
SUMMARY

This summary aims to give you an overview of the information contained in this document and is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial information appearing elsewhere in this document. As this is a summary, it does not contain all the information that may be important to you and we urge you to read the entire document carefully before making your [REDACTED] decision. There are risks associated with any [REDACTED]. Some of the particular risks in [REDACTED] in the [REDACTED] are set out in the section headed “Risk Factors” in this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED]. In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules.

OVERVIEW

We are a provider of integrated non-vascular interventional surgical solutions in China. Since our inception in 2009, we have developed proprietary technologies and are able to offer integrated solutions of active medical devices, endoscopes and non-active consumables for all major medical specialties that perform non-vascular interventional surgery, including urology, gastroenterology, hepatobiliary, respiratory, thoracic surgery, otorhinolaryngology, gynecology and general surgery. We have developed a robust portfolio of medical devices for non-vascular interventional surgeries in urology globally and in China.

As of the Latest Practicable Date, we had 36 products approved in China, the U.S., the EU and/or Japan, including five active medical devices which include our two Core Products, the plasma radio frequency generator (NW-100) and single-use electrosurgical snare, nine endoscopes and related products and 22 non-active consumables. Our plasma radio frequency generator (NW-100) is an active electrosurgery medical device that converts electric current into plasma and can be applied in a broad range of major non-vascular interventional surgeries, including EMR, ESD and ERCP. Our single-use electrosurgical snare is a flexible medical device designed to be inserted through an endoscope to remove polyps in the gastrointestinal tract. We also had 12 products under development, including five active medical devices, five endoscopes and related products and two non-active consumables. As of the Latest Practicable Date, we held 295 registered patents and patent applications around the world, including 177 registered patents and 66 patent applications in China, as well as 19 patents and 33 patent applications in countries or regions outside the PRC, including patents relating to the key design of our Core Products.

WE CANNOT GUARANTEE THAT WE WILL ULTIMATELY MARKET OUR CORE PRODUCTS SUCCESSFULLY.

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Non-vascular interventional surgeries can be broadly applied to diseases of the respiratory system, digestive system, urinary system and reproductive system. Driven by the aging population and lifestyle changes, global incidence of non-vascular diseases is on the rise, resulting in increasing demand for surgeries. Along with technological advancements in treating non-vascular diseases, interventional surgeries are becoming less invasive than ever before, with endoscopes and active medical devices rapidly replacing scalpels and sutures.

We have developed, through our in-house research and development efforts, a comprehensive product portfolio with active medical devices, endoscopes and non-active consumables that can be used in a wide range of non-vascular interventional surgeries, including urology, gastroenterology, hepatobiliary, respiratory, thoracic surgery, otorhinolaryngology, gynecology and general surgery. We have leveraged designs and technologies across our technological competencies to develop our products, which are highly compatible and synergistic, and when used together, improve surgery outcomes for patients and are user-friendly to surgeons. Moreover, in light of the gradual adoption of diagnosis-related group (DRG) systems to standardize medical service costs, one-stop solutions providers like us are becoming the provider-of-choice to hospitals, enabling them to better manage costs.

In recent years, we obtained regulatory approvals for a number of products. In 2021 and 2022, we obtained nine registration approvals for eight endoscope products in China, the U.S., the EU and/or Japan. As we gradually develop a more robust product portfolio and obtain approval for more products, we have experienced synergies across our operations. Supported by our proprietary in-house developed technologies and experienced R&D team, manufacturing and sales and marketing capabilities, we expect to continue to launch about 12 products that address medical needs globally and/or in China in the next two years, including five active medical devices, five endoscopes and two non-active consumables, bringing our portfolio to about 48 products. All of our products and product candidates are self-developed, and in the short-to-mid-term, we expect all of our products to be self-developed, other than potential acquisitions or in-licensing opportunities we may consider in the future. For details, see “Business — Our Product Portfolio.”

Our revenue increased by 33.5% from RMB255.2 million in 2021 to RMB340.8 million in 2022, primarily attributable to the increase in revenue from our sales of endoscopes and non-active consumables in line with an increase by 29.2% in sales volume of the aforementioned products. In China, our revenue increased by 14.8% from RMB181.3 million in 2021 to RMB208.1 million in 2022. In particular, our revenue derived from sale of endoscopes increased by 67.4% from RMB109.9 million in 2021 to RMB183.9 million in 2022.

