the surrounding area of the property, the stabilized market yield ranged from 4% to 5% as at the valuation date. Considering the location, risks and characteristics of the property, we have applied a market yield of 4.75% for the property as the capitalization rate in the valuation.
4. We have been provided with a legal opinion regarding the property interests by the Company’s PRC legal advisors, which contains, inter alia, the following:

Shanghai Shape Memory Alloy is legally and validly in possession of the property. Shanghai Shape Memory Alloy has the rights to occupy, use, lease, transfer or otherwise dispose of the property.
5. For the purpose of this report, the property is classified into the group as “Group II — Properties held for self-occupation by the Group in the PRC” according to the purpose for which it is held.

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

This appendix sets out a summary of the principal provisions of the Articles of Association of the Company and subsequent amendments, which will take effect from the date of [REDACTED] of the H Shares on the Stock Exchange. The main purpose of this appendix is to give potential [REDACTED] an overview of the Articles of Association, and it may not contain all the information that is important for potential [REDACTED]. Copies of the full Chinese text of the Articles of Association are available on display on the websites of the Stock Exchange and the Company as mentioned in Appendix VIII – Documents Delivered to the Registrar of Companies and Available on Display to this document.

SHARES

Shares and Registered Capital

The Company shall always maintain ordinary shares.

The Company shall always maintain ordinary shares. The Company may create other class of shares according to its requirements and upon approval of the approving authorities authorized by the State Council.

The issuance of shares by the Company shall adhere to the principles of openness, fairness and impartialness, and each share in the same category shall carry the same rights. For shares issued at the same time and within the same class, the conditions and price per share must be the same; for the shares subscribed by an entity or an individual, the price per share paid must be the same.

Subject to the approval by the securities regulatory authority of the State Council, the Company may issue shares to domestic investors and overseas investors.

With the plan for issuing overseas-listed foreign shares and domestic shares by the Company approved by the securities regulatory authority of the State Council, the Board of Directors of the Company may arrange for the implementation of such plan by means of separate issuances. The Company may implement its plan for separate issuances of overseas-listed foreign shares and Domestic Shares in accordance with the preceding paragraph. within 15 months from the date of approval by the securities regulatory authority of the State Council.

Where the Company issues overseas-listed foreign shares and Domestic Shares separately within the total number of shares specified in the issuance plan, every such issue shall be fully subscribed for in one time. Where it is impossible for every such issue to be fully subscribed for in one time due to special circumstances, the shares may be issued in several stages, subject to the approval of the securities regulatory authority of the State Council.

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

Share Increase and Decrease

The Company may, in accordance with its needs of business and development, approve the increase in its capital pursuant to relevant provisions of the Articles of Association.

The Company may increase its capital by the following ways:

- (I) offering new shares to non-specific investors;
- (II) placing new shares to existing shareholders;
- (III) distributing new shares to existing shareholders;
- (IV) converting funds in the capital reserve into share capital; and
- (V) other ways as approved by laws and regulations and the securities regulatory authority of the State Council.

The Company's increase of capital by issuing new shares shall be conducted in accordance with the procedures provided in relevant national laws and regulations, after being approved according to the Articles of Association.

In accordance with the provisions of the Articles of Association, the Company may reduce its registered capital.

Within 10 days of the date on which the resolution on reducing registered capital is made, the creditors shall be notified by the Company and a public announcement shall be made in the press within 30 days. The creditors may, within 30 days as of the receipt of the notice or within 45 days as of the issuance of the public announcement if they fail to receive a notice, require the Company to clear off its debts or to provide corresponding guarantees.

The reduced registered capital of the Company may not be less than the statutory minimum.

Repurchase of Shares

The Company may, in accordance with the procedures under the Articles of association and with the approval by the relevant competent authorities of the state, repurchase its issued shares in the following circumstances:

- (I) deregistration of shares for reducing the Company's capital;
- (II) merger with other company which holds the shares of the Company;
- (III) the shares are to be used for employee share ownership plans or equity incentives;

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

- (IV) a shareholder who objects to the resolution on the Company's merger or division passed by the shareholders' general meeting requests that the Company buy back his/her/its shares;
- (V) the shares are to be used to convert corporate bonds issued by the Company that can be converted to shares; and
- (VI) it is necessary for the Company to maintain corporate value and shareholders' interests;

A resolution of a shareholders' general meeting is required for the repurchase of shares by the Company under either of the circumstances stipulated in item (I) or item (II) above; for the Company's repurchase of shares under any of the circumstances stipulated in item (III), item (V) or item (VI) above, a resolution of a meeting of the Board of Directors shall be made by more than two-thirds of directors attending the meeting according to the provisions of the Articles of Association or as authorized by the shareholders' general meeting.

The shares acquired by the Company under the circumstance stipulated in item (I) in accordance with Article 27 of the Articles of Association shall be deregistered within 10 days from the date of acquisition of shares; the shares shall be transferred or deregistered within six months if the repurchase of shares is made under the circumstances stipulated in either item (II) or item (IV); and the shares in the Company held in total by the Company after the repurchase of shares under any of the circumstances stipulated in item (III), item (V) or item (VI) shall not exceed 10% of the Company's total outstanding shares, and shall be transferred or deregistered within three years. Where the laws, regulations, or the securities regulatory authority at the place where shares of the Company are listed have other provisions on the relevant matters related to the aforesaid share repurchase, such provisions shall prevail.

With the approval of relevant competent authorities of the state for repurchasing its shares, the Company may conduct the repurchase in one of the following manners:

- (I) to make a repurchase offer to all shareholders in the same proportion;
- (II) to repurchase its own shares through public transaction on a stock exchange;
- (III) to repurchase shares under an off-market agreement; and
- (IV) other method approved by the securities regulatory authority of the State Council.

To the extent that the Company has the right to repurchase redeemable shares:

- (I) the price shall not exceed a certain maximum price limit unless repurchased by market or by means of tender; and
- (II) If repurchased by means of tender, the proposal on tender shall be made to all shareholders equally.

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

Transfer of Shares

Unless otherwise specified by the laws, regulations and the rules of the securities regulatory authority at the place where shares of the Company are listed and Hong Kong Stock Exchange, the shares of the Company may be transferred freely without any lien attached. Transfer of overseas-listed foreign shares listed in Hong Kong shall be registered with the local share registrar in Hong Kong as delegated by the Company.

The Company shall not accept its own shares as the subject matter of a mortgage.

Financial Assistance for the Acquisition of the Shares of the Company

The Company or its subsidiaries shall not, at any time and in any manner, provide any financial assistance to purchasers or prospective purchasers of the shares of the Company. The aforesaid purchasers of shares of the Company shall include persons who directly or indirectly assume relevant obligations as a result of purchasing shares of the Company.

The Company or its subsidiaries shall not, at any time and in any manner, provide any financial assistance to the above obligators in order to reduce or discharge their obligations.

The aforesaid restriction shall not apply to the following circumstances:

- (I) where the financial assistance given by the Company is genuinely for the benefits of the Company and the main purpose of such financial assistance is not to purchase shares of the Company, or the financial assistance is an incidental part of a general plan of the Company;
- (II) distribution of the Company's properties as dividends pursuant to the law;
- (III) distribution of dividends in the form of shares;
- (IV) reduction of registered capital, buy-back of shares and adjustment of shareholding structure etc., in accordance with the Articles of Association;
- (V) provision of a loan by the Company within its business scope and in the ordinary course of its business (provided that it does not lead to a reduction in the net assets of the Company or that if it constitutes a reduction, the financial assistance was paid out of the Company's distributable profits); and
- (VI) provision of money by the Company for an employee share ownership plan (provided that it does not lead to a reduction in the net assets of the Company or that if it constitutes a reduction, the financial assistance was paid out of the Company's distributable profits).

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

SHAREHOLDERS AND SHAREHOLDERS' GENERAL MEETING

Shareholders

The Company's shareholders are persons who lawfully hold shares of the Company and have their names registered in the register of shareholders. Shareholders shall enjoy the rights and undertake obligations in accordance with the class of and number of shares held by them. Shareholders holding the same class of shares shall enjoy the same rights and bear the same obligations.

The holders of ordinary shares of the Company shall be entitled to the following rights:

- (I) receiving dividends and other kinds of profit distributions as determined by the number of shares held by them;
- (II) requiring, convening, chairing, attending or appointing a proxy to attend a shareholders' general meeting pursuant to the law and exercising the corresponding voting rights;
- (III) supervising the Company's business operations, proposing recommendations or raising questions;
- (IV) transferring, bestowing or pledging shares of the Company held by them in accordance with the laws, regulations and the Articles of Association;
- (V) obtaining related information in accordance with provisions prescribed by laws and the Articles of Association, including:
 - 1. obtaining the copies of the Article of Association after paying relevant costs;
 - 2. inspecting and photocopying, after paying a reasonable fee, the following documents:
 - (1) the share register, including information about their holdings of the shares;
 - (2) personal information on the directors, supervisors and senior management of the Company, including:
 - (a) current and previous names and aliases;
 - (b) main address (domicile);
 - (c) nationality;

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

- (d) full-time and all part-time occupations and titles; and
 - (e) identification documents and their numbers.
- (3) state of the share capital of the Company;
 - (4) reports on the aggregate par value, number of shares, and highest and lowest prices of each class of shares in relation to any repurchase by the Company of its own shares since the last accounting year, as well as all the expenses paid by the Company in relation to such repurchases;
 - (5) for shareholders only, copies of minutes of shareholders' general meetings;
 - (6) copy of the latest annual report filed with the market regulation authority or other competent authorities of China if applicable;
 - (7) special resolutions;
 - (8) bond stub of the Company;
 - (9) resolutions of Board meetings;
 - (10) resolutions of meetings of the board of supervisors;
 - (11) the latest audited financial statements, report of the Board of Directors, auditors' report and report of the board of supervisors.

The Company shall keep at its Hong Kong address the documents above other than item (2) for free reference by the public and holders of overseas-listed foreign shares.

- (VI) upon termination or liquidation of the Company, participating in the distribution of the Company's residual assets based on their shareholding;
- (VII) a shareholder who objects to the resolution on merger or division of the Company passed by a shareholders' general meeting may request the Company to acquire his/her/its shares; and
- (VIII) other rights conferred in accordance with the laws and regulations and our Articles of Association.

The Company shall not exercise any right to freeze or otherwise damage the rights attached to any shares directly or indirectly held by any person only on the ground that the said person fails to disclose his/her equity to the Company.

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

Where the contents of a resolution of shareholders' general meeting or the Board of Directors of the Company violate any laws or regulations, the resolution shall be invalid. Where the convening procedures or voting method of a shareholders' general meeting or a Board meeting violate any laws, administrative regulations or the Articles of Association, or the contents of a resolution violate the Articles of Association, a shareholder shall have the right to apply to the people's court for revocation within 60 days from passing of such resolution.

Where the directors or senior management violate the provisions of laws, regulations or the Articles of Association during the performance of their duties and cause losses to the Company, the shareholders severally or jointly holding 1% or more of the Company's shares for a period of 180 consecutive days or longer are entitled to request the board of supervisors to file a lawsuit with the people's court in writing; where the board of supervisors violates the provisions of laws, regulations or the Articles of Association in the performance of their duties and causes losses to the Company, shareholders may request the Board of Directors to file a lawsuit with the people's court in writing.

Upon receipt of shareholders' written request stipulated in the preceding paragraph, if the board of supervisors or the Board of Directors refuses to file a lawsuit or does not file a lawsuit within 30 days from receipt of such request, or in the event of emergency where the interest of the Company will suffer irreparable damages if lawsuit is not filed immediately, the shareholders severally or jointly holding 1% or more of the Company's shares for a period of 180 consecutive days or longer shall have the right to file a lawsuit directly with the people's court in their own name for the interest of the Company.

Where other persons infringe legitimate rights and interests of the Company and cause losses to the Company, the shareholders severally or jointly holding 1% or more of the Company's shares for a period of 180 consecutive days or longer may file a lawsuit with the people's court pursuant to the provisions of the preceding two paragraphs.

Where any director, supervisor or senior management violates the provisions of laws, administrative regulations or the Articles of Association and causes damages to shareholders, the shareholders may file a lawsuit with the people's court.

The holders of the Company's ordinary shares shall undertake the following obligations:

- (I) complying with laws, administrative regulations and the Articles of Association;
- (II) making payment for shares subscribed for according to the quantity of shares subscribed for and the manners of subscription;
- (III) not withdrawing the investment, except for circumstances stipulated by laws and regulations;

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

- (IV) not abusing shareholder's rights to harm the interests of the Company or other shareholders; not abusing the independent legal person status of the Company and shareholders' limited liability to harm the interests of the Company's creditors; shareholders of the Company who abuse shareholders' rights and cause damages to the Company or other shareholders shall be liable for compensation pursuant to the law.

- (V) Shareholders of the Company who abuse the independent legal person status of the Company and shareholders' limited liability to evade debts and severely infringe upon interests of the Company's creditors shall assume joint and several liabilities for the Company's debts.

- (VI) other obligations for the shareholders prescribed by laws, administrative regulations and the requirements of the Articles of Association.

Shareholders shall not be liable for any further contribution to share capital other than on the conditions agreed to by the subscribers of the relevant shares at the time of subscription.

General Rules for the Shareholder's General Meeting

The shareholders' general meeting is the organ of authority of the Company, and shall exercise following functions and powers pursuant to the law:

- (I) to decide on the Company's operational objectives and investment plans;

- (II) to elect and remove directors, and to determine the remuneration of the relevant directors;

- (III) to elect and replace the supervisors who are shareholder representatives and to decide on the matters relating to the remuneration of supervisors;

- (IV) to review and approve the reports of the Board of Directors;

- (V) to review and approve the reports of the board of supervisors;

- (VI) to deliberate and approve the Company's annual financial budget plan and final account plan;

- (VII) to deliberate and approve the Company's profit distribution plan and plan for covering losses;

- (VIII) to resolve on any increase or reduction of the Company's registered capital;

- (IX) to resolve on merger, division, dissolution and liquidation of the Company or change of its corporate form;

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

- (X) to resolve on issue of bonds or other securities and the listing of the Company;
- (XI) to resolve on the engagement, dismissal or discontinuation of the appointment of accounting firms of the Company;
- (XII) to amend the Articles of Association;
- (XIII) to examine proposals raised by the shareholders who hold 3% or more of the total voting shares of the Company;
- (XIV) [to examine and approve guarantees required to be approved by the shareholders' general meeting as stipulated by the laws, regulations and Articles of Association;]
- (XV) to deliberate matters regarding the purchase or sale of material assets by the Company that within one year exceed 30% of the latest audited total assets of the Company;
- (XVI) to review and approve matters relating to the modification of raised fund purpose;
- (XVII) to examine equity incentive plans; and
- (XVIII) to review and approve other issues which should be decided by the shareholders' general meeting as stipulated by laws, regulations, listing rules of the stock exchange where the Company's shares are listed and the Articles of Association.

The Company may not, without approval of shareholders by special resolution at shareholders' general meeting, enter into any contract with any person other than a director, supervisor and other senior management pursuant to which such person shall be responsible for the management of the whole or any substantial part of the business of the Company.

Convening of Shareholders' General Meeting

There are two types of shareholders' general meetings: annual general meetings and extraordinary general meetings. A shareholders' general meeting shall be convened by the Board of Directors. The annual general meeting shall be held once a year within six months after the end of the preceding accounting year.

An extraordinary general meeting shall be convened within two months from the date of occurrence of any of the following events:

- (I) the number of directors is less than the minimum number required by the Company Law or less than two-thirds of the number stipulated in the Articles of Association;
- (II) the outstanding losses of the company amounted to one-third of the Company's total paid-in share capital;

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

- (III) shareholders individually or in aggregate holding 10% or more of the Company's outstanding voting shares request in writing that an extraordinary general meeting is convened;
- (IV) the Board of Directors deems necessary;
- (V) it is proposed by the board of supervisors; and
- (VI) other circumstances specified by laws, regulations or the Articles of Association.

If the Board of Directors is unable or fails to fulfill the obligation of convening the shareholders' general meetings, the board of supervisors shall convene and preside over such meetings in a timely manner. If the board of supervisors does not convene or preside over such meetings, the shareholders who hold 10% or more of the Company's shares individually or jointly for 90 or more consecutive days may proceed to convene and preside over such meetings on their own initiative.

Proposal and Notification of Shareholders' General Meeting

When the Company decides to convene an annual general meeting, it shall notify the shareholders of the time, venue and matters to be considered at the meeting 20 business days prior to the meeting; and when the Company decides to convene an extraordinary general meeting, it shall notify the shareholders 15 days or 10 business days (whichever is the longer) prior to the meeting.

When the Company decides to convene a shareholders' general meeting, the Board of Directors, the board of supervisors and shareholders severally or jointly holding 3% or more of the shares of the Company shall be entitled to put forward proposals to the Company.

The shareholders severally or jointly holding 3% or more of the shares of the Company may raise interim proposals and submit them in writing to the convener 10 days prior to the convening of the shareholders' general meeting. The convener shall, within 2 days after the receipt of such proposals, issue a supplemental notice of the shareholders' general meeting, announce the contents of the interim proposals, and submit the interim proposals to the shareholders' general meeting for consideration.

Except as prescribed in the preceding paragraph, the convener, after issuing the notice and announcement of shareholders' general meeting, shall neither revise the proposals stated in the notice of shareholders' general meetings nor add new proposals.

At extraordinary general meetings, matters not specified in the notice shall not be decided on.

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

Convening of Shareholders' General Meeting

Any shareholder entitled to attend and vote at a shareholders' general meeting shall have the right to appoint one or more persons (who need not be a shareholder or shareholders) as his/her/its proxy to attend and vote on his/her/its behalf. A proxy may exercise the following powers according to the entrustment of the shareholder:

- (I) the same right of speech as the shareholder at the shareholders' general meeting;
- (II) the authority to demand or join other shareholders in demanding a poll; and
- (III) the right to vote by hand or on a poll, but when more than one proxy has been appointed, the proxies only have the right to vote on a poll.

A shareholders' general meeting shall be convened by the Board of Directors, and the chairman of the Board of Directors shall act as the chairman of the meeting. If the chairman is unable to attend the meeting for any reason, a director nominated by more than half of directors shall chair the meeting. In the event that the chairman of the meeting is not elected, the shareholders present at the meeting may elect one person at the meeting to be the chairman. If shareholders cannot elect the chairman for any reason, the shareholder (including proxies) present at the meeting who holds the largest number of voting shares shall be the chairman of the meeting. The chairman of the board of supervisors shall preside over the shareholders' general meeting convened by the board of supervisors. A supervisor shall be elected by more than half of all supervisors to preside over the meeting when the chairman of the board of supervisors fails or refuses to perform the duty. In the case of a shareholders' general meeting convened by shareholders on their own initiative, the shareholder recommended by convener(s) shall preside over the meeting and act as the chairman of the meeting.

Votes and Resolutions of Shareholders' General Meeting

Resolutions made at a shareholders' general meeting shall be divided into ordinary resolutions and special resolutions. Ordinary resolutions of the shareholders' general meeting shall be passed by more than half of the voting rights represented by shareholders (including their proxies) present at the meeting. Special resolutions made by the shareholders' general meeting shall be approved by above two-thirds of voting rights held by the shareholders (including their proxies) attending the shareholders' general meeting.

The following matters shall be approved by ordinary resolutions at a shareholders' general meeting:

- (I) work reports of the Board of Directors and the board of supervisors;
- (II) profit distribution proposals and loss recovery proposals formulated by the Board of Directors;

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- (III) appointment and dismissal of members of the Board of Directors and the board of supervisors, and their remunerations and the method of payment thereof;
- (IV) the annual budget and final accounts, the balance sheet, statements of profits and other financial statements of the Company; and
- (V) all other proposals not resolved by special resolutions as provided for in laws, administrative regulations, listing rules of the stock exchange where the Company's shares are listed or the Articles of Association.

The following matters shall be approved by special resolutions at a shareholders' general meeting:

- (I) increase or reduction in the share capital of the Company, and issuance of any class of shares, warrants or other similar securities;
- (II) issuance of corporate bonds or listing;
- (III) division, merger, dissolution and liquidation of the Company or change of its corporate form;
- (IV) amendment to the Articles of Association;
- (V) the amount of the Company's purchase or disposal of material assets or providing guarantee in one year exceeds 30% of the latest audited total assets of the Company;
- (VI) [consideration and implementation of equity incentive plans]; and
- (VII) other matters that are specified by laws, regulations or the Articles of Association to be adopted by a special resolution and that, resolved by the shareholders' general meeting by an ordinary resolution, may have a material effect on the Company and should therefore be adopted by a special resolution.

In the event the matters of connected transactions are considered at a shareholders' general meeting, connected shareholders shall abstain from voting upon such connected transactions and the number of voting shares represented by such shareholders shall not be counted in the total number of valid votes. The announcement of the resolution of such meeting shall fully disclose the votes of the unrelated shareholders.

Special Procedures for the Voting of Class Shareholders

Shareholders who hold different classes of shares shall be classified as class shareholders. Class shareholders shall enjoy rights and assume obligations in accordance with laws, administrative regulations and the Articles of Association.

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If the Company intends to change or abrogate the rights of class shareholders, it may do so only after such change or abrogation has been approved by way of a special resolution of the shareholders' general meeting and by a separate shareholders' meeting convened by the affected class shareholders.

The rights of a class shareholder shall be deemed to be changed or abrogated under any of the following circumstances:

- (I) increase or reduce the number of shares of that class, or increase or reduce the number of shares of other class with equal or more voting rights, distribution rights and other privileges;
- (II) convert all or part of the shares of that class into other class(es) or convert all or part of shares of other class(es) into that class, or grant such conversion right;
- (III) cancel or reduce the right of that class of shares to obtain dividends generated or cumulative dividends;
- (IV) reduce or remove a dividend preference or property distribution preference during liquidation of the Company attached to shares of that class;
- (V) add, remove or reduce share conversion rights, options, voting rights, transfer rights, pre-emptive rights or rights to acquire securities of the Company attached to shares of that class;
- (VI) remove or reduce rights to receive amounts payable by the Company in a specified currency attached to shares of that class;
- (VII) create new class(es) of shares entitled to equal or more voting rights, distribution rights or other privileges as compared with that class of shares;
- (VIII) impose restrictions on the transfer or ownership of that class of shares or increase such restrictions;
- (IX) issue subscription or conversion rights for shares of that class or another class;
- (X) increase the rights and privileges of other class(es) of shares;
- (XI) a restructuring plan of the Company which will cause shareholders of different categories to bear liability to different extents during the restructuring; and
- (XII) revise or nullify the provisions in this chapter.

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Affected class shareholders, whether or not having the right to vote at shareholders' general meeting, shall have the right to vote at class meetings in respect of matters referred to in Items (II) to (VIII) or (XI) to (XII) above, provided that interested shareholders shall not have the right to vote at class meetings.

A resolution of the class meeting shall be adopted by above two-thirds of the voting shares represented by shareholders of that class present at the meeting in accordance with the Articles of Association.

Apart from other classes of shareholders, the holders of Domestic Shares and overseas-listed foreign shares are deemed to be shareholders of different classes.

The special procedures for voting by a class shareholders shall not apply in the following circumstances:

- (I) upon the approval by way of a special resolution passed by a shareholders' general meeting, the Company independently or simultaneously issues Domestic Shares and/or overseas-listed foreign shares every 12 months, provided that the amount of each class of shares intended to be issued is not more than 20% of the outstanding shares of the respective class;
- (II) the Company's plan on issuing Domestic Shares and overseas-listed foreign shares at the time of incorporation, which is completed within 15 months upon the date of approval from the securities regulatory authority of the State Council;
- (III) upon the approval by securities regulatory authority of the State Council, holders of Domestic Shares and unlisted foreign shares of the Company may transfer, in whole or in part, the shares held by them to overseas investors and list and trade such shares on an overseas stock exchange; or all or part of Domestic Shares and unlisted foreign shares may be converted into overseas-listed shares and listed and traded on an overseas stock exchange.

DIRECTORS AND BOARD OF DIRECTORS

Director

The Company shall establish a Board of Directors, which shall comprise [7] directors (including executive directors, non-executive directors and independent non-executive directors) of which one shall be chairman.

Independent non-executive directors are directors holding no positions other than that of directors in the Company and having no relationship with the Company and its substantial shareholders as to hinder their independent and objective judgments. The number of

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independent non-executive directors shall be at least one third of the total membership of the Board and not less than three, and at least one independent director shall have appropriate professional qualifications, or shall have appropriate accounting or related financial management expertise.

Directors shall be elected at a shareholders' general meeting, and shall serve a term of office of [three] years. A director may serve consecutive terms if re-elected. Prior to expiry of term of office of a director, a shareholders' general meeting shall not remove the director without a reason.

The term of office of a director shall be from the date of appointment to the expiry of tenure of the current Board of Directors. Where re-election is not promptly carried out upon expiry of the term of office of a director, prior to appointment of a new director, the original director shall continue to carry out director duties pursuant to the provisions of laws, administrative regulations, departmental rules and the Articles of Association.

The chairman of the Board of Directors shall be elected and removed by more than half of all the directors. The term of office for the chairman shall be three years and he shall be eligible for re-election.

Directors are not required to hold any shares of the Company.

Board of Directors

The Board of Directors shall be responsible to the shareholders' general meetings and exercise the following functions and powers:

- (I) to convene shareholders' general meetings and report on its work to the shareholders' general meetings;
- (II) to implement resolutions of shareholders' general meeting;
- (III) to decide on the Company's operational plans and investment plans;
- (IV) to formulate the Company's annual financial budget plan and final account plan;
- (V) to formulate the Company's profit distribution plan and plan for covering losses;
- (VI) to formulate the Company's plans for increase or reduction of registered capital, issuance of bonds or other securities and listing plan;
- (VII) to formulate proposals for the merger, division or dissolution of the Company or change of corporate form;
- (VIII) to decide on the setup of the Company's internal management organs;

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- (IX) to appoint or dismiss the Company's general manager and secretary to the Board of Directors, appoint or dismiss other senior management of the Company based on the nomination of general manager, and to decide on matters relating to their emoluments;
- (X) to formulate the Company's basic management system;
- (XI) to formulate proposals for any amendment to the Articles of Association;
- (XII) to propose to the shareholders' general meeting on the appointment or replacement of accounting firm which provides audit services to the Company;
- (XIII) to decide on external guarantees of the Company beyond the scope of consideration by the shareholders' general meetings;
- (XIV) to decide on the matters in which the amount of the Company's purchase or disposal of material assets or providing guarantee in one year does not exceed 30% of the latest audited total assets of the Company;
- (XV) to approve connected transactions that are required to be approved by the Board of Directors under the laws, regulations, the listing rules of the stock exchange where the Company's shares are listed and the Articles of Association; and
- (XVI) to exercise any other functions and powers stipulated by laws, regulations or the listing rules of the stock exchange where the Company's shares are listed, and granted by the shareholders' general meetings.

Resolutions by the Board of Directors on matters referred to in the preceding paragraph may be passed by the affirmative vote of more than half of the directors, unless otherwise provided by laws, regulations and the Articles of Association and with the exception of matters on [formulating the Company's plans for increase or reduction of registered capital, issuance of bonds or other securities and listing plan, formulating proposals for the merger, division or dissolution of the Company or change of corporate form and formulating proposals for any amendment to the Articles of Association].

The chairman of the Board of Directors shall exercise the following powers and functions:

- (I) presiding over shareholders' general meetings, and convening and presiding over Board meetings;
- (II) inspecting implementation of resolutions of the Board of Directors;
- (III) signing securities issued by the Company;
- (IV) signing important legally binding documents on behalf of the Company; and
- (V) exercising other power and function granted by the Board of Directors.

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Where the chairman is incapable of performing his/her duties, a director nominated by more than half of the directors shall perform his/her duties.

Meetings of the Board of Directors shall be held at least four times each year and convened by the chairman. The notice of such meeting shall be given to all directors and supervisors 14 days before the meeting. Under any of the circumstances, the chairman shall convene an interim Board meeting within 10 days after receipt of a proposal:

- (I) shareholders representing one tenth or more voting rights propose;
- (II) one third or more of the directors propose jointly;
- (III) the board of supervisor proposes; and
- (IV) the general manager proposes.

Meetings of the Board of Directors may be held only if more than half of the directors (including proxies) attend.

Each director shall have one vote. The resolution proposed by the Board of Directors shall be passed by a simple majority of all the directors, unless otherwise stated in the Articles of Association.

When the negative votes and the affirmative votes are the same, the chairman has one more vote.

Where a director or any of its associates (as defined in the Listing Rules of The Stock Exchange of Hong Kong Limited) has any interest in the subject matter of the meeting (including the approval of any contract, transaction, arrangement, etc.) or the director has associated relationships with the enterprise related to the subject matter of the meeting, such director shall withdraw from the meeting, does not enjoy any voting rights and shall not be counted in the quorum thereof. The Board meeting may be held with the quorum of a simple majority of unrelated directors and resolutions to be passed at the Board meeting shall be passed by simple majority of votes of unrelated directors. Where the number of unrelated directors present at the Board meeting is less than 3, the matter shall be submitted to the shareholders' general meeting for deliberation.

Directors shall attend Board meetings in person and express clear views on the matters discussed. Where a director is unable to attend for any reason, he/she may appoint another director to vote on his/her behalf by a written power of attorney specifying the scope of authorization. The director who attends the meeting on his/her behalf shall exercise the director's rights within the scope of authorization. Where a director does not attend a Board meeting and does not appoint a proxy to attend on his/her behalf, he/she shall be deemed to forfeit his/her voting rights at the said meeting.

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The Board of Directors shall make minutes of the meeting's decisions on the matters discussed at the meeting, and the directors attending the meeting and the recorder shall sign the minutes. The directors shall be liable for the resolutions of the Board of Directors. If a resolution of the Board of Directors violates any laws, administrative regulations or the Articles of Association or resolutions of the shareholders' general meeting, and as a result of which the Company sustains serious losses, the directors participating in the resolution are liable to compensate the Company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director shall be relieved from that liability.

Borrowing power

The Articles of Association do not contain any special provision in respect of the manner in which borrowing powers may be exercised by the Directors nor do they contain any special provision in respect of the manner in which such power may be raised, other than: (a) provisions which give the Board of Directors the power to formulate proposals for the issuance of debentures by the Company and (b) provisions which provide that the issuance of debentures must be approved by the Shareholders in general meeting by way of a special resolution.

Secretary to the Board

The Company shall appoint a secretary to the Board of Directors. The secretary to the Board of Directors is a member of senior management of the Company, who is accountable to the Board of Directors. The secretary to the Board of Directors shall be a natural person with necessary expertise and experience and is appointed by the Board of Directors. Its primary responsibilities include:

- (I) to ensure that the Company has a complete set of constitutional documents and records;
- (II) to ensure that the Company legally prepares and submits reports and documents as required by the competent authorities;
- (III) to ensure that the share register of the Company is properly established, and that persons entitled to receive relevant records and documents of the Company are given timely access to such records and documents;
- (IV) to be responsible for the information disclosure of the Company;
- (V) to be responsible for preparing shareholders' general meetings and Board meetings; and
- (VI) other responsibilities stipulated by the rules of the stock exchange where the Company's share is listed.

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Directors or senior management of the Company may concurrently hold the position of the secretary to the Board of Directors of the Company. The accountants of the accounting firms engaged by the Company shall not concurrently hold the position of the secretary to the Board of Directors of the Company.

Where a Director concurrently serves as the secretary to the Board, if any act needs to be done separately by a Director and the secretary to the Board, the person concurrently serving as Director and the secretary to the Board of the Company shall not take such action in both capacities.

General Manager of the Company

The Company shall have one general manager to be appointed or dismissed by the Board of Directors.

The general manager of the Company, who shall be accountable to the Board of Directors, may exercise the following functions and powers:

- (I) to manage the production, operation and administration of the Company and arrange for the implementation of the resolutions of the Board of Directors;
- (II) to organize the implementation of the Company's annual business plans and investment plans;
- (III) to formulate plans for establishment of internal management organs of the Company;
- (IV) to formulate basic management system of the Company;
- (V) to formulate specific rules and regulations of the Company;
- (VI) to recommend the appointment or dismissal of any [deputy general manager] and chief financial officer of the Company;
- (VII) to appoint or dismiss management personnel (other than those required to be appointed or dismissed by the Board of Directors); and
- (VIII) any other function and power granted by the Articles of Association or the Board of Directors.

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SUPERVISORS AND BOARD OF SUPERVISORS

Supervisors

The Company shall establish a board of supervisors. The board of supervisors shall comprise [three] supervisors, including a chairman. The appointment and dismissal of the chairman of the board of supervisors shall be passed by the votes of more than two-thirds of the members of the board of supervisors. Each term of office of a supervisor is three years and he/she may serve consecutive terms if re-elected.

The board of supervisors shall be composed of representatives of the shareholders and representatives of the Company's employees. Shareholder representatives shall be elected and removed at shareholders' general meetings, and employee representatives shall be elected and removed democratically by the employees of the company. The number of employee representative supervisors of the Company shall not be less than one-third of the Supervisors.

Directors and senior management members shall not act concurrently as supervisors.

BOARD OF SUPERVISORS

The board of supervisors shall be accountable to the Shareholders' general meeting and shall exercise the following functions and powers in accordance with the law:

- (I) to check the financial situations of the Company;
- (II) to supervise the acts of the directors and senior management in performing their duties to the Company and propose the removal of those directors and senior management who violate the laws and regulations, the Articles of Association or resolutions of shareholders' general meetings;
- (III) to demand any director or senior management who acts in a manner which is detrimental to the Company's interests to rectify such behaviors;
- (IV) verifying financial information such as financial reports, business reports, profit distribution plans, etc. that the Board of Directors intends to submit to the shareholders' general meeting and, if in doubt, a registered accountant or practicing auditor shall be appointed in the name of the Company to assist in reviewing such information.
- (V) to propose the convening of extraordinary general meetings and, in case the Board of Directors does not perform the obligations to convene and preside over the shareholders' general meetings in accordance with the Articles of Association, to convene and preside over the shareholders' general meetings;

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(VI) to represent the Company to negotiate with the Directors and senior management or bring actions against Directors and senior management according to the Company Law; and

(VII) to exercise other functions and powers as specified in the Articles of Association.

Supervisors may attend board meetings and make enquiries or proposals in respect of board resolutions

Meetings of the board of supervisors shall be convened at least once each six months and be convened and presided by its chairman. Extraordinary meetings of the board of supervisors can be convened by the supervisors. A Supervisor shall be elected by more than half of all Supervisors to convene and host the meetings of the board of supervisors when the chairman fails or refuses to perform the duty. If a Supervisor fails to attend the meetings of the board of supervisors for two consecutive times in person, the Supervisor shall be deemed to be unable to perform his/her duties. The shareholders' general meeting or the staff representative assembly shall replace such Supervisor.

Notices of the meetings and extraordinary meetings of the board of supervisors may be given, in person, by facsimile, by courier or by other means of electronic communication; notice period of meeting: at least 10 days prior to the convening of the meeting of the board of supervisors, or at least three days prior to the convening of the extraordinary meeting of the board of supervisors. When an extraordinary meeting of the board of supervisors is required to be convened promptly in emergency situations, the meeting notice can be given via phone or other verbal means but the convener shall make explanations at the meeting.

The meeting of the board of supervisors shall only be held when more than two-thirds of the Supervisors are present. Each Supervisor shall have one vote. The resolution made by the board of supervisors shall be passed by more than two-thirds of all Supervisors.

Qualifications and Obligations of Directors, Supervisors, General Manager and Other Senior Management of the Company

None of the following persons shall serve as a Director, Supervisor, or Senior Management of the Company:

- (I) persons without civil capacity or with limited civil capacity for civil conduct;
- (II) persons who have committed corruption, bribery, embezzlement, misappropriation of property or disruption of the order of socialist market economy and have been sentenced to criminal punishment, where less than five years have elapsed since the date of completion of the sentence, or who have been deprived of their political rights due to the commission of a criminal offense, where less than five years have elapsed since the date of restoring their political rights;

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- (III) persons who were former directors, factory managers or managers of a company or enterprise which was declared bankrupt and was liquidated due to poor operation and management and who were personally liable for the bankruptcy of such company or enterprise, where less than three years have elapsed since the date of completion of the bankruptcy and liquidation of the company or enterprise;
- (IV) persons who were legal representatives of a company or enterprise which had its business license revoked due to violation of the laws and who were personally liable, where less than three years have elapsed since the date of the revocation;
- (V) persons with relatively large amounts of due and outstanding debt;
- (VI) a person under investigation by judicial authorities for suspected violations of criminal law and the investigation is still ongoing;
- (VII) persons who cannot serve as corporate leaders according to laws and administrative regulations;
- (VIII) non-natural persons;
- (IX) a person has been ruled as violations of the provisions of relevant securities regulations by the competent authority, involving fraud or dishonesty, and it does not exceed five years from the date of the ruling; and
- (X) circumstances as required by the relevant laws and regulations of a place where the Company's shares are listed.

The directors, supervisors and senior management of the Company shall perform their duties in accordance with the principle of honesty and shall not put themselves in a position where there is a conflict between their personal interests and their duties assumed. This principle shall include (but not limited to) the fulfilment of the following obligations:

- (I) to act honestly in the best interests of the Company;
- (II) to exercise powers within the scope of his/her functions and powers and not to act beyond such powers;
- (III) to personally exercise the discretion invested in him/her, not to allow himself/herself to be manipulated by another person and, not to delegate the exercise of his/her discretion to another party unless permitted by laws and administrative regulations or with the consent of the shareholders' general meeting that has been informed;

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- (IV) to treat shareholders of the same class equally and to treat shareholders of different classes fairly;
- (V) not to enter into any contract, transaction or arrangement with the Company unless otherwise provided by the Articles of Association or with the consent of shareholders' general meeting that has been informed;
- (VI) not to use the Company's assets for his/her own benefit in any way without the consent of the shareholders' general meeting that has been informed;
- (VII) not to make use of official powers to accept bribes or other illegal income, and not to encroach upon the Company's assets in any way, including (but not limited to) any opportunities that are favorable to the Company;
- (VIII) not to accept commissions in connection with the Company's transactions without the consent of the shareholders' general meeting that has been informed;
- (IX) to abide by the Articles of Association, perform his/her duties faithfully, protect the interests of the Company and not to seek personal gain with his/her position, functions and powers in the Company;
- (X) not to compete with the Company in any way without the consent of the shareholders' general meeting that has been informed;
- (XI) not to misappropriate the funds of the Company or lend them to others, not to deposit the Company's assets in accounts opened in his/her own or in another's name, not to use the Company's assets as security for the debts of the Company's shareholders or other individuals; and
- (XII) not to disclose confidential information relating to the Company that was acquired by him/her during his/her term of office without the consent of the shareholders' general meeting that has been informed, and not to use such information except in the interests of the Company; however, such information may be disclosed to the court or other competent government authorities if:
 - 1. provided by law;
 - 2. required in the public interest; and
 - 3. required in the own interest of such director, supervisor and senior management.

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If a Director, a Supervisor and senior management of the Company breaches his/her obligations to the Company, the Company shall, in addition to any rights and remedies provided by laws, have a right to:

- (I) require the relevant Director, Supervisor and senior management of the Company to compensate for the losses sustained by the Company as a consequence of his/her dereliction of duty;
- (II) rescind any contract or transaction concluded by the Company with the relevant Director, Supervisor and senior management of the Company and contract or transaction with a third party (where such third party is aware or should be aware that the Director, Supervisor and senior management representing the Company was in breach of his/her obligations to the Company);
- (III) require the relevant Director, Supervisor and senior management of the Company to surrender the gains derived from the breach of his/her obligations;
- (IV) recover any funds received by the relevant Director, Supervisor and senior management of the Company that should have been received by the Company, including (but not limited to) commissions; and
- (V) require the relevant Director, Supervisor and senior management of the Company to return the interest earned or possibly earned on the funds that should have been given to the Company.

The Company shall not, directly or indirectly, provide loans or loan guarantees to the Directors, Supervisors and senior management of the Company and its parent company, nor shall the Company provide the same to their connected persons.

The preceding provision shall not apply in the following circumstance:

- (I) the Company provides loans or loan guarantees to its subsidiaries;
- (II) the Company provides loans, loan guarantees or other funds to the Directors, Supervisors, or senior management personnel of the Company pursuant to their employment contracts which were adopted by the shareholders' general meeting, so that the foregoing persons can make payments in the interests of the Company or for the expenses incurred in performing their duties and responsibilities; and
- (III) in the event that the normal business scope of the Company includes provision of loans and loan guarantees, the Company can provide loans and loan guarantee to relevant Directors, Supervisors and senior management and their connected persons, provided that the loans and loan guarantees are provided on normal commercial terms and conditions.

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FINANCIAL ACCOUNTING SYSTEM AND PROFIT DISTRIBUTION

Financial Accounting System

The Company shall formulate its own financial accounting system in accordance with the laws, administrative regulations and PRC accounting standards formulated by the competent financial authority under the State Council.

The Company shall prepare financial reports at the end of each accounting year, which reports shall be subject to legal examination and verification.

The Board of Directors of the Company shall place before the Shareholders at each annual general meeting a financial report prepared by the Company as required by the relevant laws, administrative regulations and regulatory documents promulgated by the local government or competent authorities.

The Company's financial reports shall be made available for shareholders' inspection at the Company 20 days before the convening of an annual general meeting. Each Shareholder of the Company shall be entitled to obtain the financial reports referred herein this Chapter. A copy of either the directors' report, accompanied by the balance sheet (including every document required by law to be annexed thereto) and income statement, or the financial reports summary shall, at least 21 days before the date of the annual general meeting, be delivered by prepaid post to the address of the holders of overseas-listed foreign shares as registered in the share register.

The financial statements of the Company shall be prepared not only in accordance with China accounting standards, laws and regulations, but also in accordance with international accounting standards or the accounting standards of the place(s) outside China where shares of the Company are listed. If there are any material differences between the financial statements prepared in accordance with the two accounting standards, such differences shall be stated in the notes to the financial statements. The lower of the after-tax profits of a specific fiscal year stated in the statements prepared based on the above-mentioned principles shall prevail in the allocation of such profits.

The Company shall publish its financial reports twice in each accounting year. An interim financial report shall be published within 60 days after the end of the first six months of each accounting year, while an annual financial report shall be published within 120 days after the end of each accounting year.

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Profits Distribution

The profit after tax of the Company shall be applied in the following sequence:

- (I) recovery of accumulated losses;
- (II) set aside 10% of its profits after taxation for the company's statutory common reserve fund;
- (III) appropriations to a discretionary surplus reserve as approved by the Shareholders' general meeting.
- (IV) to pay dividends for the ordinary shares.

The shares of the Company held by the Company shall not be subject to profit distribution.

Such withdrawal may be stopped when the statutory common reserve fund of the Company has accumulated to at least 50% of the registered capital of the Company.

No dividend or other distribution by way of bonus shares shall be distributable before the losses have been made good and allocations have been made to the statutory common reserve fund.

Monies paid for any shares before the calls on shares shall have dividends, but the holders of such shares are not entitled to dividends declared later for the said monies.

The Company shall appoint receiving agent for holders of overseas-listed foreign shares. The receiving agent shall collect on behalf of the Shareholders concerned the dividends distributed and other payables by the Company in respect of the overseas listed foreign shares, and shall keep such monies on behalf of the Shareholders concerned for payment to them. The receiving agent appointed by the Company shall meet the requirements of the laws of the place(s) or the relevant regulations of the securities exchange(s) where the shares are listed. The receiving agent appointed by the Company for holders of overseas-listed foreign shares listed on the Hong Kong Stock Exchange shall be the trust companies registered under the Trustee Ordinance of Hong Kong.

The Company may exercise the right to seize dividends not claimed, but the said right shall not be exercised before expiry of the applicable validity period. The Company's power to cease sending dividend warrants to a holder of overseas-listed foreign shares by post shall not be exercised until such dividend warrants had been so left uncashed on two consecutive occasions. If a dividend warrants fails to reach the expected recipient in the initial mail delivery and is returned, the Company may exercise the right promptly.

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The Company is entitled to sell the shares of those un-contactable holders of overseas-listed foreign shares in a manner the Board of Directors deems fit, subject to the following terms:

- (I) dividends have been distributed for the relevant shares for at least three times in 12 years, but are not claimed in the said period; and
- (II) upon expiry of the 12-year period, the Company publishes an announcement on one or more newspapers of the place where the shares of the Company are listed, stating its intention to dispose of the shares, and notifies the stock exchange where such shares are listed.

The common reserve fund of the Company shall only be used for the following purposes:

- (I) recovery of accumulated losses;
- (II) expansion of production and operation of the Company;
- (III) converted into capital.

When the Company converts its common reserve fund into its capital upon a resolution adopted in Shareholders' general meeting, the Company shall either distribute new shares or increase the par value of each share based on the percentage of the capital of the Shareholders. However, when the statutory common reserve fund is converted into capital, the remainder of the reserve fund shall not fall below 25% of the Company's registered capital prior to conversion. the capital reserve fund cannot be used to make up losses of the Company.

Dividends shall be paid by the Company in the following forms:

- (I) in cash;
- (II) by stock.

Appointment of Accounting Firm

The Company shall appoint a qualified independent accounting firm in accordance with the related provision of the PRC Law to audit the annual financial reports and other financial reports of the Company. The first auditor may be appointed prior to holding the first annual general meeting and its term of service shall expire at the conclusion of the first annual general meeting. Where the power as set out in the preceding articles has not been exercised at the time holding the first annual general meeting, the Board may exercise such power.

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An accounting firm employed by the Company shall have the following rights:

- (I) to access the accounts books, records or vouchers of the Company at any time and to require directors, or senior management of the Company to provide the relevant information and explanations;
- (II) to require the Company to take all reasonable measures to obtain from its subsidiaries the information and explanations necessary for the accounting firm to perform its duties;
- (III) to attend shareholders' general meetings, to receive meeting notices or other information related to the meetings which any shareholder is entitled to receive, and to deliver speeches at any shareholders' general meetings on matters involving it as the accounting firm of the Company.

The engagement, dismissal or refusal of the renewal of the engagement of an accounting firm shall be decided upon by the shareholders' general meeting and reported to the securities regulatory authorities of the State Council.

Where a resolution at a shareholders' general meeting of shareholders is passed to appoint as accounting firm a person other than an incumbent accounting firm, to fill a casual vacancy in the office of accounting firm, to reappoint as accounting firm a retiring accounting firm who was appointed by the board of directors to fill a casual vacancy, or to remove an accounting firm before the expiration of its term of office, the following provisions shall apply:

- (I) The proposal for appointment or dismissal shall, before the notice of shareholders' general meeting is sent, be served to accounting firms to be appointed or to terminate service or having terminated service in the relevant fiscal year. Termination of service includes dismissal, removal and resignation.
- (II) If the accounting firms about to terminate service make a written statement and request the Company to notify the said statement to the Shareholders, the Company shall take the following actions unless the statement is received too late:
 - 1. state on the notice issued for making resolution that the accountant firms about to terminate service has made representation; and
 - 2. send the representation copy as an appendix to the notice to the Shareholders by the method required under the Articles of Association.
- (III) If the Company fails to send out the statement of the accounting firms as specified in (II) herein, the relevant accounting firms may require that the said statement be read at the shareholders' general meeting and may further lodge a complaint.

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(IV) Accounting firms about to terminate service have the right to attend the following meetings:

1. The shareholders' general meeting at which their term of appointment expires;
2. The shareholders' general meeting for filling vacancy because of their termination of service;
3. The shareholders' general meeting held because of their proactive resignation.

The accounting firms about to terminate service shall have the right to receive all notices of the aforesaid meetings or other information relating to the meetings, and to deliver speeches at the aforesaid meetings on matters involving it as the former accounting firm of the Company.

Merger and Division of the Company

The merger of the Company may take the form of either merger by absorption or merger by the establishment of a new company.