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OUR PRODUCT PORTFOLIO

Our synergistic and innovative product portfolio comprises active medical devices, endoscopes and non-active consumables. We commenced our business in 2009 with the research and development of non-active consumables, and obtained registration approval for 22 products from 2010 to 2023. With years of R&D experience for non-active consumables, we built a foundation in non-vascular interventional surgeries and our medical specialties of interest, which created synergies for our R&D of active medical devices and endoscopes. We commenced the development of endoscopes in 2014 and successfully obtained approval for our first two endoscope products in 2017. From 2017 to 2023, we obtained 23 registration approvals for nine endoscopes, including products such as our single-use ureterorenoscope (2.0) and video processor (2.0). We commenced the development of active medical devices in 2017 and obtained registration approval for our first active medical device, the single-use high-frequency sphincterotome in China and the EU in 2017. Later in 2022, we obtained registration approval for our single-use hot biopsy forceps and our two Core Products, the single-use electrosurgical snare and plasma radio frequency generator (NW-100), in China.

As of the Latest Practicable Date, we had 36 products approved in China, the U.S., the EU and/or Japan. The following table sets forth a breakdown of our revenue by product type for the years indicated.

	Year Ended December 31,			
	2021		2022	
	(RMB'000, except for percentages)			
Endoscopes ⁽¹⁾ _	109,890	43.1%	183,906	54.0%
Non-active consumables ⁽²⁾	142,533	55.8%	153,506	45.0%
Active medical devices ⁽³⁾	2,823	1.1%	3,355	1.0%
Total⁽⁴⁾	255,246	100.0%	340,767	100.0%

Notes:





























































- (1) The ex-factory prices of our single-use endoscopes generally range from approximately RMB1,060 to RMB2,630.
- (2) Our non-active consumables portfolios primarily cover five major product types, namely, guidewires, balloon catheters, retrieval baskets, occlusion catheters and sheath tubing. The ex-factory prices of these five product types range from approximately RMB320 to RMB660, RMB560 to RMB2,180, RMB530 to RMB970, RMB700 to RMB950 and RMB430 to RMB690, respectively.
- (3) The ex-factory prices of our active medical consumables range from approximately RMB100 to RMB670.
- (4) Prices of our products may vary in China and international markets, primarily due to specific market conditions, competitive landscape and patient population.

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The following table sets forth selective details of our product pipeline:

Product Type	Medical Specialty	Product Name	Application	Registration Type	Countries/Regions	Design and Development	Stage	Expected / Actual Approval Time	Actual Commercialization Time
Active Medical Devices	Gastroenterology	Single-use Electrosurgical Snare ⁶	Polyps Removal such as EMR	Class IIb Class II Class III Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Trial Clinical Evaluation ³	H2 2023 H2 2024 Aug 2022 H2 2026	H1 2023
		Single-use Hot Biopsy Forceps ⁷	EMR, ESD	Class IIb Class II Class III	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Exempted ²	H2 2023 H1 2026 Jan 2022	Oct 2022
		Plasma Radio Frequency Generator (NW-100) ⁶	Gastroenterologic Interventional Surgeries, including EMR, ESD and ERCP	Class IIb Class II Class III Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Trial Clinical Evaluation ³	H2 2023 H2 2024 Sep 2022 H2 2026	Dec 2022
		Single-use Electrosurgical Knife ⁶	ESD	Class IIb Class II Class III	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Trial	H2 2023 H1 2025 H1 2024	
		Single-use Sphincterotome ⁶	ERCP	Class IIb Class II Class III	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Trial	H2 2023 H2 2025 H2 2025	
		Single-use High-frequency Sphincterotome ⁷	Stone Capture and Removal	Class IIb Class III	 	 	Clinical Evaluation ¹ Clinical Evaluation ²	Feb 2017 Apr 2017	March 2020 Sep 2017
	Urology	Single-use Resection Electrodes ⁶	Urologic Interventional Surgeries such as TUPKP and TUKEP	Class IIb Class II Class III	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Exempted ²	H2 2023 H1 2025 June 2023	To be commercialized
		Plasma Radio Frequency Generator (NW-200) ⁷	Urologic Interventional Surgeries such as TUPKP and TUKEP	Class IIb Class II Class III	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Evaluation ³	H2 2023 H1 2025 H2 2024	
		High-frequency Electrosurgical Instrument ⁷	General Surgery Interventional Surgeries	Class IIb Class II Class III	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Exempted ²	H1 2025 H1 2026 H2 2024	
	Multiple Medical Specialties	High-frequency Electrosurgical Electrodes ⁷	General Surgery Interventional Surgeries	Class IIb Class II Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Exempted ²	H1 2025 H1 2026 H2 2024	
		Single-use High-frequency Electrosurgical Instrument ⁷	General Surgery Interventional Surgeries	Class IIb Class II Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Exempted ²	H1 2025 H1 2026 H2 2024	
Endoscopes	Urology	Fiber Ureterorenoscope	PCNL	Class II			Clinical Evaluation ¹	Jun 2020	Jan 2021
		Single-use Cystoscope	Urethra and Bladder Inspection	Class IIa Class II Class II Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Evaluation ³ Clinical Evaluation ⁴	Apr 2021 Aug 2022 H1 2023 Feb 2023	Sep 2021 Jan 2023 To be commercialized
		Single-use Ureterorenoscope (1.0)	Ureterorenoscopy such as RIRS	Class IIa Class II Class II Class II Class III	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Evaluation ³ Clinical Evaluation ⁴ Clinical Trial	Jul 2017 Jul 2018 Sep 2021 Sep 2021 Sep 2020	Mar 2018 Aug 2018 Oct 2021 Oct 2021 Dec 2020
		Single-use Ureterorenoscope (2.0)	Ureterorenoscopy such as RIRS	Class IIa Class II Class II Class II Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Evaluation ³ Clinical Evaluation ⁴ Clinical Evaluation ⁵	Apr 2020 Aug 2022 Mar 2023 Feb 2023	Dec 2021 Jan 2023 May 2023 Apr 2023
	Hepatobiliary	Single-use Cholangioscope	Biliary and Hepatic Diseases Management	Class IIa Class II Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Evaluation ³	Apr 2021 H2 2023 May 2023	Jan 2022 To be commercialized
		Single-use Bronchoscope	Upper Respiratory Tract and Bronchi Observation, and Tumors and Infectious Respiratory Diseases Treatment	Class IIa Class II Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Evaluation ³	Apr 2021 Nov 2021 Apr 2023	Feb 2023 To be commercialized To be commercialized
	Respiratory/Thoracic Surgery/Otorhinolaryngology	Single-use Rhinolaryngoscope	Nasal Lumens and Upper Respiratory Tract Visualization	Class IIa Class II Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Evaluation ³	H2 2023 H2 2023 H2 2023	
		Single-use Rhinolaryngoscope	Nasal Lumens and Upper Respiratory Tract Visualization	Class IIa Class II Class II	 	 	Clinical Evaluation ¹ Clinical Evaluation ² Clinical Evaluation ³	H2 2023 H2 2023 H2 2023	