In the event of merger of the Company, the parties to the merger shall enter into a merger agreement and prepare a balance sheet and an inventory of assets. The Company shall notify its creditors within 10 days since the date of resolution on merger, and shall make a public announcement in a newspaper within 30 days. The creditors may, Within 30 days since the date on receipt of notice or within 45 days since the date of the first announcement (if such notice is not received), require the Company to clear off its debts or to provide corresponding guarantees.

In the case of a merger, the credits and debts of the companies involved shall be succeeded by the company that survives the merger or by the newly established company.

Where the Company is divided, its properties shall be divided accordingly.

In the event of division of the Company, the parties to the division shall enter into a division agreement and prepare a balance sheet and an inventory of assets. The Company shall notify the creditors within 10 days from the date of division resolution, and shall make a public announcement in a newspaper within 30 days.

The post-division companies shall bear joint liabilities for the debts of the Company before it is divided, unless it is otherwise prescribed by the Company and the creditors before the division with regard to the clearance of debts in written agreement.

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

Dissolution and Liquidation of the Company

The Company shall be dissolved and liquidated according to law in any of the following circumstances:

- (I) if the shareholders' general meeting resolves to do so;
- (II) merger or division of the Company entails dissolution;
- (III) the Company's business licence is cancelled pursuant to the law, or the Company is ordered to be closed down or revoked pursuant to the law;
- (IV) the Company is dissolved by a people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all shareholders of the Company, on the grounds that the operation and management of the Company have suffered serious difficulties that cannot be resolved through other means, rendering ongoing existence of the Company a cause for significant losses to the shareholders;
- (V) other circumstances under which the Company should dissolve pursuant to laws and regulations.

If the Company is dissolved pursuant to Item (I), Item (III) and Item (IV) above, it shall establish a liquidation committee and commence liquidation within 15 days from occurrence of the cause of dissolution. The liquidation committee shall be composed of the directors or persons as determined by the shareholders' general meeting. If no liquidation committee is established after the said timeframe, the creditors may apply to the people's court for appointment of relevant persons to establish a liquidation committee to commence liquidation.

The liquidation committee shall notify the creditors within 10 days after its establishment and shall make announcements on newspapers within 60 days.

The creditors shall declare their creditor's rights to the liquidation committee within 30 days after receipt of the notice or 45 days after announcement if the creditors have not received the notice in person. Creditors declaring creditor's rights shall state the relevant information of the creditor's rights and provide evidentiary materials. The liquidation committee shall register the creditor's rights. During the period for declaration of creditor's rights, the liquidation committee shall not make repayment to creditors.

APPENDIX IV SUMMARY OF THE ARTICLES OF ASSOCIATION OF THE COMPANY

During liquidation, the liquidation committee shall exercise the following functions and powers:

- (I) to ascertain the Company's assets and separately prepare balance sheet and asset list;
- (II) to inform creditors by notice or announcement;
- (III) to deal with and settle the Company's outstanding business deals in relation to the liquidation;
- (IV) to pay the outstanding taxes;
- (V) to settle creditor's rights and debts;
- (VI) to dispose of the remaining assets of the Company after the repayment of debts;
- (VII) to represent the Company in any civil proceedings.

If, after sorting out the Company's assets and preparing a balance sheet and an asset list in connection with the liquidation of the Company due to its dissolution, the liquidation committee discovers that the Company's assets are insufficient to pay its debts in full, it shall immediately apply to the people's court for declaration of bankruptcy.

Liquidation of a company declared bankrupt according to laws shall be processed in accordance with the laws on corporate bankruptcy.

Upon declaration of the Company's bankruptcy pursuant to the ruling of the people's court, the liquidation committee shall hand over the liquidation matters to the people's court.

Within 30 days from the date of confirmation by the shareholders' general meeting or the relevant authorities in charge, the liquidation committee shall submit the aforesaid documents to company registration authorities and apply for deregistration and make an announcement on termination of the Company.

Procedures for amendment to the Articles of Association

According to the laws, administrative regulations, requirements of the listing rules of the place where the shares of the Company are listed and the Articles of Association, the Company may amend the Articles of Association.

The following procedures shall be followed to amend the Articles of Association:

- (I) the Board of Directors makes a proposal for the amendment of the Articles of Association;

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- (II) The aforesaid proposal is submitted in writing to the shareholders and a shareholders' general meeting is convened;
- (III) a resolution shall be adopted by more than two-thirds of voting rights of shareholders attending a shareholders' general meeting.

Settlement of Disputes

The Company shall settle disputes following the rules below:

- (I) If any disputes or claims in relation to the Company's business, with respect to any rights or obligations under the Articles of Association, the Company Law or any other relevant laws and regulations, arise between holders of overseas listed foreign shares and the Company, between holders of overseas listed foreign shares and the Company's Directors, Supervisors and senior management personnel, or between holders of overseas listed foreign shares and holders of domestic shares, the parties concerned shall submit such disputes or claims to arbitration.

The aforesaid dispute or claim submitted for arbitration shall be the entire dispute or claim; all the persons who complain for the same reason or who are required to participate in the settlement of the dispute or claim shall accept the arbitration award if they are the Company or its shareholders, directors, supervisors, senior management staff.

Disputes with respect to the definition of Shareholders and disputes concerning the register of members need not to be resolved by arbitration.

- (II) The applicant for arbitration may choose to be arbitrated either by the China International Economic and Trade Arbitration Commission in accordance with its arbitration rules or the Hong Kong International Arbitration Centre in accordance with its securities arbitration rules. Once the applicant for arbitration submits a dispute or claim to arbitration, the other party must carry out the arbitration at the arbitration institution selected by the applicant.

If the applicant for arbitration opts for arbitration by the Hong Kong International Arbitration Centre, either party may request for the arbitration to be conducted in Shenzhen in accordance with the securities arbitration rules of the Hong Kong International Arbitration Centre.

- (III) Settlement of disputes or claims set out in (I) by way of arbitration shall be governed by PRC laws (exclusive of laws of Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan for the purpose of the Articles of Association) save as otherwise specified by laws and regulations.
- (IV) The decision made by the arbitral body shall be final and binding on all parties.

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This Appendix contains a summary of laws and regulations on companies and securities in the PRC, certain major differences between the Company Law and Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Companies Ordinance as well as the additional regulatory provisions of the Stock Exchange on joint stock limited companies of the PRC. The principal objective of this summary is to provide potential [REDACTED] with an overview of the principal laws and regulations applicable to us. This summary is with no intention to include all the information which may be important to the potential [REDACTED]. For discussion of laws and regulations specifically governing the business of the Company, see section headed “Regulatory Overview” in this document.

PRC LAWS AND REGULATIONS

PRC Legal System

The PRC legal system is based on the PRC Constitution (the “Constitution”) and is made up of written laws, administrative regulations, local regulations, autonomous regulations, separate regulations, rules and regulations of State Council departments, rules and regulations of local governments, laws of special administrative regions and international treaties of which the PRC government is the signatory and other regulatory documents. Court judgments do not constitute legally binding precedents, although they are used for the purposes of judicial reference and guidance.

Pursuant to the Constitution and the Legislation Law of the PRC (《中華人民共和國立法法》) (the “Legislation Law”), the National People’s Congress (the “NPC”) and its Standing Committee are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing State organs, civil, criminal and other matters. The Standing Committee of the NPC is empowered to formulate and amend laws other than those required to be enacted by the NPC and to supplement and amend parts of the laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of state administration and has the power to formulate administrative regulations based on the Constitution and laws.

The people’s congresses of the provinces, autonomous regions and municipalities directly under the central government and their respective standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such regulations do not contravene any provision of the Constitution, laws or administrative regulations. The people’s congresses of cities divided into districts and their respective standing committees may formulate local regulations with respect to urban and rural construction and administration, environmental protection, historical and

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cultural protection and other aspects according to the specific circumstances and actual needs of such cities, provided that such local regulations do not contravene any provision of the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. If the law provides otherwise on the formulation of local regulations by cities divided into districts, those provisions shall prevail. Such local regulations will become enforceable after being reported to and approved by the standing committees of the People's congresses of the relevant provinces or autonomous regions. The standing committees of the people's congresses of the provinces or autonomous regions shall examine the legality of local regulations submitted for approval, and such approval should be granted within four months if they are not in conflict with the Constitution, laws, administrative regulations and local regulations of the provinces or autonomous regions concerned. Where, during the examination for approval of local regulations of cities with districts by the standing committees of the people's congresses of the provinces or autonomous regions, conflicts are identified with the rules and regulations of the people's governments of the provinces or autonomous regions concerned, a decision should be made by the standing committees of the people's congresses of provinces or autonomous regions to handle the issue.

The ministries and commissions of the State Council, the PBoC, the National Audit Office and the subordinate institutions with administrative functions directly under the State Council, including the State Administration for Market Regulation, may formulate departmental rules and regulations within the permissions of their respective departments based on the laws and administrative regulations, and the decisions and orders of the State Council. Provisions of departmental rules should be the matters related to the enforcement of the laws and administrative regulations, the decisions and orders of the State Council. The people's governments of the provinces, autonomous regions, municipalities directly under the central government and cities with districts may formulate rules and regulations based on the laws, administrative regulations and local regulations of such provinces, autonomous regions and municipalities directly under the central government.

According to the Constitution, the power to interpret laws is vested in the Standing Committee of the NPC. Pursuant to the Resolution of the Standing Committee of the NPC Providing an Improved Interpretation of the Law (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) passed on June 10, 1981, issues related to the further clarification or supplement of laws should be interpreted or provided by the Standing Committee of the NPC, issues related to the application of laws in a court trial should be interpreted by the Supreme People's Court, issues related to the application of laws in a prosecution process should be interpreted by the Supreme People's Procuratorate, and the legal issues other than the above-mentioned should be interpreted by the State Council and the competent authorities. The State Council and its ministries and commissions are also vested with the power to give interpretations of the administrative regulations and departmental rules which they have promulgated. At the regional level, the power to interpret regional laws is vested in the regional legislative and administrative authorities which promulgate such laws.

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PRC Judicial System

Under the Constitution and the Law of Organization of the People’s Courts of the PRC (《中華人民共和國人民法院組織法》), the people’s courts are classified into the Supreme People’s Court, the local people’s courts at various local levels, and other special people’s courts. The local people’s courts at various local levels are divided into three levels, namely, the primary people’s courts, the intermediate people’s courts and the higher people’s courts. The primary people’s courts are further divided into civil, criminal and economic divisions. The intermediate people’s courts have divisions similar to those of the primary people’s courts and other special divisions, such as the intellectual property division. These two levels of people’s courts are subject to supervision by people’s courts at higher levels. The Supreme People’s Procuratorate is authorized to supervise the judgment and ruling of the people’s courts at all levels which have been legally effective, and the people’s procuratorate at a higher level is authorized to supervise the judgment and ruling of a people’s court at a lower level which have been legally effective. The Supreme People’s Court is the highest judicial authority in the PRC. It supervises the administration of justice by the people’s courts at all levels.

The people’s courts employ a two-tier appellate system. The judgments or rulings of the second instance at a people’s court are final. A party may appeal against the judgment or ruling of the first instance of a local people’s court. The people’s procuratorate may present a protest to the people’s court at the next higher level in accordance with the procedures stipulated by the laws. In the absence of any appeal by the parties and any protest by the people’s procuratorate within the stipulated period, the judgments or rulings of the people’s court are final. Judgments or rulings of the second instance of the intermediate people’s courts, the higher people’s courts and the Supreme People’s Court are final. Judgments or rulings of the first instance of the Supreme People’s Court are also final. However, if the Supreme People’s Court or a people’s court at the next higher level discovers an error in a final and binding judgment or ruling which has taken effect in any people’s court at a lower level, or the presiding judge of a people’s court finds an error in a final and binding judgment or ruling which has taken effect in the court over which he presides, a retrial of the case may be initiated according to the judicial supervision procedures.

The Civil Procedure Law of the PRC (《中華人民共和國民事訴訟法》) (the “PRC Civil Procedure Law”) adopted on April 9, 1991 and amended on October 28, 2007, August 31, 2012 and June 27, 2017, respectively, prescribes the conditions for instituting a civil action, the jurisdiction of the people’s courts, the procedures to be followed for conducting a civil action, and the procedures for enforcement of a civil judgment or ruling. All parties to a civil action conducted within the PRC must abide by the PRC Civil Procedure Law. A civil case is generally heard by the court located in the defendant’s place of domicile. The court of jurisdiction in respect of a civil action may also be chosen by explicit agreement among the parties to a contract, provided that the people’s court having jurisdiction should be located at places directly connected with the disputes, such as the plaintiff’s or the defendant’s place of domicile, the place where the contract is executed or signed or the place where the object of the action is located. However, such choice shall not in any circumstances contravene the regulations of differential jurisdiction and exclusive jurisdiction.

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A foreign individual, a person without nationality, a foreign enterprise or a foreign organization that institute or respond to proceedings in a people’s court is given the same litigation rights and obligations as a citizen or legal person of the PRC. Should a foreign court limit the litigation rights of PRC citizens and enterprises, the PRC court shall apply the same limitations to the citizens and enterprises of such foreign country. A foreign individual, a person without nationality, a foreign enterprise or a foreign organization must engage a PRC lawyer in case he or it needs to engage a lawyer for the purpose of initiating actions or defending against litigations at a PRC court. In accordance with the international treaties to which the PRC is a signatory or a participant or according to the principle of reciprocity, a people’s court and a foreign court may request each other to serve documents, conduct investigation, collect evidence and conduct other actions on its behalf. A PRC court shall not accommodate any request made by a foreign court which will result in the violation of sovereignty, security or public interests of the PRC.

All parties to a civil action shall perform legally effective judgments and rulings. If any party to a civil action refuses to abide by a judgment or ruling made by a people’s court or an award made by an arbitration tribunal in the PRC, the other party may apply to the people’s court for the enforcement of the same within two years, subject to application for postponed enforcement or revocation. If a party fails to satisfy within the stipulated period a judgment which the court has granted an enforcement approval, the court may, upon the application of the other party, mandatorily enforce the judgment. A party seeking to enforce a judgment or ruling of a people’s court against another party who is not or whose property is not within the PRC may apply to a foreign court with jurisdiction over the case for recognition and enforcement of such judgment or ruling. Alternatively, the people’s court may, pursuant to an international treaty concluded or acceded to by the PRC or in accordance with the principle of reciprocity, request the foreign court to recognize and execute the judgment or ruling. Likewise, if the PRC has entered into either a treaty relating to judicial enforcement with the relevant foreign country or a relevant international treaty or according to the principle of reciprocity, a foreign judgment or ruling may also be recognized and enforced in accordance with the PRC enforcement procedures by a PRC court unless the people’s court considers that the recognition or enforcement of such judgment or ruling would violate the basic legal principles of the PRC, its sovereignty or national security, or would not be in the public interest.

The Company Law, Special Regulations and Mandatory Provisions

The Company Law was adopted by the Standing Committee of the Eighth NPC at its Fifth Session on December 29, 1993 and came into effect on July 1, 1994. It was successively amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018. The latest revised Company Law came into effect on October 26, 2018.

The Special Regulations of the State Council on the Overseas Offering and the Listing of Shares by Joint Stock Limited Companies (《國務院關於股份有限公司境外募集股份及上市的特別規定》) (the “Special Regulations”) were passed at the 22nd Standing Committee Meeting of the State Council on July 4, 1994 and promulgated and implemented on August 4, 1994. The Special Regulations include provisions in respect of the overseas share offering and listing of joint stock limited companies.

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The Mandatory Provisions jointly promulgated by the former Securities Commission of the State Council and the former State Restructuring Commission on August 27, 1994 prescribe the provisions which must be incorporated in the articles of association of joint stock limited companies to be listed on overseas stock exchanges. Accordingly, the Mandatory Provisions have been incorporated in the Articles of Association of the Company. References to a "company" made in this Appendix are to a joint stock limited company established under the Company Law with H Shares to be issued. Set out below is a summary of the major provisions of the Company Law, the Special Regulations and the Mandatory Provisions.

General

A "joint stock limited company" refers to a corporate legal person established in China under the Company Law with independent legal person properties and entitlements to such legal person properties. The liability of the company is limited to the total amount of all assets it owns and the liability of its shareholders is limited to the extent of the shares they subscribe for.

Incorporation

A company may be incorporated by promotion or subscription. A company shall be incorporated by a minimum of two but no more than 200 promoters, and at least half of the promoters must be residents within the PRC. Companies incorporated by promotion are companies of which the entire registered capital is subscribed for by the promoters. Shares in the company incorporated by promotion shall not be offered to others unless the registered capital has been fully paid up. For companies incorporated by subscription, the registered capital is the total paid-up capital as registered with the relevant registration authorities. If laws, administrative regulations and decisions of the State Council have separate provisions on paid-in registered capital and the minimum registered capital, the company should follow such provisions.

For companies incorporated by way of promotion, the promoters shall subscribe in writing for the shares required to be subscribed for by them and pay up their capital contributions under the articles of association. Procedures relating to the transfer of titles to non-monetary assets shall be duly completed if such assets are to be contributed as capital. Promoters who fail to pay up their capital contributions in accordance with the foregoing provisions shall assume default liabilities in accordance with the covenants set out in the promoters' agreements. After the promoters have confirmed the capital contribution under the articles of association, a board of directors and a board of supervisors shall be elected and the board of directors shall apply for registration of incorporation by filing the articles of association with the company registration authority, and other documents as required by laws or administrative regulations.

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Where companies are incorporated by subscription, not less than 35% of their total number of shares must be subscribed for by the promoters, unless otherwise provided for by laws or administrative regulations. A promoter who offers shares to the public must publish a share offering prospectus and prepare a share subscription form to be completed, signed and sealed by subscribers, specifying the number and amount of shares to be subscribed for and the subscribers' addresses. The subscribers shall pay up monies for the shares they subscribe for. Where a promoter is offering shares to the public, such offer shall be underwritten by security companies established under PRC laws, and an underwriting agreement shall be concluded thereon. A promoter offering shares to the public shall also enter into agreements with banks in relation to the receipt of subscription monies. The receiving banks shall receive and keep in custody the subscription monies, issue receipts to subscribers who have paid the subscription monies and is obliged to furnish evidence of receipt of those subscription monies to relevant authorities. After the subscription monies for the share issue have been paid in full, a capital verification institution established under PRC laws must be engaged to conduct a capital verification and furnish a certificate thereon. The promoters shall preside over and convene an inauguration meeting within 30 days from the date of the full payment of subscription monies. The inauguration meeting shall be formed by the promoters and subscribers. Where the shares issued are not fully subscribed for within the offer period stipulated in the share offering prospectus, or where the promoter fails to convene an inauguration meeting within 30 days of the subscription monies for the shares issued being fully paid up, the subscribers may demand that the promoters refund the subscription monies so paid together with the interest calculated at bank rates of a deposit for the same period. Within 30 days of the conclusion of the inauguration meeting, the board of directors shall apply to the registration authority for registration of the establishment of the company. A company is formally established and has the status of a legal person after approval of registration has been given by the relevant administration bureau for industry and commerce and a business license has been issued.

A company's promoters shall be liable for:

- (i) the debts and expenses incurred in the incorporation process jointly and severally if the company cannot be incorporated;
- (ii) the refund of subscription monies paid by the subscribers together with interest calculated at bank rates of deposit for the same period jointly and severally if the company cannot be incorporated; and
- (iii) the compensation of any damages suffered by the company in the course of its incorporation as a result of the promoters' fault.

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Share Capital

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind, intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation of the assets contributed must be carried out pursuant to the provisions of laws or administrative regulations on valuation without any over-valuation or under-valuation.

The issuance of shares shall be conducted in a fair and equitable manner. Each share of the same class must carry equal rights. Shares issued at the same time and within the same class must be issued on the same conditions and at the same price. The same price per share shall be paid by any share subscriber (whether an entity or an individual). The share offering price may be equal to or greater than the par value of the share, but may not be less than the par value.

A company must obtain the approval of the CSRC to offer its shares to the overseas public. The Special Regulations and the Mandatory Provisions provide that shares issued to foreign investors and listed overseas shall be in registered form, denominated in Renminbi and subscribed for in foreign currencies. Shares issued to foreign investors and investors from the territories of Hong Kong, Macau and Taiwan and listed in Hong Kong are classified as H Shares, and those shares issued to investors within the PRC, except these regions above, are known as domestic shares. Under the Special Regulations, upon approval of the CSRC, a company may agree, in the underwriting agreement in respect of an issue of H Shares, to retain not more than 15% of the aggregate number of overseas listed foreign invested shares proposed to be issued in addition to the number of underwritten shares.

Under the Company Law, a company issuing registered share certificates shall maintain a shareholder registry which sets forth the following matters:

- (i) the name and domicile of each shareholder;
- (ii) the number of shares held by each shareholder;
- (iii) the serial numbers of shares held by each shareholder; and
- (iv) the date on which each shareholder acquired the shares.

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Increase in Share Capital

Pursuant to the Company Law, where a company is issuing new shares, resolutions shall be passed at general meeting in accordance with the articles of association in respect of the class and amount of the new shares, the issue price of the new shares, the commencement and end dates for the issue of the new shares and the class and amount of the new shares proposed to be issued to existing shareholders.

When a company launches a public issue of new shares upon the approval by the CSRC, a new share offering prospectus and financial accounting report must be published and a subscription form must be prepared. After the new share issue of the company has been paid up, the change must be registered with the relevant registration department and a public announcement must be made accordingly. Where an increase in registered capital of a company is made by means of an issue of new shares, the subscription of new shares by shareholders shall be made in accordance with the relevant provisions on the payment of subscription monies for the incorporation of a company.

Reduction of Share Capital

A company may reduce its registered capital in accordance with the following procedures prescribed by the Company Law:

- (i) the company shall prepare a balance sheet and an inventory of assets;
- (ii) the reduction of registered capital must be approved by shareholders at the general meeting;
- (iii) the company shall notify its creditors of the reduction in share capital within 10 days and publish an announcement of the reduction in newspapers within 30 days of the resolution approving the reduction being passed;
- (iv) the creditors of the company may within the statutory time limit require the company to repay its debts or provide guarantees for covering the debts; and
- (v) the company must apply to the relevant company registration authority for registration of the change and reduction in registered capital.

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Repurchase of Shares

Pursuant to the Company Law, a company shall not repurchase its own shares other than in any of the following circumstances:

- (i) reducing its registered capital;
- (ii) merging with another company which holds its shares;
- (iii) utilizing the shares for employee stock ownership plan or stock ownership incentive scheme;
- (iv) acquiring its own shares at the request of its shareholders who vote in a shareholders' general meeting against a resolution regarding a merger or separation;
- (v) utilizing the shares for conversion of corporate bonds which are convertible into shares issued by a listed company; and
- (vi) where it is necessary for a listed company to maintain its corporate value and stockholders' equity.

Any company's purchase of its own shares for any reason specified in item (i) and item (ii) of the preceding paragraph shall be subject to a resolution of the general meeting; any company's purchase of its own shares for any reason specified in item (iii), item (v) and item (vi) of the preceding paragraph may be subject to a resolution of the board meeting with more than two thirds of directors present, according to the provisions of the articles of associations or upon authorization by the general meeting.

The shares acquired under the circumstance stipulated in item (i) hereof shall be deregistered within 10 days from the date of acquisition of shares; the shares shall be assigned or deregistered within six months if the share buyback is made under the circumstances stipulated in either item (ii) or item (iv); and the shares held in total by a company after a share buyback under any of the circumstances stipulated in item (iii), item (v) or item (vi) shall not exceed 10% of the company's total outstanding shares, and shall be assigned or deregistered within three years.

Listed companies making a share buyback shall perform their obligation of information disclosure according to the provisions of the Securities Law of the People's Republic of China. If the share buyback is made under any of the circumstances stipulated in item (iii), item (v) or item (vi) hereof, centralized trading shall be adopted publicly.

A company shall not accept its own shares as the subject matter of pledge.

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Transfer of Shares

Shares held by shareholders may be transferred in accordance with the relevant laws. Pursuant to the Company Law, a shareholder should effect a transfer of his shares on a stock exchange established in accordance with laws or by any other means as required by the State Council. Registered shares may be transferred after the shareholders endorse the back of the share certificates or in any other manner specified by laws or administrative regulations. Following the transfer, the company shall enter the names and addresses of the transferees into its share register. No changes of registration in the share register described above shall be effected during a period of 20 days prior to convening a shareholders’ general meeting or 5 days prior to the record date for the purpose of determining entitlements to dividend distributions, subject to any legal provisions on the registration of changes in the share register of listed companies. The transfer of bearer share certificates shall become effective upon the delivery of the certificates to the transferee by the shareholder. The Mandatory Provision provides that changes due to share transfer should not be made to shareholder registry within 30 days before a shareholders’ general meeting or within 5 days before the record date for the purpose of determining entitlements to dividend distributions.

Pursuant to the Company Law, shares held by promoters may not be transferred within one year of the establishment of the company. Shares of the company issued prior to the public issue of shares may not be transferred within one year of the date of the company’s listing on a stock exchange. Directors, supervisors and the senior management of a company shall declare to the company their shareholdings in it and any changes in such shareholdings. During their terms of office, they may transfer no more than 25% of the total number of shares they hold in the company every year. They shall not transfer the shares they hold within one year of the date of the company’s listing on a stock exchange, nor within six months after they leave their positions in the company. The articles of association may set out other restrictive provisions in respect of the transfer of shares in the company held by its directors, supervisors and the senior management.

Shareholders

Under the Company Law and the Mandatory Provisions, the rights of shareholders include the rights:

- (i) to receive a return on assets, participate in significant decision-making and select management personnel;
- (ii) to petition the people’s court to revoke any resolution passed on a shareholders’ general meeting or a meeting of the board of directors that has not been convened in compliance with the laws, regulations or the articles of association or whose voting has been conducted in an invalid manner, or any resolution the contents of which is in violation of the articles of association, provided that such petition shall be submitted within 60 days of the passing of such resolution;

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- (iii) to transfer the shares of the shareholders according to the applicable laws and regulations and the articles of association;
- (iv) to attend or appoint a proxy to attend shareholders' general meetings and exercise the voting rights;
- (v) to inspect the articles of association, share register, counterfoil of company debentures, minutes of shareholders' general meetings, board resolutions, resolutions of the board of supervisors and financial and accounting reports, and to make suggestions or inquiries in respect of the company's operations;
- (vi) to receive dividends in respect of the number of shares held;
- (vii) to participate in distribution of residual properties of the company in proportion to their shareholdings upon the liquidation of the company; and
- (viii) any other shareholders' rights provided for in laws, administrative regulations, other normative documents and the articles of association.

The obligations of shareholders include the obligation to abide by the company's articles of association, to pay the subscription monies in respect of the shares subscribed for, to be liable for the company's debts and liabilities to the extent of the amount of subscription monies agreed to be paid in respect of the shares taken up by them and any other shareholder obligation specified in the articles of association.

Shareholders' General Meetings

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the Company Law. The general meeting may exercise its powers:

- (i) to decide on the company's operational objectives and investment plans;
- (ii) to elect and remove the directors and supervisors (not being representative(s) of employees) and to decide on the matters relating to the remuneration of directors and supervisors;
- (iii) to review and approve the reports of the board of directors;
- (iv) to review and approve the reports of the board of supervisors or supervisors;
- (v) to review and approve the company's annual financial budgets and final accounts plan;

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- (vi) to review and approve the company's profit distribution proposals and loss recovery proposals;
- (vii) to decide on any increase or reduction of the company's registered capital;
- (viii) to decide on the issue of corporate bonds;
- (ix) to decide on merger, division, dissolution and liquidation of the company or change of its corporate form;
- (x) to amend the company's articles of association; and
- (xi) to exercise any other authority stipulated in the articles of association.

Pursuant to the Company Law and the Mandatory Provisions, a shareholders' general meeting is required to be held once every year within six months after the end of the previous accounting year. An extraordinary general meeting is required to be held within two months of the occurrence of any of the following:

- (i) the number of directors is less than the number stipulated by the law or less than two thirds of the number specified in the articles of association;
- (ii) the outstanding losses of the company amounted to one-third of the company's total paid in share capital;
- (iii) shareholders individually or in aggregate holding 10% or more of the company's shares request that an extraordinary general meeting is convened;
- (iv) the board of directors deems necessary;
- (v) the board of supervisors so proposes; or
- (vi) any other circumstances as provided for in the articles of association.

A shareholders' general meeting shall be convened by the board of directors and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or is not performing his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or is not performing his duties, a director nominated by half or more of the directors shall preside over the meeting. Where the board of directors is incapable of performing or is not performing its duties to convene the general meeting, the board of supervisors shall convene and preside over such meeting in a timely manner. If the board of supervisors fails to convene and preside over such meeting, shareholders individually or in aggregate holding 10% or more of the company's shares for 90 days or more consecutively may unilaterally convene and preside over such meeting.

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In accordance with the Company Law, a notice of the general meeting stating the date and venue of the meeting and the matters to be considered at the meeting shall be given to all shareholders 20 days before the meeting. A notice of extraordinary general meeting shall be given to all shareholders 15 days prior to the meeting. For the issuance of bearer share certificates, the time and venue of and matters to be considered at the meeting shall be announced 30 days before the meeting.

In accordance with the Mandatory Provisions, a written notice of the general meeting stating the date and venue of the meeting and the matters to be considered at the meeting shall be given to all shareholders 45 days before the meeting. A shareholder who intends to attend the meeting shall deliver his written reply regarding his attendance of the meeting to the company 20 days before the date of the meeting.

There is no specific provision in the Company Law regarding the number of shareholders constituting a quorum in a shareholders’ general meeting, although the Special Regulations and the Mandatory Provisions provide that a company’s general meeting may be convened when written replies to the notice of that meeting from shareholders holding shares representing no less than 50% of the voting rights in the company have been received 20 days before the proposed date. If that 50% level is not achieved, the company shall notify shareholders again within five days by announcement of the matters to be considered at the meeting as well as the date and venue of the meeting, and the general meeting may be held by the company thereafter.

According to the Official Reply of the State Council on Adjusting the Provisions Governing Matters Including the Application of the Notice Period for the Convening of Shareholders’ General Meetings by Companies Listed Overseas (《國務院關於調整適用在境外上市公司召開股東大會通知期限等事項規定的批覆》) promulgated by the State Council on October 17, 2019, for those companies registered in the PRC and listed overseas, provisions and requirements stipulated in the Company Law in relation to the notice period, shareholders’ right to submit proposals to, and the procedures for convening, shareholders’ general meetings shall apply, and Article 20 to Article 22 of the Special Regulations shall no longer apply.

Pursuant to the Company Law, shareholders present at a shareholders’ general meeting have one vote for each share they hold, save that shares held by the company are not entitled to any voting rights.

An accumulative voting system may be adopted for the election of directors and supervisors at the general meeting pursuant to the provisions of the articles of association or a resolution of the general meeting. Under the accumulative voting system, each share shall be entitled to the number of votes equivalent to the number of directors or supervisors to be elected at the general meeting, and shareholders may consolidate their votes for one or more directors or supervisors when casting a vote.

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Pursuant to the Company Law, resolutions of the general meeting must be passed by more than half of the voting rights held by shareholders present at the meeting, with the exception of resolutions relating to merger, division or dissolution of the company, increase or reduction of registered share capital, change of corporate form or amendments to the articles of association, which in each case must be passed by more than two-thirds of the voting rights held by the shareholders present at the meeting. Where the Company Law and the articles of association provide that the transfer or acquisition of significant assets or the provision of external guarantees by the company must be approved by way of resolution of the general meeting, the board of directors shall convene a shareholders' general meeting promptly to vote on such matters.

A shareholder may entrust a proxy to attend the general meeting on his/her behalf. The proxy shall present the shareholders' power of attorney to the company and exercise voting rights within the scope of authorization.

Minutes shall be prepared in respect of matters considered at the general meeting and the chairman and directors attending the meeting shall endorse such minutes by signature. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

Pursuant to the Mandatory Provisions, the increase or reduction of share capital, the issuance of shares of any class, warrants or other similar securities and corporate bonds, the division, merger, dissolution and liquidation of the company, the amendments to the articles of association and any other matters, which, as resolved by way of an ordinary resolution of the general meeting, may have a material impact on the company and require adoption by way of a special resolution, must be approved through special resolutions by more than two-thirds of the voting rights held by shareholders (including his/her proxies) present at the meeting.

The Mandatory Provisions require a special resolution to be passed at the general meeting and a class meeting to be held in the event of a variation or derogation of the class rights of a shareholder class. For this purpose, holders of domestic shares and H Shares are deemed to be shareholders of different classes.

Board of Directors

A company shall have a board of directors which shall consist of 5 to 19 members. Members of the board of directors may include staff representatives, who shall be democratically elected by the company's staff at a staff representative assembly, general staff meeting or otherwise. The term of a director shall be stipulated in the articles of association, provided that no term of office shall last for more than three years. A director may serve consecutive terms if re-elected. A director shall continue to perform his/her duties as a director in accordance with the laws, administrative regulations and the articles of association until a duly re-elected director takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of directors results in the number of directors being less than the quorum.

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Under the Company Law, the board of directors may exercise its powers:

- (i) to convene shareholders' general meetings and report on its work to the shareholders' general meetings;
- (ii) to implement the resolutions passed by the shareholders at the shareholders' general meetings;
- (iii) to decide on the company's operational plans and investment proposals;
- (iv) to formulate proposals for the company's annual financial budgets and final accounts;
- (v) to formulate the company's profit distribution proposals and loss recovery proposals;
- (vi) to formulate proposals for the increase or reduction of the company's registered capital and the issue of corporate bonds;
- (vii) to formulate proposals for the merger, division or dissolution of the company or change of corporate form;
- (viii) to decide on the setup of the company's internal management organs;
- (ix) to appoint or dismiss the company's manager and decide on his/her remuneration and, based on the manager's recommendation, to appoint or dismiss any deputy manager and financial officer of the company and to decide on their remunerations;
- (x) to formulate the company's basic management system; and
- (xi) to exercise any other authority stipulated in the articles of association.

Meetings of the board of directors shall be convened at least twice each year. Notices of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of the voting rights, more than one-third of the directors or the board of supervisors. The chairman shall convene the meeting within 10 days of receiving such proposal, and preside over the meeting. The board of directors may otherwise determine the means and the period of notice for convening an interim board meeting. Meetings of the board of directors shall be held only if more than half of the directors are present. Resolutions of the board of directors shall be passed by more than half of all directors. Each director shall have one vote for a resolution to be approved by the board of directors. Directors shall attend the meetings of the board of directors in person. If a director is unable to attend for any reason, he/she may appoint another director to attend the meeting on his/her behalf by a written power of attorney specifying the scope of authorization. The board of directors shall make minutes of the meeting's decisions on the matters discussed at the meeting, and the directors attending the meeting shall sign the minutes.

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If a resolution of the board of directors violates any laws, administrative regulations or the articles of association or resolutions of the general meeting, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director shall be relieved from that liability.

Under the Company Law, the following person may not serve as a director in a company:

- (i) a person who is unable or has limited ability to undertake any civil liabilities;
- (ii) a person who has been convicted of an offense of corruption, bribery, embezzlement, misappropriation of property or destruction of the socialist economic order, or who has been deprived of his political rights due to his crimes, in each case where no more than five years have elapsed since the date of completion of the sentence;
- (iii) a person who has been a former director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where no more than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise;
- (iv) a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law or has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation; and
- (v) a person who is liable for a relatively large amount of debts that are overdue.

Where a company elects or appoints a director to which any of the above circumstances applies, such election or appointment shall be null and void. A director to which any of the above circumstances applies during his/her term of office shall be released of his/her duties by the company.

In addition, the Mandatory Provisions further stipulate other circumstances under which a person is disqualified from acting as a director of a company, including: (1) the person is under investigation by the judicial authorities after a claim has been brought for violating the criminal law and the case has yet to be settled; (2) a person cannot assume the position of leader of an enterprise according to laws and administrative regulations; (3) the person is not a natural person; and (4) no more than 5 years has elapsed since the date the person was found to be in violation of the provisions of relevant securities regulations and was involved in deceitful or dishonest activities as ruled by the competent authority.

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Pursuant to the Company Law, the board of directors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman shall be elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and review the implementation of board resolutions. The vice chairman shall assist the chairman to perform his/her duties. Where the chairman is incapable of performing or is not performing his/her duties, the duties shall be performed by the vice chairman. Where the vice chairman is incapable of performing or is not performing his/her duties, a director elected by more than half of the directors shall perform his/her duties.

Board of Supervisors

Pursuant to the Company Law, a company shall have a board of supervisors composed of not less than three members. The board of supervisors shall consist of representatives of the shareholders and an appropriate proportion of representatives of the company's staff, among which the proportion of representatives of the company's staff shall not be less than one-third, and the actual proportion shall be determined in the articles of association. Representatives of the company's staff at the board of supervisors shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. The board of supervisors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the board of supervisors shall be elected by more than half of the supervisors. Directors and senior management shall not act concurrently as supervisors.

The chairman of the board of supervisors shall convene and preside over board of supervisors meetings. Where the chairman of the board of supervisors is incapable of performing or is not performing his/her duties, the vice chairman of the board of supervisors shall convene and preside over supervisory board meetings. Where the vice chairman of the board of supervisors is incapable of performing or is not performing his/her duties, a supervisor nominated by more than half of the supervisors shall convene and preside over meetings of the board of supervisors.

Each term of office of a supervisor is three years and he/she may serve consecutive terms if re-elected. A supervisor shall continue to perform his/her duties as a supervisor in accordance with the laws, administrative regulations and the articles of association until a duly re-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of supervisors results in the number of supervisors being less than the quorum.

The board of supervisors may exercise its powers:

- (i) to review the company's financial position;
- (ii) to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or shareholders' resolutions;

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- (iii) when the acts of directors or senior management personnel are detrimental to the company's interests, to require the director and senior management to correct these acts;
- (iv) to propose the convening of extraordinary shareholders' general meetings and to convene and preside over shareholders' general meetings when the board fails to perform the duty of convening and presiding over shareholders' general meetings under the Company Law;
- (v) to submit proposals to the shareholders' general meetings;
- (vi) to bring actions against directors and senior management personnel pursuant to the relevant provisions of the Company Law; and
- (vii) to exercise any other authority stipulated in the articles of association.

Supervisors may be present at board meetings and make inquiries or proposals in respect of the resolutions of the board. The board of supervisors may investigate any irregularities identified in the operation of the company and, when necessary, may engage an accounting firm to assist its work at the cost of the company.

Manager and Senior Management

Pursuant to the Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. The manager may exercise his/her powers:

- (i) to manage the production, operation and administration of the company and arrange for the implementation of the resolutions of the board of directors;
- (ii) to arrange for the implementation of the company's annual operation plans and investment proposals;
- (iii) to formulate proposals for the establishment of the company's internal management organs;
- (iv) to formulate the fundamental management system of the company;
- (v) to formulate the company's specific rules and regulations;
- (vi) to recommend the appointment or dismissal of any deputy manager and any financial officer of the company;
- (vii) to appoint or dismiss management personnel (other than those required to be appointed or dismissed by the board of directors); and
- (viii) to exercise any other authority granted by the board of directors.

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Other provisions in the articles of association on the manager's powers shall also be complied with. The manager shall be present at meetings of the board of directors. However, the manager shall have no voting rights at meetings of the board of directors unless he/she concurrently serves as a director.

Pursuant to the Company Law, senior management refers to the manager, deputy manager, financial officer, secretary to the board of directors of a listed company and other personnel as stipulated in the articles of association.

Duties of Directors, Supervisors, Managers and Other Senior Management

Directors, supervisors and senior management are required under the Company Law to comply with the relevant laws, regulations and the articles of association, and shall be obliged to be faithful and diligent towards the Company.

Directors, supervisors and management personnel are prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's property. Directors and senior management are prohibited from:

- (i) misappropriating company funds;
- (ii) depositing company funds into accounts under their own names or the names of other individuals;
- (iii) loaning company funds to others or providing guarantees in favor of others supported by company's property in violation of the articles of association or without approval of the general meeting or the board of directors;
- (iv) entering into contracts or transactions with the company in violation of the articles of association or without approval of the general meeting;
- (v) using their position to procure business opportunities for themselves or others that should have otherwise been available to the company or operating businesses similar to that of the company for their own benefits or on behalf of others without approval of the general meeting;
- (vi) accepting commissions paid by a third party for transactions conducted with the company for their own benefit;
- (vii) unauthorized divulgence of confidential information of the company; and
- (viii) other acts in violation of their duty of loyalty to the company.

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Income generated by directors or senior management in violation of aforementioned shall be returned to the company.

A director, supervisor or senior management who contravenes any laws, regulations or the company's articles of association in the performance of his/her duties resulting in any loss to the company shall be liable to the company for compensation.

Where a director, supervisor or senior management is required to attend a shareholders' general meeting, such director, supervisor or senior management shall attend the meeting and answer the inquiries from shareholders. Directors and senior management shall furnish all true information and materials to the board of supervisors, without impeding the discharge of duties by the board of supervisors or supervisors.

Where a director or senior management contravenes any laws, regulations or the company's articles of association in the performance of his/her duties resulting in any loss to the company, shareholder(s) holding individually or in aggregate more than 1% of the company's shares consecutively for more than 180 days may request in writing that the board of supervisors institute litigation at a people's court. Where the board of supervisors violates the laws or administrative regulations or the articles of association in the discharge of its duties resulting in any loss to the company, such shareholder(s) may request in writing that the board of directors institute litigation at a people's court on its behalf. If the board of supervisors or the board of directors refuses to institute litigation after receiving the abovementioned written request from the shareholder(s), or fails to institute litigation within 30 days of the date of receiving the request, or in case of emergency where failure to institute litigation immediately will result in irrecoverable damage to the company's interests, such shareholder(s) shall have the power to institute litigation directly at a people's court in its own name for the company's benefit. For other parties who infringe the lawful interests of the company resulting in loss to the company, such shareholder(s) may institute litigation at a people's court in accordance with the procedure described above. Where a director or senior management contravenes any laws, administrative regulations or the articles of association in infringement of shareholders' interests, a shareholder may also institute litigation at a people's court.

The Special Regulations and the Mandatory Provisions provide that a company's directors, supervisors, managers and other senior management shall have fiduciary duties towards the company. They are required to faithfully perform their duties, to protect the interests of the company and not to use their positions in the company for their own benefits. The Mandatory Provisions contain detailed stipulations on these duties.

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Finance and Accounting

Pursuant to the Company Law, a company shall establish its own financial and accounting systems according to the laws, administrative regulations and the regulations of the competent financial departments of the State Council. At the end of each financial year, a company shall prepare a financial report which shall be audited by an accounting firm in accordance with the laws. The financial and accounting reports shall be prepared in accordance with the laws, administrative regulations and the regulations of the financial departments of the State Council.

The company's financial reports shall be made available for shareholders' inspection at the company 20 days before the convening of an annual general meeting. A joint stock limited company that makes public stock offerings shall publish its financial reports.

When distributing each year's profits after taxation, the company shall set aside 10% of its profits after taxation for the company's statutory common reserve fund until the fund has reached more than 50% of the company's registered capital. When the company's statutory common reserve fund is not sufficient to make up for the company's losses for the previous years, the current year's profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon passing a resolution at a shareholders' general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its discretionary common reserve fund, the remaining profits after taxation shall be distributed in proportion to the number of shares held by the shareholders, except for those which are not distributed in a proportionate manner as provided by the articles of association.

Profits distributed to shareholders by a resolution of a shareholders' general meeting or the board of directors before losses have been made good and allocations have been made to the statutory common reserve fund in violation of the requirements described above must be returned to the company. The company shall not be entitled to any distribution of profits in respect of shares held by it.

The premium over the nominal value of the shares of the company on issue and other income as required by relevant government authorities to be treated as the capital reserve fund shall be accounted for as the capital reserve fund. The common reserve fund of a company shall be applied to make good the company's losses, expand its business operations or increase its capital. The capital reserve fund, however, shall not be used to make good the company's losses. Upon the transfer of the statutory common reserve fund into capital, the balance of the fund shall not be less than 25% of the registered capital of the company before such transfer.

The company shall have no accounting books other than the statutory books. The company's assets shall not be deposited in any account opened under the name of an individual.

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Appointment and Dismissal of Auditors

Pursuant to the Company Law, the appointment or dismissal of an accounting firm responsible for the company’s auditing shall be determined by shareholders at a shareholders’ general meeting or the board of directors in accordance with the articles of association. The accounting firm should be allowed to make representations when the general meeting or the board of directors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidence, accounting books, financial and accounting reports and other accounting information to the engaged accounting firm without any refusal, withholding or falsification of information.

The Special Regulations require a company to engage an independent qualified accounting firm to audit the company’s annual reports and to review and check other financial reports of the company. The accounting firm’s term of office shall commence from the end of the shareholders’ annual general meeting to the end of the next shareholders’ annual general meeting.

Profit Distribution

According to the Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve fund is provided. The Special Regulations require that dividends and other distributions to be paid to holders of H Shares shall be declared and calculated in RMB and paid in foreign currencies. Under the Mandatory Provisions, the payment of foreign currency to shareholders shall be made through receiving agents.

Amendments to the Articles of Association

Pursuant to the Company Law, the resolution of a shareholders’ general meeting regarding any amendment to a company’s articles of association requires affirmative votes by more than two-thirds of the votes held by shareholders attending the meeting. Pursuant to the Mandatory Provisions, the company may amend its articles of association according to the laws, administrative regulations and the articles of association. The amendment to articles of association involving content of the Mandatory Provisions will only be effective upon approval of the department in charge of company examination and approval and the securities regulatory department authorized by the State Council, while the amendment to articles of association involving matters of company registration must be registered with the relevant authority in accordance with applicable laws.

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Dissolution and Liquidation

Pursuant to the Company Law, a company shall be dissolved for any of the following reasons:

- (i) the term of its operation set out in the articles of association has expired or other events of dissolution specified in the articles of association have occurred;
- (ii) the shareholders have resolved at a shareholders' general meeting to dissolve the company;
- (iii) the company is dissolved by reason of its merger or division;
- (iv) the business license of the company is revoked or the company is ordered to close down or to be dissolved in accordance with the laws; or
- (v) the company is dissolved by a people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all shareholders of the company, on the grounds that the operation and management of the company has suffered serious difficulties that cannot be resolved through other means, rendering ongoing existence of the company a cause for significant losses to the shareholders' interests.

In the event of paragraph (i) above, the company may carry on its existence by amending its articles of association. The amendments to the articles of association in accordance with the provisions described above shall require the approval of more than two-thirds of voting rights of shareholders attending a shareholders' general meeting.

Where the company is dissolved under the circumstances set forth in paragraph (i), (ii), (iv) or (v) above, it should establish a liquidation committee within 15 days of the date on which the dissolution matter occurs. The liquidation committee shall be composed of directors or any other persons determined by a shareholders' general meeting. If a liquidation committee is not established within the prescribed period, the company's creditors may file an application with a people's court, requesting that the court appoint relevant personnel to form a liquidation committee to administer the liquidation. The people's court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

The liquidation committee may exercise following powers during the liquidation:

- (i) to dispose of the company's assets and to prepare a balance sheet and an inventory of assets;
- (ii) to notify the company's creditors or publish announcements;

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- (iii) to deal with and settle any outstanding business related to the liquidation;
- (iv) to pay any overdue tax together with any tax arising during the liquidation process;
- (v) to settle the company's claims and liabilities;
- (vi) to handle the company's remaining assets after its debts have been paid off; and
- (vii) to represent the company in any civil procedures.

The liquidation committee shall notify the company's creditors within 10 days from its establishment, and publish an announcement in newspapers within 60 days.

A creditor shall lodge his claim with the liquidation committee within 30 days of receipt of the notification or within 45 days of the date of the announcement if he has not received any notification.

A creditor shall, in making his claim, state matters relevant to his creditor's rights and furnish relevant evidence. The liquidation committee shall register such creditor's rights. The liquidation committee shall not make any settlement to creditors during the period of the claim.

Upon disposal of the company's property and preparation of the required balance sheet and inventory of assets, the liquidation committee shall draw up a liquidation plan and submit this plan to a shareholders' general meeting or a people's court for endorsement. The remaining assets of the company, after payment of liquidation expenses, employee wages, social insurance expenses and statutory compensation, outstanding taxes and the company's debts, shall be distributed to shareholders in proportion to shares held by them. The company shall continue to exist during the liquidation period, although it cannot engage in operating activities that are not related to the liquidation. The company's property shall not be distributed to shareholders before repayments are made in accordance with the requirements described above.

Upon liquidation of the company's property and preparation of the required balance sheet and inventory of assets, if the liquidation committee becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to a people's court for a declaration of bankruptcy in accordance with the laws. Following such declaration by the people's court, the liquidation committee shall hand over the administration of the liquidation to the people's court.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report and submit it to the shareholders' general meeting or a people's court for confirmation of its completion, and to the company registration authority to cancel the company's registration, and an announcement of its termination shall be published. Members of the liquidation committee are required to discharge their duties in good faith and in compliance

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with relevant laws. Members of the liquidation committee shall be prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's properties. Members of the liquidation committee are liable to indemnify the company and its creditors in respect of any loss arising from their willful or material default.

Liquidation of a company declared bankrupt according to laws shall be processed in accordance with the laws on corporate bankruptcy.

Overseas Listing

The shares of a company shall only be listed overseas after obtaining approval from CSRC, and the listing must be arranged in accordance with procedures specified by the State Council. Pursuant to the Special Regulations, a company may issue shares to overseas investors and list its shares overseas upon approval from the CSRC. Subject to approval of the company's plans to issue overseas-listed foreign shares and domestic shares by the CSRC, the board of directors of the company may make arrangement to implement such plans for the issuance of the foreign shares and domestic shares, respectively, within fifteen (15) months from the date of approval by the CSRC.

At the same time, according to the provisions of the Mandatory Provisions, if the company's shares determined by the company's issuance plan are not fully issued, new shares which were not included in the original issue plan shall not be issued by the company. If the company needs to adjust the issuance plan, the general meeting of shareholders shall make a resolution. After being approved by the company's examination and approval department authorized by the State Council, it shall be submitted to the CSRC for examination and approval.

Loss of Share Certificates

A shareholder may, in accordance with the public notice procedures set out in the PRC Civil Procedure Law, apply to a people's court if his share certificate(s) in registered form is either stolen, lost or destroyed, for a declaration that such certificate(s) will no longer be valid. After such a declaration has been obtained, the shareholder may apply to the company for the issue of a replacement certificate(s).

A separate procedure regarding the loss of share certificates and H Share certificates of the overseas-listed foreign shareholders of the PRC is provided for in the Mandatory Provisions, details of which are set out in the articles of association.

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Merger and Division

Pursuant to the Company Law, a merger agreement shall be signed by merging companies and the involved companies shall prepare respective balance sheets and inventory of assets. The companies shall within 10 days from the date of passing the resolution approving the merger notify their respective creditors and publicly announce the merger in newspapers within 30 days. A creditor may, within 30 days of receipt of the notification, or within 45 days from the date of the announcement if he has not received the notification, request the company to settle any outstanding debts or provide corresponding guarantees.

In case of a merger, the credits and debts of the merging parties shall be assumed by the surviving or the new company. In case of a division, the company’s assets shall be divided and a balance sheet and an inventory of assets shall be prepared. When a resolution regarding the company’s division is approved, the company should notify all its creditors within 10 days from the date of passing such resolution and publicly announce the division in newspapers within 30 days. Unless an agreement in writing is reached with creditors in respect of the settlement of debts, the liabilities of the company which have accrued prior to the separation shall be jointly borne by the separated companies.

Changes in the registration as a result of the merger or division shall be registered with the relevant administration authority.

The PRC Securities Laws, Regulations and Regulatory Regimes

The PRC has promulgated a series of regulations that relate to the issue and trading of the shares and disclosure of information. In October 1992, the State Council established the Securities Committee and the CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities-related institutions in the PRC and administering the CSRC. The CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions governing securities markets, supervising securities companies, regulating public offerings of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the Securities Committee and the CSRC and reformed the CSRC.

On April 22, 1993, the State Council promulgated the Provisional Regulations Concerning the Issue and Trading of Shares (《股票發行與交易管理暫行條例》) govern the application and approval procedures for public offerings of equity securities, trading in equity securities, the acquisition of listed companies, deposit, clearing and transfer of listed equity securities, the disclosure of information, investigation, penalties and dispute resolutions with respect to a listed company.

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On December 25, 1995, the State Council promulgated the Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies (《國務院關於股份有限公司境內上市外資股的規定》). These regulations principally govern the issue, subscription, trading and declaration of dividends, other distributions of domestic listed foreign shares and disclosure of information of joint stock limited companies having domestic listed foreign shares.

The Securities Law of the PRC (《中華人民共和國證券法》) (the “PRC Securities Law”) took effect on July 1, 1999 and was revised as of August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest revised PRC Securities Law came into effect on March 1, 2020. It was the first national securities law in the PRC, and is divided into 14 chapters and 226 articles regulating, among other matters, the issue and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of the State Council’s securities regulatory authorities. The PRC Securities Law comprehensively regulates activities in the PRC securities market. Article 224 of the PRC Securities Law provides that domestic enterprises shall satisfy the relevant requirements of the State Council when it issues or lists shares outside the PRC directly or indirectly. Currently, the issue and trading of foreign issued securities (including shares) are principally governed by the rules and regulations promulgated by the State Council and the CSRC.

Arbitration and Enforcement of Arbitral Awards

The Arbitration Law of the PRC (《中華人民共和國仲裁法》) (the “PRC Arbitration Law”) was enacted by the Standing Committee of the NPC on August 31, 1994, which became effective on September 1, 1995 and was amended on August 27, 2009 and September 1, 2017. The PRC Arbitration Law is applicable to, among other matters, economic disputes involving foreign parties where all parties have entered into a written agreement to resolve disputes by arbitration before an arbitration committee constituted in accordance with the PRC Arbitration Law. The PRC Arbitration Law provides that an arbitration committee may, before the promulgation of arbitration regulations by the PRC Arbitration Association, formulate interim arbitration rules in accordance with the PRC Arbitration Law and the PRC Civil Procedure Law. Where the parties have agreed to settle disputes by means of arbitration, a people’s court will refuse to handle a legal proceeding initiated by one of the parties at such people’s court, unless the arbitration agreement has lapsed.

The Listing Rules and the Mandatory Provisions require an arbitration clause to be included in the articles of association of a company listed in Hong Kong and, in the case of the Listing Rules, in a contract between the company and each of the directors and supervisors. Pursuant to such clause, whenever a dispute or claim arises from any right or obligation provided in the abovementioned contracts, the articles of association, the Company Law or other relevant laws and administrative regulations concerning the affairs of the company between (i) a holder of overseas listed foreign shares and the company; (ii) a holder of overseas listed foreign shares and a holder of domestic shares; (iii) a holder of overseas listed foreign

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shares and the company’s directors, supervisors or other management personnel; or (iv) the company and its directors or officers, such parties shall be required to refer such dispute or claim to arbitration at either the China International Economic and Trade Arbitration Commission (the “CIETAC”) or the Hong Kong International Arbitration Center (the “HKIAC”). Disputes in respect of the definition of shareholder and disputes in relation to the company’s shareholder registry need not be resolved by arbitration. If the party seeking arbitration elects to arbitrate the dispute or claim at the HKIAC, then either party may apply to have such arbitration conducted in Shenzhen in accordance with the securities arbitration rules of the HKIAC.

Under the PRC Arbitration Law and the PRC Civil Procedure Law, an arbitral award shall be final and binding on the parties involved in the arbitration. If any party fails to comply with the arbitral award, the other party to the award may apply to a people’s court for its enforcement. A people’s court may refuse to enforce an arbitral award made by an arbitration commission if there is any procedural irregularity (including, but not limited to, irregularity in the composition of the arbitration committee, the jurisdiction of the arbitration commission, or the making of an award on matters beyond the scope of the arbitration agreement).

Any party seeking to enforce an arbitral award of a foreign affairs arbitration organ of the PRC against a party who or whose property is not located within the PRC may apply to a foreign court with jurisdiction over the case for recognition and enforcement of the award. Likewise, an arbitral award made by a foreign arbitration body may be recognized and enforced by a PRC court in accordance with the principle of reciprocity or any international treaties concluded or acceded to by the PRC.

The PRC acceded to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the “New York Convention”) adopted on June 10, 1958 pursuant to a resolution of the Standing Committee of the NPC passed on December 2, 1986. The New York Convention provides that all arbitral awards made in a state which is a party to the New York Convention shall be recognized and enforced by other parties thereto subject to their rights to refuse enforcement under certain circumstances, including where the enforcement of the arbitral award is against the public policy of that state. At the time of the PRC’s accession to the Convention, the Standing Committee of the NPC declared that (i) the PRC will only apply the New York Convention to the recognition and enforcement of arbitral awards made in the territory of another contracting state based on the principle of reciprocity; and (ii) the New York Convention will only apply to disputes deemed under PRC law to be arising from contractual or non-contractual mercantile legal relations.

An agreement has been reached between Hong Kong and the Supreme People’s Court of the PRC for the mutual enforcement of arbitral awards. On June 18, 1999, the Supreme People’s Court of the PRC adopted the Arrangement on Mutual Enforcement of Arbitral Awards between Mainland and Hong Kong Special Administrative Region (《關於內地與香港特別行政區相互執行仲裁裁決的安排》), which became effective on February 1, 2000. The arrangement is made in accordance with the spirit of the New York Convention. Pursuant to

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this arrangement, awards made by PRC arbitral authorities acknowledged by Hong Kong arbitration rules can be enforced in Hong Kong, and Hong Kong arbitration awards are also enforceable in the Mainland. Where a court of the Mainland finds that enforcement in the Mainland of the ruling made by the Hong Kong arbitral authority will violate public interests of the Mainland, execution of the ruling may be ignored. On November 26, 2020, the Supreme People’s Court of the PRC published the Supplemental Arrangement on Mutual Enforcement of Arbitral Awards between Mainland and Hong Kong Special Administrative Region (《關於內地與香港特別行政區相互執行仲裁裁決的補充安排》), which expands the scope of awards that can be acknowledged and enforced. Arbitration awards made in accordance with the PRC Arbitration Law may be applied for acknowledgement and enforcement in Hong Kong, and arbitration awards made in accordance with the Arbitration Ordinance of the Hong Kong may be applied for acknowledgement and enforcement in the Mainland.

HONG KONG LAWS AND REGULATIONS

Material Differences between Certain Aspects of Corporation Law in the PRC and Hong Kong

Hong Kong company law is primarily set out in the Companies Ordinance and the Companies (Winding Up and Miscellaneous Provisions) Ordinance, supplemented by common law and rules of equity that apply to Hong Kong. As a joint stock limited company incorporated in the PRC that is seeking a listing of shares on the Stock Exchange, we are governed by the Company Law and all other rules and regulations promulgated pursuant to the Company Law. Set out below is a summary of certain material differences between Hong Kong company law and the Company Law. This summary is, however, not intended to be an exhaustive comparison.

Corporate Existence

Under Hong Kong company law, a company with share capital is incorporated by the Registrar of Companies in Hong Kong, which issues a certificate of incorporation to the Company upon its incorporation, and the company will acquire an independent corporate existence henceforth. A company may be incorporated as a public company or a private company. Pursuant to the Companies Ordinance, the articles of association of a private company incorporated in Hong Kong shall contain certain pre-emptive provisions. A public company’s articles of association do not contain such pre-emptive provisions.

Under the Company Law, a joint stock limited company may be incorporated by promotion or public subscription.

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Share Capital

Under Hong Kong law, the directors of a Hong Kong company may, with the prior approval of the shareholders if required, issue new shares of the company. The Company Law has no provisions on minimum registered capital of joint stock companies, except that laws, administrative regulations and State Council decisions have separate provisions on paid-in registered capital and the minimum registered capital of joint stock companies, in which case the company should follow such provisions. The Company’s registered capital is the amount of its issued share capital. Any increase in the Company’s registered capital must be approved at the general meeting and shall be approved by/filed with the relevant PRC governmental and regulatory authorities (if applicable).

The Companies Ordinance does not prescribe any minimum capital requirement for companies incorporated in Hong Kong.

Under the Company Law, the shares may be subscribed for in the form of money or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws or administrative regulations). For non-monetary assets to be used as capital contributions, appraisals must be carried out to ensure there is no over-valuation or under-valuation of the assets. There is no such restriction on a company incorporated in Hong Kong.

Restrictions on Shareholding and Transfer of Shares

Generally, Domestic Shares, which are denominated and subscribed for in Renminbi, can be subscribed for and traded by PRC investors, qualified overseas institutional investors or qualified overseas strategic investors.

Overseas listed shares, which are denominated in Renminbi and subscribed for in a currency other than Renminbi, may only be subscribed for, and traded by, investors from Hong Kong, Macau and Taiwan or any country and territory outside the PRC, or qualified domestic institutional investors. If the H shares are eligible securities under the Southbound Trading Link, they are also subscribed for and traded by PRC investors in accordance with the rules and limits of Shanghai-Hong Kong Stock Connect or Shenzhen-Hong Kong Stock Connect. When the application for “full circulation” has been approved by the CSRC, the domestic unlisted shares of the H-share listed company might be listed and circulated on the Stock Exchange.

Under the Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares it holds for a period of one year after the date of establishment of the company. Shares in issue prior to a public offering of the company cannot be transferred within one year from the listing date of the shares on a stock exchange. Shares in a joint stock limited liability company held by its directors, supervisors and senior management and transferred each year during their term of office shall not exceed 25% of the total shares they held in a company, and the shares they held in a company cannot be transferred within one year from

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the listing date of the shares, and also cannot be transferred within half a year after the said personnel has left office. The articles of association may set other restrictive requirements on the transfer of a company's shares held by its directors, supervisors and senior management. There are no restrictions on shareholdings and transfers of shares under Hong Kong law apart from (i) the restriction on the Company to issue additional Shares within six months, and (ii) 12-month lockup on Controlling Shareholders' disposal of Shares, after the [REDACTED].

Financial Assistance for Acquisition of Shares

The Company Law does not prohibit or restrict a joint stock limited company or its subsidiaries from providing financial assistance for the purpose of an acquisition of its own or its holding company's shares. However, the Mandatory Provisions contain certain restrictions on a company and its subsidiaries on providing such financial assistance similar to those under Hong Kong company law.

Notice of Shareholders' Meetings

Under the Company Law, notice of a shareholder's annual general meeting must be given not less than 20 days before the meeting. Whereas notice of an extraordinary general meeting must be given not less than 15 days before the meeting. If a company issues bearer shares, notice of a shareholder's general meeting must be given at least 30 days prior to the meeting.

For a company incorporated in Hong Kong with limited liability, the minimum period of notice of a general meeting is 14 days. Further, where a meeting involves consideration of a resolution requiring special notice, the company must also give its shareholders notice of the resolution at least 14 days before the meeting. The notice period for the annual shareholders' general meeting is 21 days.

Quorum for Shareholders' Meetings

The Company Law does not specify any quorum requirement for a shareholders' general meeting.

Under Hong Kong law, the quorum for a shareholders' meeting is two members, unless the articles of association of a company specifies otherwise or the company has only one member, in which case the quorum is one.

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Voting at Shareholders’ Meetings

Under the Company Law, the passing of any resolution requires more than one-half of the voting rights represented by our shareholders present in person or by proxy at a shareholders’ meeting except in cases such as proposed amendments to our Articles of Association, increase or decrease of registered capital, merger, division, dissolution or transformation, which require more than two-thirds of the voting rights represented by shareholders present in person or by proxy at a shareholders’ general meeting.

Under Hong Kong law, an ordinary resolution is passed by a simple majority of affirmative votes cast by shareholders present in person, or by proxy, at a general meeting, and a special resolution is passed by not less than three-fourths of affirmative votes casted by shareholders present in person, or by proxy, at a general meeting.

Variation of Class Rights

The Company Law makes no specific provision relating to variation of class rights. However, the Company Law states that the State Council can promulgate requirements relating to other kinds of shares. The Mandatory Provisions contain detailed provisions relating to the circumstances which are deemed to be variations of class rights and the approval procedures required to be followed in respect thereof. These provisions have been incorporated in the Articles of Association, which are summarized in “Appendix IV — Summary of the Articles of Association of the Company.”

Under the Companies Ordinance, no rights attached to any class of shares can be varied except (i) with the passing of a special resolution by the shareholders of the relevant class at a separate meeting sanctioning the variation, (ii) with the written consent of shareholders representing at least three-fourths of the total voting rights of shareholders of the relevant class, or (iii) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

As required by the Listing Rules and the Mandatory Provisions, we have adopted in the Articles of Association provisions protecting class rights in a similar manner to those found in Hong Kong law. Holders of overseas listed shares and domestic shares are defined in the Articles of Association as different classes. The special procedures for voting by a class of Shareholders shall not apply in the following circumstances: (i) where we issue, either separately or concurrently in any 12-month period, upon approval by special resolutions passed at a general meeting, domestic shares and H shares not more than 20% of each of the existing domestic shares and H shares, respectively; (ii) where the plan for the issue of domestic shares and H shares upon our establishment is fulfilled within 15 months following the date of approval by the securities regulatory authorities under the State Council; and (iii) with the approval of the securities regulatory authority under the State Council and with the consent of the HKEX, the Company’s domestic shares may be transferred to foreign investors and listed on the overseas stock exchange, and all or part of the domestic shares of the Company may be converted into foreign shares, and the converted shares may be listed and traded on the overseas stock exchange.

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Derivative Action By Minority Shareholders

Under Hong Kong company law, a shareholder may, with the leave of the Court, start a derivative action on behalf of a company for any misconduct committed by its directors against the company. For example, leave may be granted where the directors control a majority of votes at a general meeting, and could thereby prevent the company from suing the directors in its own name.

Pursuant to the Company Law, in the event where the directors and senior management violate their obligations and cause damages to a company, shareholders of a joint stock limited company individually or jointly holding more than 1% of the shares in the company for more than 180 consecutive days may request in writing the board of supervisors to initiate proceedings in the people’s court. In the event that the board of supervisors violates their obligations and cause damages to a company, the above said shareholders may send written request to the board of directors to initiate proceedings in the people’s court. Upon receipt of such written request from the shareholders, if the board of supervisors or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days upon receipt of the request, or if under urgent situations, failure of initiating immediate proceeding may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company’s interests, have the right to initiate proceedings directly to the people’s court in their own name. In addition, the Mandatory Provisions provide us with certain remedies against the Directors, Supervisors and senior management who breach their duties to the Company. In addition, as a condition to the listing of overseas listed foreign Shares on the Stock Exchange, each director and supervisor of a joint stock limited company is required to give an undertaking to observe the articles of association in favor of the company. This allows minority Shareholders to take action against our Directors and Supervisors in default.

Minority Shareholder Protection

Under the Companies Ordinance, a shareholder who alleges that the affairs of a company are conducted in a manner unfairly prejudicial to his interests may petition to the Court to make an appropriate order to give relief to the unfairly prejudicial conduct. Alternatively, pursuant to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, a shareholder may seek to wind up the company on the just and equitable ground. In addition, on the application of a specified number of members, the Financial Secretary may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated or registered in Hong Kong. The Company Law provides that any shareholders holding 10% or above of voting rights of all issued shares of a company may request a People’s Court to dissolve the company to the extent that the operation or management of the company experiences any serious difficulties and its continuous existence would cause serious losses to them, and no other alternatives can resolve such difficulties.

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The Company, as required by the Mandatory Provisions, has adopted in its Articles of Association minority Shareholder protection provisions similar to (though not as comprehensive as) those available under the Hong Kong law. These provisions state that a controlling shareholder may not exercise its voting rights in a manner prejudicial to the interests of other shareholders, may not relieve a director or supervisor of his duty to act honestly in our best interests or may not approve the expropriation by a director or supervisor of our assets or the individual rights of other shareholders.

Board of Directors

The Company Law, unlike Hong Kong company law, does not contain any requirements relating to the declaration of directors’ interests in material contracts, restrictions on companies providing certain benefits to directors and guarantees in respect of directors’ liability and prohibitions against compensation for loss of office without shareholders’ approval. The Mandatory Provisions, however, contain certain restrictions on interested contracts and specify the circumstances under which a director may receive compensation for loss of office.

Board of Supervisors

Under the Company Law, a joint stock limited company’s directors and members of the senior management are subject to the supervision of the board of supervisors. There is no mandatory requirement for the establishment of the board of supervisors for a company incorporated in Hong Kong. The Mandatory Provisions provide that each supervisor owes a duty, in the exercise of his powers, to act in good faith and honestly in what he considers to be in the best interests of the company and to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

Fiduciary Duties

In Hong Kong, directors owe fiduciary duties to the company, including the duty not to act in conflict with the company’s interests. Furthermore, the Companies Ordinance has codified the directors’ statutory duty of care. Under the Company Law and the Special Regulations, directors, supervisors, managers and other members of senior management of the company shall honestly and diligently perform their duties for the company.

Financial Disclosure

Under the PRC Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report 20 days before its shareholders’ annual general meeting. In addition, a joint stock limited company of which the shares are publicly offered must publish its financial report. The Companies Ordinance requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial statements, auditors’ report and directors’ report, which are to be presented before the company in its annual general meeting, not less than 21 days before such meeting. A joint stock

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limited liability company is required under the PRC law to prepare its financial statements in accordance with the PRC GAAP. The Mandatory Provisions require that a company must, in addition to preparing financial statements according to the PRC GAAP, have its financial statements prepared and audited in accordance with international or Hong Kong accounting standards and its financial statements must also contain a statement of the financial effect of the material differences (if any) from the financial statements prepared in accordance with the PRC GAAP. The lower of the after-tax profits of a specific fiscal year stated in the statements prepared based on the above-mentioned principles shall prevail in the allocation of such profits. The company shall publish its financial reports twice in each accounting year. An interim financial report shall be published within 60 days after the end of the first six months of each accounting year, while an annual financial report shall be published within 120 days after the end of each accounting year.

The Special Regulations require that there should not be any contradiction between the information disclosed within and outside the PRC and that, to the extent that there are differences in the information disclosed in accordance with the relevant PRC and overseas laws, regulations and requirements of the relevant stock exchanges, such differences should also be disclosed simultaneously.

Information on Directors and Shareholders

The PRC Company Law gives shareholders the right to inspect the company’s articles of association, minutes of the shareholders’ general meetings, share register, counterfoil of company debentures, resolutions of board meetings, resolutions of the board of supervisors and financial and accounting reports, which is similar to the shareholders’ rights of Hong Kong companies under Hong Kong law.

Receiving Agent

Under the Hong Kong law, dividends once declared by the board of directors will become debts payable to shareholders. The limitation period for debt recovery action under Hong Kong law is six years, while under the PRC law this limitation period is three years. The Mandatory Provisions require that the relevant company shall appoint a receiving agent for shareholders who hold overseas listed foreign shares, and the receiving agent shall receive on behalf of such holders of shares dividends declared and other monies owed by the company in respect of its overseas listed foreign shares.

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Corporate Reorganization

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance or a compromise or arrangement between the company and its creditors or between the company and its members pursuant to Section 673 and Division 2 of Part 13 of the Companies Ordinance, which requires the sanction of the court. In addition, subject to the shareholders’ approval, an intra-group wholly-owned subsidiary company may also be amalgamated horizontally or vertically under the Companies Ordinance. Under PRC law, merger, division, dissolution or change to the status of a joint stock limited liability company has to be approved by shareholders in general meeting.

Mandatory Deductions

With a view to increasing the level of protection afforded to investors, the Stock Exchange requires the incorporation, in the articles of association of a PRC company whose primary listing is on the Stock Exchange, of the Mandatory Provisions and provisions relating to the change, removal and resignation of auditors, class meetings and the conduct of the board of supervisors of the company. [Such provisions have been incorporated into the Articles of Association, a summary of which is set out in Appendix IV to this document.]

Arbitration of Disputes

In Hong Kong, disputes between shareholders on the one hand, and a company incorporated in Hong Kong or its directors on the other hand, may be resolved through legal proceedings in the courts. The Mandatory Provisions provide that such disputes should be submitted to arbitration at either the HKIAC or the CIETAC, at the claimant’s choice.

Remedies of a Company

Under the PRC Company Law, if a director, supervisor or senior management in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, that director, supervisor or senior management should be responsible to the company for such damages. In addition, the Listing Rules require listed companies’ articles of association to provide for remedies of the company similar to those available under Hong Kong law (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management).

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Dividends

The company has the power in certain circumstances to withhold, and pay to the relevant tax authorities, any tax payable under PRC laws on any dividends or other distributions payable to a shareholder. Under Hong Kong law, the limitation period for an action to recover a debt (including the recovery of dividends) is six years, whereas under PRC laws, the relevant limitation period is three years. The company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable limitation period.

Closure of Register of Shareholders

The Companies Ordinance requires that the register of shareholders of a company must not be closed for the registration of transfers of shares for more than 30 days (extendable to 60 days in certain circumstances) in a year. Unless otherwise stipulated by laws, share transfers shall not be registered within 20 days prior to convening a shareholders' general meeting or 5 days before the base date of distribution of dividends.

Listing Rules

The Listing Rules provide additional requirements which apply to an issuer which is incorporated in the PRC as a joint stock limited company and seeks a primary listing or whose primary listing is on the Stock Exchange. Set out below is a summary of such principal additional requirements which apply to the Company.

Compliance advisor

A company seeking listing on the Stock Exchange is required to appoint a compliance advisor acceptable to the Stock Exchange for the period from its listing date up to the date of the publication of its first full year's financial results, to provide the company with professional advice on continuous compliance with the Listing Rules and all other applicable laws, regulations, rules, codes and guidelines, and to act at all times, in addition to the company's two authorized representatives, as the principal channel of communication with the Stock Exchange. The appointment of the compliance advisor may not be terminated until a replacement acceptable to the Stock Exchange has been appointed.

If the Stock Exchange is not satisfied that the compliance advisor is fulfilling its responsibilities adequately, it may require the company to terminate the compliance advisor's appointment and appoint a replacement.

The compliance advisor must keep the company informed on a timely basis of changes in the Listing Rules and any new or amended law, regulation or code in Hong Kong applicable to the company.

It must act as the company's principal channel of communication with the Stock Exchange if the authorized representatives of the company are expected to be frequently outside Hong Kong.

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Accountant's report

An accountant's report for a PRC issuer will not normally be regarded as acceptable by the Stock Exchange unless the relevant accounts have been audited to a standard comparable to that required in Hong Kong or under International Standards on Auditing or China Auditing Standards. Such report will normally be required to conform to Hong Kong or international accounting standards or China Accounting Standards for Business Enterprises.

Process agent

The Company is required to appoint and maintain a person authorized to accept service of process and notices on its behalf in Hong Kong throughout the period during which its securities are listed on the Stock Exchange and must notify the Stock Exchange of his appointment, the termination of his appointment and his contact particulars.

Public shareholdings

If at any time there are existing issued securities of a PRC issuer other than foreign shares which are listed on the Stock Exchange, the Listing Rules require that the aggregate amount of such foreign shares held by the public must constitute not less than 25% of the issued share capital and that such foreign shares for which listing is sought must not be less than 15% of the total issued share capital if the company has an expected market capitalization at the time of listing of not less than HK\$50,000,000. The Stock Exchange may, at its discretion, accept a lower percentage of between 15% and 25% if the company has an expected market capitalization at the time of listing of over HK\$10,000,000,000.

Independent non-executive directors and supervisors

The independent non-executive directors of a PRC issuer are required to demonstrate an acceptable standard of competence and adequate commercial or professional expertise to ensure that the interests of the general body of shareholders will be adequately represented. The supervisors of a PRC issuer must have the character, expertise and integrity and be able to demonstrate a standard of competence commensurate with their position as supervisors.

Subject to governmental approvals and the provisions of the Articles of Association, the Company may repurchase its own H shares on the Stock Exchange in accordance with the provisions of the Listing Rules. Approval by way of special resolution of the holders of domestic shares and the holders of H shares at separate class meetings conducted in accordance with the Articles of Association is required for share repurchases. In seeking approvals, the Company is required to provide information on any proposed or actual purchases of all or any of its equity securities, whether or not listed or traded on the Stock Exchange. The Directors must also state the consequences of any purchases which will arise under either or both of the Takeovers Code and any similar PRC law of which the directors are aware, if any.

Any general mandate given to the directors to repurchase the foreign shares must not exceed 10% of the total amount of existing issued foreign shares of the company.

APPENDIX V SUMMARY OF PRINCIPAL PRC AND HONG KONG LEGAL AND REGULATORY PROVISIONS

Mandatory provisions

With a view to increasing the level of protection afforded to investors, the Stock Exchange requires the incorporation, in the articles of association of a PRC company whose primary listing is on the Stock Exchange, of the Mandatory Provisions and provisions relating to the change, removal and resignation of auditors, class meetings and the conduct of the board of supervisors of the company. Such provisions have been incorporated into the Articles of Association, a summary of which is set out in Appendix IV.

Redeemable shares

The Company must not issue any redeemable shares unless the Stock Exchange is satisfied that the relative rights of the holders of the foreign shares are adequately protected.

Pre-emptive rights

Except in the circumstances mentioned below, the directors of a company are required to obtain the approval by a special resolution of shareholders in general meeting, and the approvals by special resolutions of the holders of domestic shares and foreign shares (each being otherwise entitled to vote at general meetings) at separate class meetings conducted in accordance with the company’s articles of association, prior to (1) authorizing, allotting, issuing or granting shares or securities convertible into shares, or options, warrants or similar rights to subscribe for any shares or such convertible securities; or (2) any major subsidiary of the company making any such authorization, allotment, issue or grant so as materially to dilute the percentage equity interest of the company and its shareholders in such subsidiary.

No such approval will be required, but only to the extent that, the existing shareholders of the company have by special resolution in general meeting given a mandate to the directors, either unconditionally or subject to such terms and conditions as may be specified in the resolution, to authorize, allot or issue, either separately or concurrently once every 12 months, not more than 20% of the existing domestic shares and foreign shares as of the date of the passing of the relevant special resolution or of such shares that are part of the company’s plan at the time of its establishment to issue domestic shares and foreign shares and which plan is implemented within 15 months from the date of approval by CSRC; or where upon approval by securities supervision or administration authorities of State Counsel, the shareholders of domestic invested shares of the company transfer its shares to overseas investors and such shares are listed and traded in foreign markets.

Supervisors

The Company is required to adopt rules governing dealings by its Supervisors in securities of the Company in terms no less exacting than those of the model code (set out in Appendix 10 to the Listing Rules) issued by the Stock Exchange.

APPENDIX V SUMMARY OF PRINCIPAL PRC AND HONG KONG LEGAL AND REGULATORY PROVISIONS

The Company is required to obtain the approval of its shareholders at a general meeting (at which the relevant Supervisor and his associates shall not vote on the matter) prior to the Company or any of its subsidiaries entering into a service contract of the following nature with a Supervisor or proposed Supervisor of the Company or its subsidiary: (1) the term of the contract may exceed three years; or (2) the contract expressly requires the Company to give more than one year's notice or to pay compensation or make other payments equivalent to the remuneration more than one year in order for it to terminate the contract.

The remuneration committee of the Company or an independent board committee must form a view in respect of service contracts that require shareholders' approval and advise shareholders (other than shareholders with a material interest in the service contracts and their associates) as to whether the terms are fair and reasonable, advise whether such contracts are in the interests of the Company and its Shareholders as a whole and advise Shareholders on how to vote.

Amendment to the Articles of Association

The Company is required not to permit or cause any amendment to be made to its Articles of Association which would cause the same to cease to comply with the mandatory provisions of the Listing Rules or the Mandatory Provisions or the Company Law.

Documents on display

The Company is required to make available on display on the websites of the Stock Exchange and the Company copies of the following:

- a complete duplicate register of shareholders;
- a report showing the state of the issued share capital of the Company;
- the Company's latest audited financial statements and the reports of the Directors, auditors and Supervisors (if any) thereon;
- special resolutions of the Company;
- reports showing the number and nominal value of securities repurchased by the Company since the end of the last financial year, the aggregate amount paid for such securities and the maximum and minimum prices paid in respect of each class of securities repurchased (with a breakdown between Domestic Shares and H Shares);
- a copy of the latest annual return filed with the Beijing Administration for Industry and Commerce; and
- for Shareholders only, copies of minutes of meetings of shareholders.

APPENDIX V SUMMARY OF PRINCIPAL PRC AND HONG KONG LEGAL AND REGULATORY PROVISIONS

Receiving agents

The Company is required to appoint one or more receiving agents in Hong Kong and pay to such agent(s) dividends declared and other monies owing in respect of the H Shares to be held, pending payment, in trust for the holders of such H Shares.

Statements in H share certificates

The Company is required to ensure that all of its listing documents and H share certificates include the statements stipulated below and to instruct and cause each of its share registrars not to register the subscription, purchase or transfer of any of its shares in the name of any particular holder unless and until such holder delivers to such share registrar a signed form in respect of such shares bearing statements to the following effect that the acquirer of shares:

- agrees with the Company and each Shareholder of the Company, and the Company agrees with each shareholder of the Company, to observe and comply with the Company Law, the Special Regulations, the Articles of Association and other relevant laws and administrative regulations;
- agrees with the Company, each Shareholder, Director, Supervisor, manager and officer of the Company, and the Company acting for itself and for each Director, Supervisor, manager and officer of the Company agrees with each shareholder, to refer all differences and claims arising from the Articles of Association or any rights or obligations conferred or imposed by the Company Law or other relevant laws and administrative regulations concerning the affairs of the Company to arbitration in accordance with the Articles of Association, and any reference to arbitration shall be deemed to authorize the arbitration tribunal to conduct hearings in open session and to publish its award. Such arbitration shall be final and conclusive;
- agrees with the Company and each shareholder of the Company that the H Shares are freely transferable by the holder thereof; and
- authorizes the Company to enter into a contract on his behalf with each Director, Supervisors, managers and officer of the Company whereby each such Director and officer undertakes to observe and comply with his obligation to shareholders as stipulated in the Articles of Association.

Compliance with the Company Law, the Special Regulations and the Articles of Association

The Company is required to observe and comply with the Company Law, the Special Regulations and the Articles of Association.

APPENDIX V SUMMARY OF PRINCIPAL PRC AND HONG KONG LEGAL AND REGULATORY PROVISIONS

Contract between the Company and its Directors, officers and Supervisors

The Company is required to enter into a contract in writing with every Director and officer containing at least the following provisions:

- an undertaking by the Director or officer to the Company to observe and comply with the Company law, the Special Regulations, the Articles of Association, the Takeovers Codes and an agreement that the Company shall have the remedies provided in the Articles of Association and that neither the contract nor his office is capable of assignment;
- an undertaking by the Director or officer to the Company acting as agent for each shareholder to observe and comply with his obligations to shareholders as stipulated in the Articles of Association;
- an arbitration clause which provides that whenever any disputes or claims arise from that contract, the Articles of Association or any rights or obligations conferred or imposed by the Company Law or other relevant law and administrative regulations concerning the affairs of the Company between the Company and its Directors or officers and between a holder of H Shares and a Director or officer of the Company, such disputes or claims will be referred to arbitration at either the CIETAC in accordance with its rules or the HKIAC in accordance with its Securities Arbitration Rules, at the election of the claimant and that once a claimant refers a dispute or claim to arbitration, the other party must submit to the arbitral body elected by the claimant. Such arbitration will be final and conclusive;
- disputes over who is a shareholder and over the share registrar do not have to be resolved through arbitration;
- if the party seeking arbitration elects to arbitrate the dispute or claim at HKIAC, then either party may apply to have such arbitration conducted in Shenzhen according to the Securities Arbitration Rules of HKIAC;
- PRC laws shall govern the arbitration of disputes or claims referred to above, unless otherwise provided by law or administrative regulations;
- the award of the arbitral body is final and shall be binding on the parties thereto;
- the agreement to arbitrate is made by the Director or officer with the Company on its own behalf and on behalf of each shareholder; and
- any reference to arbitration shall be deemed to authorize the arbitral tribunal to conduct hearings in open session and to publish its award.

The Company is also required to enter into a contract in writing with every supervisor containing statements in substantially the same terms.

APPENDIX V SUMMARY OF PRINCIPAL PRC AND HONG KONG LEGAL AND REGULATORY PROVISIONS

Subsequent listing

The Company must not apply for the listing of any of its foreign shares on a PRC stock exchange unless the Stock Exchange is satisfied that the relative rights of the holders of foreign shares are adequately protected.

English translation

All notices or other documents required under the Listing Rules to be sent by the Company to the Stock Exchange or to holders of H Shares are required to be in the English language, or accompanied by a certified English translation.

General

If any change in the PRC law or market practices materially alters the validity or accuracy of any of the basis upon which the additional requirements have been prepared, then the Stock Exchange may impose additional requirements or make listing of the equity securities of a PRC issuer, including the Company, subject to special conditions as the Stock Exchange considers appropriate. Whether or not any such changes in the PRC law or market practices occur, the Stock Exchange retains its general power under the Listing Rules to impose additional requirements and make special conditions in respect of the Company’s listing.

Other Legal and Regulatory Provisions

Upon the Company’s listing, the provisions of the Securities and Futures Ordinance, the Takeovers Codes and such other relevant ordinances and regulations as may be applicable to companies listed on the Stock Exchange will apply to the Company.

Securities Arbitration Rules

The Articles of Association provide that certain claims arising from the Articles of Association, Company Law and other applicable laws shall be arbitrated at either the CIETAC or the HKIAC in accordance with their respective rules. The Securities Arbitration Rules of the HKIAC contain provisions allowing an arbitral tribunal to conduct a hearing in Shenzhen for cases involving the affairs of companies incorporated in the PRC and listed on the Stock Exchange so that PRC parties and witnesses may attend.

Where any party applies for a hearing to take place in Shenzhen, the tribunal shall, where satisfied that such application is based on bona fide grounds, order the hearing to take place in Shenzhen conditional upon all parties including witnesses and the arbitrators being permitted to enter Shenzhen for the purpose of the hearing. Where a party (other than a PRC party) or any of its witnesses or any arbitrator is not permitted to enter Shenzhen, then the tribunal shall order that the hearing be conducted in any practicable manner, including the use of electronic media. For the purpose of the Securities Arbitration Rules, a PRC party means a party domiciled in the PRC other than the territories of Hong Kong, Macau and China Taiwan.

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TAXATION OF SECURITY HOLDERS

The following summary of certain Hong Kong and PRC tax consequences of the purchase, ownership and disposition of the H Shares is based upon the laws, regulations, rules and decisions now in effect, all of which are subject to change (possibly with retroactive effect). The summary does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase, own or dispose of the H Shares and does not purport to apply to all categories of prospective [REDACTED], some of whom may be subject to special rules, which does not and shall not be deemed as constituting a legal or taxation suggestion. Prospective [REDACTED] should consult their own tax advisers concerning the application of Hong Kong and PRC tax laws to their particular situation as well as any consequences of the purchase, ownership and disposition of the shares arising under the laws of any other taxing jurisdiction.

The taxation of the Company and that of the Shareholders is described below. Where Hong Kong and PRC tax laws are discussed, these are merely an outline implications of such laws. It should not be assumed that the relevant tax authorities or the PRC or Hong Kong courts will accept or agree with the explanations or conclusions that are set out below.

[REDACTED] should note that the following statements are based on advice received by the Company regarding taxation laws, regulations and practice in force as at the date of this document, which may be subject to change.

TAXATION IN THE PRC

Taxation on Dividends

Individual Investors

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) (the “IIT Law”), which was latest amended on August 31, 2018 and the Regulations on Implementation of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was latest amended on December 18, 2018, dividends paid by PRC enterprises are subject to individual income tax levied at a flat rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless specifically exempted by the tax authority of the State Council or reduced by an applicable tax treaty.

Pursuant to the Notice of the State Administration of Taxation on Issues Concerning Taxation and Administration of Individual Income Tax After the Repeal of the Document Guo Shui Fa [1993] No. 45 (《國家稅務總局關於國稅發[1993]045號文件廢止後有關個人所得稅徵管問題的通知》) issued by the SAT on June 28, 2011, domestic non-foreign-invested enterprises issuing shares in Hong Kong may, when distributing dividends, withhold individual income tax at the rate of 10%. For the individual holders of H Shares receiving dividends who are citizens of countries that have entered into a tax treaty with the PRC with tax rates lower

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than 10%, the non-foreign-invested enterprise whose shares are listed in Hong Kong may apply on behalf of such holders for enjoying the lower preferential tax treatments, and, upon approval by the tax authorities, the amount which is over withheld will be refunded. For the individual holders of H Shares receiving dividends who are citizens of countries that have entered into a tax treaty with the PRC with tax rates higher than 10% but lower than 20%, the non-foreign-invested enterprise is required to withhold the tax at the agreed rate under the treaties, and no application procedures will be necessary. For the individual holders of H Shares receiving dividends who are citizens of countries without taxation treaties with the PRC or are under other situations, the non-foreign-invested enterprise is required to withhold the tax at a rate of 20%.

Enterprise Investors

In accordance with the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the "EIT Law"), which was latest amended and came into effect on December 29, 2018, and the Implementation provisions for the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》), which was latest amended and came into effect on April 23, 2019, a non-resident enterprise is generally subject to a 10% enterprise income tax on PRC-sourced income (including dividends received from a PRC resident enterprise that issues shares in Hong Kong), if such non-resident enterprise does not have an establishment or place in the PRC or has an establishment or place in the PRC but the PRC-sourced income is not connected with such establishment or place in the PRC. The aforesaid income tax may be reduced pursuant to applicable treaties to avoid double taxation. Such withholding tax for non-resident enterprises are deducted at source, where the payer of the income are required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due.

The Circular of the SAT on Issues Relating to the Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid by Chinese Resident Enterprises to Overseas Non-PRC Resident Enterprise Shareholders of H Shares (《國家稅務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) (Guo Shui Han [2008] No. 897) which was issued by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold enterprise income tax at a rate of 10% on dividends paid to overseas non-resident enterprise shareholders of H Shares for 2008 and subsequent years. In addition, the Response to Questions on Levying Enterprise Income Tax on Dividends Derived by Non-resident Enterprise from Holding Stock such as B-shares (《國家稅務總局關於非居民企業取得B股等股票股息徵收企業所得稅問題的批覆》) (Guo Shui Han [2009] No. 394) which was issued by the SAT and came into effect on July 24, 2009, further provides that any PRC-resident enterprise that is listed on overseas stock exchanges must withhold enterprise income tax at a rate of 10% on dividends of 2008 and onwards that it distributes to non-resident enterprises. Such tax rates may be further modified pursuant to the tax treaty or agreement that China has concluded with the relevant jurisdiction, where applicable.

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Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) signed on August 21, 2006, PRC Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion issued by the State Administration of Taxation (《國家稅務總局關於〈內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排〉第五議定書》) effective on December 6, 2019 states that such provisions shall not apply to any arrangement or transactions made for the primary purpose of gaining such tax benefit. The application of the dividend clause of tax agreements shall be subject to the PRC tax laws and regulations, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81).

Tax Treaties

Non-PRC resident investors residing in jurisdictions which have entered into treaties for the avoidance of double taxation with the PRC are entitled to a reduction of the withholding taxes imposed on the dividends received from PRC companies. The PRC currently has Avoidance of Double Taxation Treaties or Arrangements with a number of countries and regions including Hong Kong Special Administrative Region, Macau Special Administrative Region, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant income tax treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the withholding tax in excess of the agreed tax rate, and the refund payment is subject to approval by the Chinese tax authorities.

Taxation on Share Transfer

Value-Added Tax (“VAT”) and Local Surcharges

Pursuant to the Notice on the Full Implementation of Pilot Program for Transition from Business Tax to VAT (《關於全面推開營業稅改徵增值稅試點的通知》) (Cai Shui [2016] No. 36) (“Circular 36”), effective from May 1, 2016, entities and individuals engaged in sales of services within the PRC shall be subject to VAT and ‘sales of services within the PRC’ refers to the situation where either the seller or the buyer of a taxable service is located within the PRC. Circular 36 also provides that transfer of financial products, including transfer of the ownership of marketable securities, shall be subject to VAT at 6% on the taxable turnover (which is the balance of sales price upon deduction of purchase price), for a general or a foreign VAT taxpayer. However, individuals are exempt from VAT upon transfer of financial products.

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In accordance with these rules, upon the sale or disposal of H Shares, the holders are exempt from VAT in the PRC if they are non-resident individuals; in case the holders are non-resident enterprises, they may not be subject to the VAT in the PRC if the purchasers of the H Shares are individuals or entities located outside of the PRC whereas the holders may be subject to the VAT in the PRC if the purchasers of the H Shares are individuals or entities located in the PRC.

However, in absence of explicit rules, there remains uncertainty in the interpretation and application of the foregoing rules as to whether the disposal of H Shares by non-PRC resident enterprises is subject to PRC VAT.

Meanwhile, VAT taxpayers are also subject to urban maintenance and construction tax, education surcharge and local education surcharge (collectively, "local surcharges"), which is usually at 12% of the VAT payable, if any.

Individual Investors

According to the IIT Law and its implementation provisions, gains on the transfer of equity interests in the PRC resident enterprises are subject to the individual income tax at a rate of 20%.

Pursuant to the Circular of the MOF and the State Administration of Taxation on Declaring that Individual Income Tax Continues to be Exempted over Individual Income from Transfer of Shares (《財政部、國家稅務總局關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) (Cai Shui Zi [1998] No. 61) issued by the MOF and the State Administration of Taxation on March 30, 1998, from January 1, 1997, income of individuals from the transfer of shares of listed enterprises shall continue to be exempted from individual income tax. In the latest IIT Law and its implementation rules, the SAT has not explicitly stated whether it will continue to exempt individuals from income tax on income derived from the transfer of listed shares.

However, on December 31, 2009, the MOF, the SAT and the CSRC jointly issued the Circular on Relevant Issues Concerning the Collection of Individual Income Tax over the Income Received by Individuals from Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》 (Cai Shui [2009] No. 167), effective on January 1, 2010, which states that individuals' income from the transfer of listed shares on certain domestic exchanges shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction as defined in the Supplementary Circular on Relevant Issues Concerning the Collection of Individual Income Tax over the Income Received by Individuals from Transfer of Listed Shares Subject to Sales Limitation (關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知) (Cai Shui [2010] No. 70). As of the Latest Practicable Date, the aforesaid provision has not expressly provided that individual income tax shall be collected from non-PRC resident individuals on the sale of shares of PRC resident enterprises listed on overseas stock exchanges. To our knowledge, in practice, there are no laws and regulations expressly requiring that the income tax from non-PRC resident individuals on gains from the sale of shares of PRC resident enterprises listed on overseas stock exchanges shall be collected.

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Enterprise Investors

In accordance with the EIT Law and its implementation provisions, a non-resident enterprise is generally subject to a 10% enterprise income tax on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or place in the PRC or has an establishment or premises in the PRC but the PRC-sourced income is not connected in reality with such establishment or premise. Such income tax for non-resident enterprises are deducted at source, where the payer of the income are required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due. The withholding tax may be reduced or exempted pursuant to applicable treaties or agreements on avoidance of double taxation.

Stamp Duty

Pursuant to the Provisional Regulations of the PRC Concerning Stamp Duty (《中華人民共和國印花稅暫行條例》) which was latest amended on January 8, 2011, and the Detailed Rules for Implementation of Provisional Regulations of the PRC Concerning Stamp Duty (《中華人民共和國印花稅暫行條例施行細則》) effective on October 1, 1988, PRC stamp duty only applies on specific taxable document executed or received within the PRC and having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

As of the date of this document, no estate duty has been levied in the PRC under the PRC laws.

TAXATION IN HONG KONG

Profits Tax

The Company will be subject to Hong Kong profits tax in respect of profits arising in or derived from Hong Kong at the current rate of 16.5% unless such profits are chargeable under the half-rate of 8.25% that may apply for the first HK\$2 million of assessable profits for years of assessment beginning on or after April 1, 2018. Dividend income derived by the Company from its subsidiaries will be excluded from Hong Kong profits tax.

Hong Kong Taxation of Shareholders

Tax on Dividends

No tax is payable in Hong Kong in respect of dividends paid by the Company.

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Profits Tax

Hong Kong profits tax will not be payable by any Shareholders (other than Shareholders carrying on a trade, profession or business in Hong Kong and holding the H Shares for trading purposes) on any capital gains made on the sale or other disposal of the H Shares. Trading gains from the sale of H Shares by persons carrying on a trade, profession or business in Hong Kong where such gains are derived from or arise in Hong Kong from such trade, profession or business will be chargeable to Hong Kong income tax rates of 16.5% on corporations and 15.0% on individuals, unless such gains are chargeable under the respective half-rates of 8.25% and 7.5% that may apply for the first HK\$2 million of assessable profits for years of assessment beginning on or after 1 April 2018. Gains from sales of H Shares effected on the Stock Exchange will be considered by the Hong Kong Inland Revenue Department to be derived from or arise in Hong Kong. Shareholders should take advice from their own professional advisers as to their particular tax position.

Stamp Duty

Hong Kong stamp duty will be charged on the sale and purchase of H Shares at the current rate of 0.26% of the consideration for, or (if greater) the value of, the H Shares being sold or purchased, whether or not the sale or purchase is on or off the Stock Exchange. The Shareholder selling the H Shares and the purchaser will each be liable for one-half of the amount of Hong Kong stamp duty payable upon such transfer. In addition, a fixed duty of HK\$5 is currently payable on any instrument of transfer of Shares.

Estate Duty

Hong Kong estate duty was abolished effective from 11 February 2006. No Hong Kong estate duty is payable by Shareholders in relation to the H Shares owned by them upon death.

PRINCIPAL TAXATION OF OUR COMPANY IN THE PRC

Enterprise Income Tax

According to the EIT Law, a resident enterprise shall pay EIT on its income originating from both inside and outside the PRC at an EIT rate of 25%. Foreign invested enterprises in the PRC falls into the category of resident enterprises, which shall pay EIT for the income originated from domestic and overseas sources at an EIT rate of 25%.

Value-added Tax

According to the Provisional Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》) (the “**Regulations on VAT**”), which was promulgated by the State Council on December 13, 1993 and latest amended on November 19, 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the Ministry of

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Finance of the PRC, came into effect on December 25, 1993 and latest amended on October 28, 2011, all the taxpayers engaged in sales of goods or provision of processing, repair and maintenance labor or import of goods in China shall be subject to value-added tax. Unless specified by the Regulations on VAT, for the sales or import of goods by general taxpayers, the VAT rate shall be 17%; for provision of processing, repair and maintenance labor by taxpayers, the VAT rate shall be 17%; for export of goods by taxpayers, the VAT rate shall be nil, unless otherwise provided.

Pursuant to Notice on Implementing the Pilot Reform for Transition from Business Tax to Value-added Tax Nationwide issued by the MOF and SAT (《關於全面推開營業稅改徵增值稅試點的通知》) (Cai Shui [2016] No. 36) promulgated on March 23, 2016, the pilot reform for the transition from business tax to VAT is implemented nationwide, and the financial industry is included in such pilot and is required to pay VAT instead of business tax. Pursuant to the Implementation Measures for Transition from Business Tax to Value-added Tax (《營業稅改徵增值稅試點實施辦法》), unless otherwise provided in the implementation measures.

According to the Circular of the Ministry of Finance and the State Taxation Administration on Adjusting Value-added Tax Rates (《財政部、稅務總局關於調整增值稅稅率的通知》), which was issued on April 4, 2018 and came into effect on May 1, 2018, where a tax payer engages in a taxable sales activity for the value-added tax purpose or imports goods, the previous applicable reduced 17% and 11% tax rates are adjusted to be 16% and 10%, respectively. According to the Announcement of the Ministry of Finance, the State Taxation Administration and the General Administration of Customs on Deepening Policies in relation to Value-added Tax Reform (《財政部、稅務總局、海關總署關於深化增值稅改革有關政策的公告》) which was promulgated on March 20, 2019 and became effective on April 1, 2019, the VAT rates are reduced to 13% and 9%, respectively.

FOREIGN EXCHANGE CONTROL IN THE PRC

The lawful currency of the PRC is the Renminbi, which is currently subject to foreign exchange control and is not freely convertible into foreign exchange. The SAFE, with the authorization of the PBoC, is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

On January 29, 1996, the State Council promulgated the Regulations for Foreign Exchange Control of the PRC (《中華人民共和國外匯管理條例》) (the "Foreign Exchange Control Regulations") which became effective on April 1, 1996. The Foreign Exchange Control Regulations classifies all international payments and transfers into current items and capital items. Most of the current items are no longer subject to SAFE's approval, while capital items are still subject to such approval. The Foreign Exchange Control Regulations were subsequently amended on January 14, 1997 and August 5, 2008, pursuant to which, the PRC will not impose any restriction on international current payments and transfers.

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On June 20, 1996, PBoC promulgated the Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) (the "Settlement Regulations") which became effective on July 1, 1996. The Settlement Regulations removed the remaining restrictions on convertibility of foreign exchange under current items, while retaining the existing restrictions on foreign exchange transactions under capital account items.

According to the Announcement on Improving the Reform of the Renminbi Exchange Rate Formation Mechanism (《關於完善人民幣匯率形成機制改革的公告》) (PBoC Announcement [2005] No. 16), issued by PBoC and effective on July 21, 2005, the PRC began to implement a managed floating exchange rate system in which the exchange rate would be determined based on market supply and demand and adjusted with reference to a basket of currencies. The Renminbi exchange rate was no longer pegged to the U.S. dollar. PBoC would publish the closing price of the exchange rate of the Renminbi against trading currencies such as the U.S. dollar in the interbank foreign exchange market after the closing of the market on each working day, as the central parity of the currency against Renminbi transactions on the following working day.

Starting from January 4, 2006, the PBoC introduced over-the-counter transactions into the interbank spot foreign exchange market for the purpose of improving the formation mechanism of the central parity of Renminbi exchange rates, and the practice of matching was kept at the same time. In addition to the above, the PBOC introduced the market-maker rule to provide liquidity to the foreign exchange market. On July 1, 2014, the PBoC further improved the formation mechanism of the RMB exchange rate by authorizing the China Foreign Exchange Trade System to make inquiries with the market makers before the interbank foreign exchange market opens every day for their offered quotations which are used as samples to calculate the central parity of the RMB against the USD on that day using the weighted average of the remaining market makers' offered quotations after excluding the highest and lowest quotations, and announce the central parity of the RMB against currencies such as the USD at 9:15 a.m. on each working day. On August 11, 2015, the PBoC announced to improve the central parity quotations of RMB against the USD by authorizing market-makers to provide central parity quotations to the China Foreign Exchange Trading System before the interbank foreign exchange market opens every day with reference to the interbank foreign exchange market closing rate of the previous day, the supply and demand for foreign exchange as well as changes in major international currency exchange rates.

On August 5, 2008, the State Council promulgated the revised Foreign Exchange Control Regulations, which have made substantial changes to the foreign exchange supervision system of the PRC. First, it has adopted an approach of balancing the inflow and outflow of foreign exchange. Foreign exchange income received overseas can be repatriated or deposited overseas, and foreign exchange and settlement funds under the capital account are required to be used only for purposes as approved by the competent authorities and foreign exchange administrative authorities; second, it has improved the RMB exchange rate floating system based on market supply and demand under management; third, in the event that international balance of payment suffer or may suffer a material imbalance, or the national economy

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encounters or may encounter a severe crisis, the State may adopt necessary safeguard or control measures against international balance of payment; fourth, it has enhanced the supervision and administration of foreign exchange transactions and grant extensive authorities to the SAFE to enhance its supervisory and administrative powers.

According to the relevant laws and regulations in the PRC, PRC enterprises (including foreign-invested enterprises) which need foreign exchange for current item transactions may, without the approval of the SAFE, effect payment from foreign exchange accounts at the designated foreign exchange banks, on the strength of valid transaction receipt or evidence. Foreign-invested enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange (such as our Company) may, on the strength of resolutions of the board of directors or the shareholders' meeting on the distribution of profits, effect payment from foreign exchange accounts at the designated foreign exchange banks or effect exchange and payment at the designated foreign exchange banks.

On October 23, 2014, the State Council promulgated the Decisions on Matters including Canceling and Adjusting a Batch of Administrative Approval Items (《國務院關於取消和調整一批行政審批項目等事項的決定》) (Guo Fa [2014] No. 50), which canceled the approval requirement of the SAFE and its branches for the remittance and settlement of the proceeds raised from the overseas listing of the foreign shares into RMB domestic accounts.

On December 26, 2014, the SAFE issued the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) (Hui Fa [2014] No. 54), pursuant to which a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the SAFE's local branch at the place of its incorporation; and the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the prospectus and other disclosure documents.

On February 13, 2015, the SAFE issued the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) (Hui Fa [2015] No. 13), which came into effect on June 1, 2015. The notice has cancelled the confirmation of foreign exchange registration under domestic direct investment and the confirmation of foreign exchange registration under overseas direct investment, instead, banks shall directly examine and handle foreign exchange registration under domestic direct investment and foreign exchange registration under overseas direct investment, and the SAFE and its local offices shall indirectly regulate the foreign exchange registration of direct investment through banks.

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According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionizing and Regulating Capital Account Settlement Management Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (Hui Fa [2016] No. 16), which was issued by the SAFE and came into effect on June 9, 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions. The tentative percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%, subject to adjust of the SAFE in due time in accordance with international revenue and expenditure situations.

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A. FURTHER INFORMATION ABOUT OUR COMPANY TOGETHER WITH OUR SUBSIDIARIES

1. Incorporation

The Company was incorporated under the laws of the PRC as a joint stock limited liability company on January 29, 2021. Our registered address is at Room 201 Building 41, No. 258, Xinzhuan Road, Songjiang District, Shanghai, PRC. A summary of our Articles is set out in “Appendix IV — Summary of the Articles of Association of the Company” to this document. As at the date of this document, our Company’s head office is located at 1/F, 5/F, Building 41, No. 258, Xinzhuan Road, Songjiang District, Shanghai, PRC.

Our Company has established a principal place of business in Hong Kong at 31/F, Tower Two, Times Square, 1 Matheson Street, Causeway Bay, Hong Kong, and was registered with the Registrar of Companies in Hong Kong as a non-Hong Kong company under Part 16 of the Companies Ordinance on August 17, 2021. Ms. Ng Ka Man (吳嘉雯) of TMF Hong Kong Limited at 31/F, Tower Two, Times Square, 1 Matheson Street, Causeway Bay, Hong Kong has been appointed as the authorized representative of our Company for the acceptance of service of process and notice in Hong Kong.

The Company has applied for the [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares, which involves [REDACTED] Domestic Shares and [REDACTED] Unlisted Foreign Shares. The [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H shares has been approved by the CSRC on November 11, 2021 and is still subject to approval by the Stock Exchange.

As the Company was incorporated in the PRC, its operations are subject to the relevant laws and regulations of the PRC. A summary of the Articles of Association and the relevant aspects of laws and regulations of the PRC is set out in Appendix IV and V, respectively, to this document.

2. Changes in Share Capital of Our Company

At the time of our establishment as a joint stock limited company, our initial registered share capital was RMB280,000,000.00, divided into 280,000,000 Domestic Shares, each with a nominal value of RMB1.00, all of which had been fully paid. On April 26, 2021, the share capital of the Company was increased from RMB280,000,000 to RMB294,736,842 by way of capital injection by Ningbo Jiadu and Ningbo Jiacheng. See “History, Reorganization and Corporate Structure — Our Corporate Development — Establishment of Ningbo Jiadu and Ningbo Jiacheng as the shareholding platforms.” On May 28, 2021, the share capital of the Company was further increased from RMB294,736,842 to RMB324,294,997 by way of capital injection by the [REDACTED]. See “History, Reorganization and Corporate Structure — [REDACTED].”

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Upon completion of the [REDACTED] and [REDACTED] of Domestic Shares and Unlisted Foreign Shares into H Shares, the registered share capital of our Company will increase to RMB[REDACTED], comprising [REDACTED] H Shares, assuming the [REDACTED] is not exercised; and RMB[REDACTED] comprising [REDACTED] H shares, assuming the [REDACTED] is exercised.

Save as disclosed herein, there has been no alteration in our share capital and no redemption, repurchase or sale of any of our share capital since our incorporation.

3. Changes in the Share Capital of Our Subsidiary

A summary of the corporate information and the particulars of our subsidiary are set out in Note 1.2 to the Accountant’s Report as set out in Appendix I to this document.

There has been no alteration in the share capital of any of the principal operating entities of the Company within the two years immediately preceding the date of this document.

4. Resolutions of Our Shareholders in Relation to the [REDACTED]

[REDACTED]

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2. Intellectual Property Rights of Our Group




(a) Trademarks

(i) Registered Trademarks

As of the Latest Practicable Date, we had registered the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Place of Registration	Registration No.	Registered Owner	Class	Expiry Date
1.		PRC	39924531	Shanghai Shape Memory Alloy	10	2030.03.27
2.		PRC	39912937	Shanghai Shape Memory Alloy	10	2030.03.27
3.		PRC	39900010	Shanghai Shape Memory Alloy	10	2030.05.06
4.		PRC	38856906	Shanghai Shape Memory Alloy	10	2030.03.06
5.		PRC	14806585	Shanghai Shape Memory Alloy	10	2025.12.20
6.	形状记忆	PRC	13376551	Shanghai Shape Memory Alloy	44	2025.03.06
7.	形状记忆	PRC	13376543	Shanghai Shape Memory Alloy	42	2025.03.06
8.	形状记忆	PRC	13376535	Shanghai Shape Memory Alloy	40	2025.02.06
9.	形状记忆	PRC	13376527	Shanghai Shape Memory Alloy	37	2025.01.20
10.	形状记忆	PRC	13376519	Shanghai Shape Memory Alloy	35	2025.01.20
11.	形状记忆	PRC	13376511	Shanghai Shape Memory Alloy	10	2025.01.20
12.	形状记忆	PRC	13376501	Shanghai Shape Memory Alloy	16	2025.02.06
13.	形状记忆	PRC	13376496	Shanghai Shape Memory Alloy	7	2025.03.06
14.	形状记忆	PRC	13376483	Shanghai Shape Memory Alloy	5	2025.01.20
15.	MemoPart	PRC	8724531	Shanghai Shape Memory Alloy	10	2031.10.20

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No.	Trademark	Place of Registration	Registration No.	Registered Owner	Class	Expiry Date
16.		PRC	4414170	Shanghai Shape Memory Alloy	10	2027.09.27
17.	NeoSorb	PRC	39924570	Shanghai Shape Memory Alloy	10	2030.03.13
18.	GuiBend	PRC	61838700	Shanghai Shape Memory Alloy	10	2032.06.27
19.	G-cruiser	PRC	61834240	Shanghai Shape Memory Alloy	10	2032.06.20
20.	Gruiser	PRC	61825408	Shanghai Shape Memory Alloy	10	2032.06.20
21.	GuiFinder	PRC	61813466	Shanghai Shape Memory Alloy	10	2032.06.20
22.	GuiFlex	PRC	61813458	Shanghai Shape Memory Alloy	10	2032.06.20
23.	Bio-Lefort	PRC	60540409	Shanghai Shape Memory Alloy	10	2032.05.20
24.	Scienmelon	PRC	58762457	Shanghai Shape Memory Alloy	10	2032.03.06
25.	ScienCrown	PRC	58754338	Shanghai Shape Memory Alloy	10	2032.03.06
26.	MemoClamp	PRC	56876954	Shanghai Shape Memory Alloy	10	2032.06.13
27.	MemoClip	PRC	56865987	Shanghai Shape Memory Alloy	10	2031.12.27
28.	NeoSorb	PRC	39924570	Shanghai Shape Memory Alloy	10	2030.03.13
29.	心泰医疗 心泰醫療	Hong Kong	305565565	the Company	10, 16, 35	2031.03.17
30.	ScienTech Medical	Hong Kong	305565574	the Company	10, 16, 35	2031.03.17
31.		Hong Kong	305575140	the Company	10, 16, 35	2031.03.25
32.		Hong Kong	305575186	the Company	10, 16, 35	2031.03.25

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(ii) *Trademark under application*

As of the Latest Practicable Date, there was no trademark under application which we consider to be or may be material to our business.

(b) *Patents*

Registered patents

As of the Latest Practicable Date, we were the registered owner of and had the right to use the following patents which we consider to be or may be material to our business:

No.	Patent	Patentee	Place of Registration	Patent Number	Application Date	Expiry Date
1.	Medical Occluder and Delivery System Thereof ⁽¹⁾	Shanghai Shape Memory Alloy	PRC	2012103709631	2012.09.28	2032.09.28
2.	Adjustable Occlusion Device and Release Method Thereof	Shanghai Shape Memory Alloy	PRC	2015100265308	2015.01.19	2035.01.19
3.	Sectioned Degradable Plugging Device	Shanghai Shape Memory Alloy	PRC	2015100874626	2015.02.25	2035.02.25
4.	A Self-adaptive Occluder with a Variable Angle	Shanghai Shape Memory Alloy	PRC	201510578225X	2015.09.11	2035.09.11
5.	Braided Degradable Plugging Device	Shanghai Shape Memory Alloy	PRC	2017104613770	2017.06.16	2037.06.16
6.	A Nano-film Single-riveting Occluder	Shanghai Shape Memory Alloy	PRC	2013208555023	2013.12.23	2023.12.23
7.	An Adjustable Patent Foramen Ovale Occluder in Waist-full Form	Shanghai Shape Memory Alloy	PRC	2013208556986	2013.12.23	2023.12.23
8.	A Degradable Occluder	Shanghai Shape Memory Alloy	PRC	2014203175060	2014.06.13	2024.06.13
9.	An Occluder Fully Degradable in Human Body	Shanghai Shape Memory Alloy	PRC	2015206053892	2015.08.12	2025.08.12
10.	A Tunnel-like Patent Foramen Ovale Occluder	Shanghai Shape Memory Alloy	PRC	2016211529032	2016.10.31	2026.10.31

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No.	Patent	Patentee	Place of Registration	Patent Number	Application Date	Expiry Date
11.	A Thin-waist-big-side Ventricular Septal Defect Occluder	Shanghai Shape Memory Alloy	PRC	2016214035284	2016.12.20	2026.12.20
12.	A Ventricular Septal Defect Occluder with Different Size of Edges	Shanghai Shape Memory Alloy	PRC	2016214110529	2016.12.20	2026.12.20
13.	A Braided Occluder for Apical Prolapse	Shanghai Shape Memory Alloy	PRC	201720476670X	2017.05.02	2027.05.02
14.	A Tunnel-like Patent Foramen Ovale Occluder	Shanghai Shape Memory Alloy	PRC	2017203736745	2017.04.11	2027.04.11
15.	An Absorbable Heart Defect Occluder	Shanghai Shape Memory Alloy	PRC	2017218142858	2017.12.22	2027.12.22
16.	Degradable Occluder	Shanghai Shape Memory Alloy	PRC	2019212821816	2019.08.06	2029.08.06
17.	Packing Box 1	Shanghai Shape Memory Alloy	PRC	2020300637872	2020.02.28	2030.02.28
18.	A Valve Conveying System for Valve Implantation from Apex Cordis	Shanghai Shape Memory Alloy	PRC	2011101261448	2011.05.17	2031.05.17
19.	A Split Aortic Valve Stent Assembly	Shanghai Shape Memory Alloy	PRC	2017112100108	2017.11.27	2037.11.27
20.	Left Atrial Appendage Occluder And Its Manufacturing Method	Shanghai Shape Memory Alloy	PRC	2014100858883	2014.03.10	2034.03.10
21.	Left Atrial Appendage Occluder	Shanghai Shape Memory Alloy	PRC	2014105131343	2014.09.29	2034.09.29
22.	Left Atrial Appendage Occluder	Shanghai Shape Memory Alloy	PRC	2014105280437	2014.10.09	2034.10.09
23.	An Occlusion Device	Shanghai Shape Memory Alloy	PRC	2014103473257	2014.07.21	2034.07.21
24.	A Left Atrial Appendage Occlusion Device and Occlusion System	Shanghai Shape Memory Alloy	PRC	2015100825795	2015.02.15	2035.02.15
25.	Variable Waist Design Left Atrial Appendage Occluder	Shanghai Shape Memory Alloy	PRC	2016105457012	2016.07.12	2036.07.12
26.	An Adhesive Left Atrial Appendage Occluder	Shanghai Shape Memory Alloy	PRC	2016206400869	2016.06.24	2026.06.24

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No.	Patent	Patentee	Place of Registration	Patent Number	Application Date	Expiry Date
27.	A Kind of Weaving Type Left Atrial Appendage Occluder	Shanghai Shape Memory Alloy	PRC	201721704594X	2017.12.08	2027.12.08
28.	Packing Box II	Shanghai Shape Memory Alloy	PRC	2020300637798	2020.02.28	2030.02.28
29.	Vena Cava Filter	Shanghai Shape Memory Alloy	PRC	2014107682069	2014.12.12	2034.12.12
30.	An Intervention-type Blood Vessel Hemostasis Device	Shanghai Shape Memory Alloy	PRC	2014108536248	2014.12.31	2034.12.31
31.	A Kind of Weaving Type Vena Cava Filter and Weaving Method	Shanghai Shape Memory Alloy	PRC	2016102435859	2016.04.19	2036.04.19
32.	Bronchial Fistula Occlusion Device	Shanghai Shape Memory Alloy	PRC	2017113828837	2017.12.20	2037.12.20
33.	An Occluder Without Choked Flow Film	Shanghai Shape Memory Alloy	PRC	2014203932107	2014.07.16	2024.07.16
34.	An Aneurysm Embolization Device	Shanghai Shape Memory Alloy	PRC	2015204819657	2015.07.06	2025.07.06
35.	An Aneurysm Occlusion Device	Shanghai Shape Memory Alloy	PRC	2015204820315	2015.07.06	2025.07.06
36.	Weaving Type Vena Cava Filter	Shanghai Shape Memory Alloy	PRC	2016203277129	2016.04.19	2026.04.19
37.	A Vena Cava Filter	Shanghai Shape Memory Alloy	PRC	2016212425153	2016.11.21	2026.11.21
38.	A Vena Cava Filter	Shanghai Shape Memory Alloy	PRC	2016213896394	2016.12.16	2026.12.16
39.	A Membrane-Free Double Waist Occluder	Shanghai Shape Memory Alloy	PRC	2017207347445	2017.06.22	2027.06.22
40.	A Combination Device for Treatment of Dissection of Aorta	Shanghai Shape Memory Alloy	PRC	2017214888277	2017.11.09	2027.11.09
41.	A Vascular Plug	Shanghai Shape Memory Alloy	PRC	2018222780324	2018.12.30	2028.12.30
42.	Left Ventricle Capacity-reduction Device	Shanghai Shape Memory Alloy	PRC	2015100947491	2015.03.03	2035.03.03

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No.	Patent	Patentee	Place of Registration	Patent Number	Application Date	Expiry Date
43.	Woven Type Capacity-reduction Device	Shanghai Shape Memory Alloy	PRC	2015100949800	2015.03.03	2035.03.03
44.	Device for Improvement of Cardiac Function	Shanghai Shape Memory Alloy	PRC	2015201080003	2015.02.13	2025.02.13
45.	A Percutaneous Intervention Heart Failure Slowing Instrument	Shanghai Shape Memory Alloy	PRC	201520912376X	2015.11.16	2025.11.16
46.	A Ventricular Volume Reduction Apparatus Delivered Through the Left Ventricular Wall	Shanghai Shape Memory Alloy	PRC	2015209124387	2015.11.16	2025.11.16
47.	A Braided Left Ventricular Volume Reduction Apparatus	Shanghai Shape Memory Alloy	PRC	2015209205191	2015.11.18	2025.11.18
48.	An Atrial Shunt Apparatus	Shanghai Shape Memory Alloy	PRC	2015209902326	2015.12.03	2025.12.03
49.	Braided Left Ventricular Volume Reduction Apparatus	Shanghai Shape Memory Alloy	PRC	2015210352613	2015.12.11	2025.12.11
50.	An Apparatus for Treating Heart Failure	Shanghai Shape Memory Alloy	PRC	2015210459358	2015.12.15	2025.12.15
51.	A Braided Left Ventricular Volume Reduction Apparatus	Shanghai Shape Memory Alloy	PRC	2016207059602	2016.07.06	2026.07.06
52.	An Atrial Shunt	Shanghai Shape Memory Alloy	PRC	2016213479112	2016.12.09	2026.12.09
53.	Eccentric Single Rivet Atrial Shunt	Shanghai Shape Memory Alloy	PRC	2019202071654	2019.02.18	2029.02.18
54.	A Multiple-Loop Snare with Controllable Size	Shanghai Shape Memory Alloy	PRC	2015105822492	2015.09.14	2035.09.14
55.	Multi-Loop Snare	Shanghai Shape Memory Alloy	PRC	2015204799988	2015.07.06	2025.07.06
56.	A Multi-Loop Snare Used for Interventional Treatment of Congenital Heart Disease	Shanghai Shape Memory Alloy	PRC	201520480099X	2015.07.06	2025.07.06
57.	Delivery Apparatus ⁽¹⁾	Shanghai Shape Memory Alloy	PRC	2010105996504	2010.12.22	2030.12.22

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No.	Patent	Patentee	Place of Registration	Patent Number	Application Date	Expiry Date
58.	A Delivery Apparatus for Implantable Medical Device	Shanghai Shape Memory Alloy	PRC	2014102469288	2014.06.05	2034.06.05
59.	A Cardiac Defect Occluder Delivery System	Shanghai Shape Memory Alloy	PRC	2014108518644	2014.12.31	2034.12.31
60.	An Occluder Intervention and Delivery Apparatus	Shanghai Shape Memory Alloy	PRC	2012205602511	2012.10.29	2022.10.29
61.	Heart Defect Occluder Delivery System	Shanghai Shape Memory Alloy	PRC	2013204166115	2013.07.12	2023.07.12
62.	A Push Rod	Shanghai Shape Memory Alloy	PRC	2013208555042	2013.12.23	2023.12.23
63.	A Buckle for Delivery System and The Delivery System with Buckle	Shanghai Shape Memory Alloy	PRC	2013207186360	2013.11.14	2023.11.14
64.	An Occluder Remote Delivery System	Shanghai Shape Memory Alloy	PRC	2015207628469	2015.09.29	2025.09.29
65.	A Connecting Structure of Occluder And Delivery System	Shanghai Shape Memory Alloy	PRC	2016208895885	2016.08.16	2026.08.16
66.	A Preparation Method of Biodegradable Occluder With Controllable Degradation Rate	Shanghai Shape Memory Alloy	PRC	2018102373851	2018.03.21	2038.03.21
67.	Biodegradable Occluder with Parachute Design	Shanghai Shape Memory Alloy	PRC	2020203199179	2020.03.15	2030.03.15
68.	A Head-End Hugging Clamping Delivery System	Shanghai Shape Memory Alloy	PRC	2020211083390	2020.06.16	2030.06.16
69.	Transapical Artificial Tendon Repair System ⁽¹⁾	Shanghai Shape Memory Alloy	PRC	2018115874213	2019.02.13	2039.02.13

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Pending Patents

No.	Patent Title	Place of registration	Applicant	Application number	Application Date
1.	Tunnel-Shaped PFO Occluder	PRC	Shanghai Shape Memory Alloy	2017102343955	2017.04.11
2.	Biodegradable Occluder And Its Preparation Method	PRC	Shanghai Shape Memory Alloy	2019107214663	2019.08.06
3.	A Preparation Method of Biodegradable Hand-Knitted Occluder Net	PRC	Shanghai Shape Memory Alloy	2019107213637	2019.08.06
4.	A Biodegradable Occluder With Parachute Design	PRC	Shanghai Shape Memory Alloy	2020101790582	2020.03.15
5.	A Method for Preparing Oxide Film of Occluder	PRC	Shanghai Shape Memory Alloy	202010729683X	2020.07.27
6.	A PFO Occluder With Adjustable Disc	PRC	Shanghai Shape Memory Alloy	2020111728450	2020.10.28
7.	Interventional System for Repairing Mitral Valve	PRC	Shanghai Shape Memory Alloy	2017104831830	2017.06.22
8.	A Small Barbed Implanted Device	PRC	Shanghai Shape Memory Alloy	2019100062797	2019.01.04
9.	Atrial Shunt	PRC	Shanghai Shape Memory Alloy	2016111283639	2016.12.09
10.	Head-End Hugging Clamping Delivery System	PRC	Shanghai Shape Memory Alloy	202010546781X	2020.06.16
11.	A Multi-Disc Plug Extractor and Its Delivery Device and Delivery Method	PRC	Shanghai Shape Memory Alloy	2017103171782	2017.05.08
12.	A Special Sinus Aneurysm Plug for Ruptured Aortic Sinus Aneurysm	PRC	Shanghai Shape Memory Alloy	2020115957586	2020.12.29
13.	A annular contraction device for the mitral valve ring	PRC	Shanghai Shape Memory Alloy	2021105600774	2021.05.21
14.	A Hole-Cut Non-Implanted Atrial Shunt Device ⁽¹⁾	PRC	Shanghai Shape Memory Alloy	2019114258242	2019.12.31
15.	A Reaming Non-Implanted Atrial Shunt Device ⁽¹⁾	PRC	Shanghai Shape Memory Alloy	2019114020751	2019.12.30
16.	Electrode Catheter System ⁽¹⁾	PRC	Shanghai Shape Memory Alloy	202010610369X	2020.06.29

APPENDIX VII STATUTORY AND GENERAL INFORMATION

No.	Patent Title	Place of registration	Applicant	Application number	Application Date
17.	A Transcatheter Implanted Heart Valve Clamp ⁽¹⁾	PRC	Shanghai Shape Memory Alloy	2019106270933	2019.07.12
18.	A Transcatheter Heart Valve Clamping System ⁽¹⁾	PRC	Shanghai Shape Memory Alloy	2019106738708	2019.07.24
19.	A Connection Release Structure and Its System ⁽¹⁾	PRC	Shanghai Shape Memory Alloy	2019104053710	2019.05.16
20.	Loading Sheath and Delivery System ⁽¹⁾	U.S.		16526612	
		Europe		19189269.4	
		PRC	Shanghai Shape Memory Alloy	2019105410950	2019.06.21
21.	Locking Device and Delivery System with The Locking Device ⁽¹⁾	U.S.		16721172	
		Europe		19220039.2	
		PRC	Shanghai Shape Memory Alloy	2019104395031	2019.05.24
22.	Reaming Type Non-Implanted Atrial Shunt Device ⁽¹⁾	U.S.	Shanghai Shape Memory Alloy	17056656	2019.12.30
23.	Expanding Non-Implanted Atrial Shunt Device ⁽¹⁾	Europe	Shanghai Shape Memory Alloy	19928295.5	2019.12.30
24.	Electrode Catheter System ⁽¹⁾	U.S.	Shanghai Shape Memory Alloy	17056690	2020.11.18
25.	Electrode Catheter System ⁽¹⁾	Europe	Shanghai Shape Memory Alloy	20803731.7	2020.11.18
26.	Connection release structure and system thereof ⁽¹⁾	U.S.	Shanghai Shape Memory Alloy	16526612	2019.07.30
27.	Connection release structure and system thereof ⁽¹⁾	Europe	Shanghai Shape Memory Alloy	19189269.4	2019.07.31
28.	Loading sheathing canal and delivery system ⁽¹⁾	U.S.	Shanghai Shape Memory Alloy	16721172	2019.12.19
29.	Loading sheathing canal and delivery system ⁽¹⁾	Europe	Shanghai Shape Memory Alloy	19220039.2	2019.12.30

Note:

- (1) On January 20, 2021, Shanghai Shape Memory Alloy entered into an agreement in respect of the transfers of patents (“Transfers of Patents”) with Lepu Medical, pursuant to which, among others, Lepu Medical transferred the patents in relevant jurisdictions to us.
- (2) Prior to the Transfers of Patents, such patent was jointly owned by Lepu Medical, the Fuwai Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College. Upon the Transfers of Patents, such patent became jointly owned by Shanghai Shape Memory Alloy, the Fuwai Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College.

APPENDIX VII STATUTORY AND GENERAL INFORMATION

(c) Domain Names

As of the Latest Practicable Date, we have registered the following domain name that we consider to be or may be material to our business:

<u>No.</u>	<u>Domain Name</u>	<u>Registrant</u>	<u>Expiry Date</u>
1	scienteched.com	the Company	2026.03.17

Save as disclosed above, as of the Latest Practicable Date, there were no other trade or service marks, patents, intellectual or industrial property rights which were material in relation to our business.

C. FURTHER INFORMATION ABOUT OUR DIRECTORS, SUPERVISORS AND SUBSTANTIAL SHAREHOLDERS

1. Particulars of Directors’ and Supervisors’ Service Contracts and Letters of Appointment

(a) Executive Directors

Each of Ms. Chen Juan (陳娟) and Ms. Zhang Yuxin (張昱昕), being our executive Directors, has entered into a service contract with our Company on October 20, 2022 pursuant to Rule 19A.54 of the Listing Rules. Each service contract is for an initial term of three years commencing from the [REDACTED]. The service contracts may be renewed in accordance with the Articles and the applicable laws, rules and regulations.

(b) Non-executive Director and Independent non-executive Directors

Each of Mr. Fu Shan (付山) and Mr. Zheng Guorui (鄭國銳), being our non-executive Directors, Ms. CHAN Ka Lai Vanessa (陳嘉麗), Mr. Zheng Yufeng (鄭玉峰) and Mr. Liu Daozhi (劉道志), being our independent non-executive Directors, has entered into a letter of appointment with our Company on October 20, 2022. Each letter of appointment is for an initial term of three years commencing from the [REDACTED]. The letters of appointment may be renewed in accordance with the Articles and the applicable laws, rules and regulations.

(c) Supervisors

Each of Mr. Wang Xinglin (王興林), Ms. Wang Xiaoyong (王曉勇) and Mr. Qian Weidong (錢衛東), being our Supervisors, has entered into a service contract with our Company on October 20, 2022 pursuant to Rule 19A.55 of the Listing Rules. Each service contract is for an initial term of three years commencing from the [REDACTED]. The service contracts may be renewed in accordance with the Articles and the applicable laws, rules and regulations.

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STATUTORY AND GENERAL INFORMATION

2. Remuneration of Directors and Supervisors

The aggregate remuneration (including fees, salaries, contribution to pension schemes, housing allowances, other allowances and benefits-in-kind and discretionary bonuses) paid to our Directors and Supervisors for the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, were approximately RMB2.0 million, RMB2.0 million, RMB8.1 million and RMB4.4 million, respectively.

Based on the arrangements in force as of the Latest Practicable Date, it is estimated that the total remuneration paid to the Directors and Supervisors for the year ending December 31, 2022 will be approximately RMB9.0 million.

During the Track Record Period, no remuneration was paid by us to, or receivable by, our Directors, Supervisors or the five highest paid individuals as an inducement to join or upon joining our Company. No compensation was paid by us to, or receivable by, our Directors, former Directors, Supervisors, former Supervisors or the five highest-paid individuals for each of the Track Record Period for the loss of any office in connection with the management of the affairs of any members of our Group. Furthermore, none of the Directors or Supervisors had waived agreed to waive any emoluments during the same periods.

Save as disclosed above, no other payments have been made or are payable in respect of the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 by any member of our Group to any of our Directors.

3. Disclosure of interests

Disclosure of interests of Directors, Supervisors and chief executive of our Company

Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), there is no interest or short position of our Directors, Supervisors or chief executives of our Company in the Shares, underlying Shares and debentures of our Company or its associated corporations (within the meaning of Part XV of the SFO) which will be required to be notified to our Company and the Hong Kong Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interest or short positions which they were taken or deemed to have under such provisions of the SFO) or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required, pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules, to be notified to our Company and the Hong Kong Stock Exchange.

Disclosure of interests of substantial shareholders

Save as disclosed in the section headed “Substantial Shareholders” in this document, our Directors are not aware of any other person who will, immediately following the completion of the [REDACTED] have an interest or short position in the Shares or the underlying Shares which are required to be disclosed to our Company and the Stock Exchange under the provisions of Division 2 and 3 of Part XV of the SFO, or directly or indirectly, be interested in 10% of more of the nominal value of any class of share capital carrying the rights to vote in all circumstances at the general meetings of our Company.

4. Agency Fees or Commissions Received

Save as disclosed in the section headed “[REDACTED]” in this document, no commissions, discounts, brokerages or other special terms were granted within the two years preceding the date of this document in connection with the issue or sale of any capital or security of any member of our Group.

5. Disclaimers

Save as disclosed herein:

- (a) none of our Directors, Supervisors or the chief executive of our Company has any interest or short position in the Shares, underlying Shares or debentures of our Company or any of its associated corporation (within the meaning of the SFO) which will have to be notified to our Company and the Hong Kong Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to our Company and the Hong Kong Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers once the H Shares are [REDACTED];
- (b) none of our Directors, Supervisors or any of the experts referred to under paragraph headed “D. Other Information — 12. Qualification of Experts” in this appendix has any direct or indirect interest in the promotion of our Company, or in any assets which have within the two years immediately preceding the date of this document been acquired or disposed of by or leased to any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group;
- (c) none of our Directors or Supervisors is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group;

APPENDIX VII

STATUTORY AND GENERAL INFORMATION

- (d) none of our Directors or Supervisors has any existing or proposed service contracts with any member of our Group (excluding contracts expiring or determinable by the employer within one year without payment of compensation (other than statutory compensation));
- (e) so far as is known to our Directors, Supervisors or the chief executive of our Company, no person (not being a Director, Supervisors or chief executive of our Company) will, immediately following the completion of the [REDACTED], have an interest or short position in the Shares or underlying Shares of our Company which would fall to be disclosed to our Company under the provisions of Divisions 2 and 3 of Part XV of SFO or be interested, directly or indirectly, in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Group; and
- (f) none of our Directors, Supervisors or their respective close associates (as defined under the Listing Rules) or our Shareholders who are interested in more than 5% of the issued share capital of our Company has any interest in the five largest customers or the five largest suppliers of our Group.

D. OTHER INFORMATION

1. Estate Duty

We have been advised that no material liability for estate duty under PRC law is likely to fall upon the Group.

2. Litigation

During the Track Record Period and up to the Latest Practicable Date, so far as our Directors are aware, no litigation or claim of material importance (to our Group's financial condition or results of operation) is pending or threatened against any member of our Group.

3. Sole Sponsor

The Sole Sponsor has made an application on our behalf to the [REDACTED] Committee of the Hong Kong Stock Exchange for the [REDACTED] of, and permission to [REDACTED] in, the H Shares to be [REDACTED] as mentioned in this document. All necessary arrangements have been made enabling the H Shares to be admitted into [REDACTED].

The Sole Sponsor satisfies the independence criteria applicable to sponsors as set out in Rule 3A.07 of the Listing Rules. The sponsor fee payable to the Sole Sponsor in connection with the [REDACTED] payable by our Company is US\$0.5 million.

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STATUTORY AND GENERAL INFORMATION

4. Compliance Advisor

Our Company has appointed Halcyon Capital Limited as our compliance advisor in compliance with Rules 3A.19 and 19A.05 of the Listing Rules.

5. Preliminary Expenses

As of the Latest Practicable Date, our Company has not incurred material preliminary expenses.

6. Promoters

The promoters of our Company are Lepu Medical and Target Medical.

Within the two years immediately preceding the date of this document, no cash, securities or other benefit have been paid, allotted or given or have been proposed to be paid, allotted or given to the above promoters in connection with the [REDACTED] or related transactions in this document within the two years immediately preceding the date of this document.

7. Consents of Experts

Each of the experts as referred to in “— 12. Qualification of Experts” in this appendix has given and has not withdrawn its consent to the issue of this document with the inclusion of its view, report and/or letter and/or legal opinion (as the case may be) and references to its name included herein in the form and context in which it respectively appears.

None of the experts named above has any shareholding interest in our Company or any of our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in our Company or any of our subsidiaries.

8. Binding Effect

This document shall have the effect, if an application is made in pursuance hereof, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

9. Bilingual Document

The English language and Chinese language versions of this document are being published separately in reliance on the exemption provided in section 4 of the Companies Ordinance (Exemption of Companies and Prospectus from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

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STATUTORY AND GENERAL INFORMATION

10. Taxation of Holders of H Shares

(a) Hong Kong

The sale, purchase and transfer of H Shares are subject to Hong Kong stamp duty if such sale, purchase and transfer is effected on the H Share register of members of our Company, including in circumstances where such transaction is effect on the Hong Kong Stock Exchange. The current rate of Hong Kong stamp duty for such sale, purchase and transfer is HK\$2.60 for every HK\$1,000 (or part thereof) of the consideration or, if higher, the fair value of the H Shares being sold or transferred. For further information in relation to taxation, see “Appendix VI — Taxation and Foreign Exchange” to this document.

(b) Consultation with Professional Advisors

Intending holders of the H Shares are recommended to consult their professional advisors if they are in any doubt as to the taxation implications of subscribing for, purchasing, holding or disposing of or [REDACTED] in the H Shares. It is emphasized that none of our Company, our Directors, Supervisors or the other parties involved in the [REDACTED] will accept responsibility for any tax effect on, or liabilities of, holders of H Shares resulting from their subscription for, purchase, holding or disposal of or [REDACTED] in the H Shares or exercise of any rights attaching to them.

11. Other Indemnities

Lepu Medical entered into the Deed of Indemnity with and in favor of our Company (being the contract referred to in paragraph (d) of the paragraph headed “— B. Further Information about Our Business — 1. Summary of Material Contracts” above) to provide indemnities in respect of, among other matters, any claim to which any member of our Group may be subject and payable before the date when the [REDACTED] becomes unconditional and all losses, liabilities or damages suffered by it in connection with the legal proceedings and/or non-compliance before the date when the [REDACTED] becomes unconditional.

APPENDIX VII STATUTORY AND GENERAL INFORMATION

12. Qualification of Experts

The following are the qualifications of the experts who have given opinion or advice which are contained in this document:

Name	Qualifications
China International Capital Corporation Hong Kong Securities Limited	A licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts) and Type 6 (advising on corporate finance) of the regulated activities under the SFO
Haiwen & Partners	PRC Legal Advisors
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Industry consultant
PricewaterhouseCoopers	Certified Public Accountants under Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong) Registered Public Interest Entity Auditor under the Accounting and Financial Reporting Council Ordinance (Chapter 588 of the Laws of Hong Kong)
Jones Lang LaSalle Corporate Appraisal and Advisory Limited	Independent property valuer
Hogan Lovells	Legal advisors to the Company as to international sanctions law

13. Miscellaneous

- (a) within the two years immediately preceding the date of this document:
 - (i) save as disclosed in the section headed “History, Reorganization and Corporate Structure” in this document, no share or loan capital of our Company or any of our subsidiaries had been [REDACTED] or agreed to be [REDACTED] or proposed to be fully or partly paid either for cash or a consideration other than cash;
 - (ii) save as disclosed in the section headed “[REDACTED]” in this document, no commissions, discounts, brokerages or other special terms had been granted or agreed to be granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries;
 - (iii) save as disclosed in the section headed “[REDACTED]” in this document, no commission had been paid or payable for subscription, agreeing to subscribe, procuring subscription or agreeing to procure subscription of any share in our Company or any of our subsidiaries;
- (b) save as disclosed in the section headed “History, Reorganization and Corporate Structure” in this document, no share or loan capital of our Company or any of our subsidiaries had been under option or agreed conditionally or unconditionally to be put under option;
- (c) there are no founder, management or deferred shares, convertible debt securities nor any debentures in our Company or any of our subsidiaries;
- (d) none of the persons named in the sub-paragraph headed “D. Other Information — 12. Qualification of Experts” in this appendix is interested beneficially or otherwise in any shares of any member of our Group or has any right or option (whether legally enforceable or not) to subscribe for or nominate persons to subscribe for any securities in any member of our Group;
- (e) save as disclosed in “Summary — Recent Development” in this document, our Directors confirm that there has been no material adverse change in the financial or trading position of our Group since June 30, 2022 (being the date to which the latest audited consolidated financial statements of our Group were made up);
- (f) there has not been any interruption in the business of our Group which may have or has had a significant effect on the financial position of our Group in the 12 months preceding the date of this document;

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STATUTORY AND GENERAL INFORMATION

- (g) no company within our Group is [REDACTED] on any stock exchange or traded on any trading system and at present, and our Group is not seeking or proposing to seek any [REDACTED] of, or permission to deal in, the share or loan capital of our Company on any other stock exchange; and there is no arrangement under which future dividends are waived or agreed to be waived; and

- (h) The Company currently does not intend to apply for the status of a sino-foreign investment joint stock limited liability company and does not expect to be subject to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》).

APPENDIX VIII

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND AVAILABLE ON DISPLAY

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to a copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) a copy of the [REDACTED];
- (b) a copy of each of the material contracts referred to in the sub-section headed “Appendix VII — Statutory and General Information — B. Further Information about Our Business — 1. Summary of Material Contracts” to this document; and
- (c) the written consents referred to in the sub-section headed “Appendix VII — Statutory and General Information — D. Other Information — 7. Consents of Experts” to this document.

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the website of the Stock Exchange at www.hkexnews.hk and our website at www.scientechmed.com up to and including the date which is 14 days from the date of this document:

- (a) the Articles of Association of the Company;
- (b) the Accountant’s Report for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 from PricewaterhouseCoopers, the text of which is set out in “Appendix I — Accountant’s Report” to this document;
- (c) the report on the [REDACTED] financial information from PricewaterhouseCoopers, the text of which is set out in “Appendix II — [REDACTED] Financial Information” to this document;
- (d) the audited consolidated financial statements of our Company for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022;
- (e) the PRC legal opinions issued by Haiwen & Partners, our PRC legal advisor, in respect of certain aspects of our Group;
- (f) copies of the Company Law of the PRC, the Special Regulations of the State Council on the Overseas Offering and the Listing of Shares by Joint Stock Limited Companies (《國務院關於股份有限公司境外募集股份及上市的特別規定》) and Mandatory Provisions, together with unofficial English translations thereof;

APPENDIX VIII

**DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND AVAILABLE ON DISPLAY**

- (g) the material contracts referred to in the sub-section headed “Appendix VII — Statutory and General Information — B. Further Information about Our Business — 1. Summary of Material Contracts” to this document;
- (h) the written consents referred to in the sub-section headed “Appendix VII — Statutory and General Information — D. Other Information — 7. Consents of Experts” to this document;
- (i) the service contracts and the letters of appointment referred to in the sub-section headed “Appendix VII — Statutory and General Information — C. Further Information about Our Directors, Supervisors and Substantial Shareholders — 1. Particulars of Directors’ and Supervisors’ Service Contracts and Letters of Appointment” to this document;
- (j) the International Sanctions memorandum issued by Hogan Lovells, our International Sanctions Legal Advisors;
- (k) the industry report issued by Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., the summary of which is set forth in the section headed “Industry Overview” in this document; and
- (l) the letter, summary of valuation and valuation certificates relating to the property interests held by our Group prepared by Jones Lang LaSalle Corporate Appraisal and Advisory Limited, the text of which is set out in “Appendix III — Property Valuation Report” to this document.