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Product Type	Medical Specialty	Product Name	Application	Registration Type	Countries/ Regions	Design and Development	Stage	Expected / Actual Approval Time	Actual Commercialization Time
Endoscopes	Gastroenterology	Single-use Duodenoscope	ERCP	Class IIa Class II Class II	  	  	Clinical Evaluation ³ Clinical Evaluation ⁴ Clinical Evaluation ¹	H2 2025 H2 2025 H2 2026	To be commercialized
		Single-use Cholangioscope	ERCP	Class IIa Class II Class II	  	  	Clinical Evaluation ³ Clinical Evaluation ⁴ Clinical Evaluation ¹	Feb 2022 H2 2023 H2 2023	
		Single-use Laparoscope	Non-vascular Interventional Surgeries within the Thoracic and Peritoneal Cavities	Class IIa Class II Class II	  	  	Clinical Evaluation ³ Clinical Evaluation ⁴ Clinical Evaluation ¹	H2 2025 H2 2025 H2 2026	
		Single-use Hysteroscope	Hysteroscopy	Class IIa Class II Class II	  	  	Clinical Evaluation ³ Clinical Evaluation ⁴ Clinical Evaluation ¹	H2 2023 H2 2023 H2 2023	
	Multiple Medical Specialties	Video Processor (1.0)	Electric Signals Transmission and Image Recording	Class IIa Class II Class II	  	  	Clinical Evaluation ³ Clinical Evaluation ⁴ Exempted ⁵	Jul 2017 Jul 2018 Sep 2021	Mar 2018 Aug 2018 Oct 2021
		Video Processor (2.0)	Electric Signals Transmission and Image Recording	Class IIa Class II Class II	  	  	Clinical Evaluation ³ Clinical Evaluation ⁴ Exempted ⁵	Apr 2020 Nov 2021 Feb 2023	Sep 2021 Jan 2023 Apr 2023
		Portable Video Processor (3.0)	Electric Signals Transmission and Image Recording	Class IIa Class II Class II	  	  	Clinical Evaluation ³ Clinical Evaluation ⁴ Exempted ⁶	H2 2023 H2 2023 H2 2023	May 2023
		Ureteral Occlusion Catheter	Stone Fragments Migration Control	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Trial	Feb 2017 Jul 2010	Oct 2020 Oct 2010
		Occlusion Catheter	Stone Fragments Migration Control	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ⁴	Feb 2017 Jul 2017	To be commercialized Nov 2017
		Ureteral Access Sheath	Working Channel Establishment	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ³	Feb 2017 May 2015	Mar 2018 Sep 2015
Non-active Consumables	Urology	Single-use Stone Retrieval Basket	Stone Capture and Removal	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ³	Feb 2017 Jul 2010	Jul 2020 Mar 2018
		Non-vascular Luminal Guidewire	Instruments Guidance	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ⁴	Feb 2018 Jul 2017	Jul 2020 Dec 2019
		Ureteral Stent	Urine Drainage	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ³	Dec 2018 Nov 2018	Oct 2020 Apr 2019
		Percutaneous Nephropuncture Kit	Upper Urinary Tract Decompression during PCNL	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ³	Dec 2018 May 2019	Jul 2020 Dec 2019
		Ureteral Negative Pressure Access Sheath	Working Channel Establishment	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ³	Feb 2017 Apr 2019	Sep 2020 Nov 2019
		Ureteral Dilation Balloon Catheter	Ureter or Ureteral Stricture Dilation	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ³	Feb 2018 Jul 2017	Jul 2020 Nov 2017
	Gastroenterology	Negative Pressure Drainage Device ^a	Fluid Drainage	Class I			Clinical Evaluation ³	Feb 2021	Mar 2022
		Negative Pressure Drainage Device(2.0)	Fluid Drainage	Class II			Exempted ²	Jan 2023	To be commercialized
		Single-use Stone Extraction Balloon	Stone Removal Facilitation	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ³	Feb 2017 Jul 2013	Mar 2020 Jun 2014
		Dilation Balloon Catheter	Gastrointestinal Tract Dilation	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ³	Feb 2018 Jul 2017	Mar 2020 Mar 2018
		Single-use Biliary Drainage Catheter	Bile Drainage	Class IIa Class II	 	 	Clinical Evaluation ³ Clinical Evaluation ³	Feb 2017 Mar 2016	Oct 2020 Oct 2016

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Product Type	Medical Specialty	Product Name	Application	Registration Type	Countries/Regions	Stage			Expected / Actual Approval time	Actual Commercialization Time
						Design and Development	Clinical Evaluation	Registration		
Non-active Consumables	Gastroenterology	Single-use Nasobiliary Drainage Catheter	Biliary Duct Drainage	Class IIa Class II	 		Clinical Evaluation ¹		Feb 2017	Oct 2020
							Clinical Evaluation ¹		May 2015	Aug 2015
	Respiratory/Thoracic Surgery/Otorhinolaryngology	Airway Balloon Dilation Catheter	Airway Stricture Dilation	Class II			Clinical Evaluation ¹		May 2019	May 2020
		Respiratory Occlusion Balloon Catheter	Airway Occlusion	Class II			Exempted ²		Dec 2022	Apr 2023
		Respiratory Interventional Biopsy Forceps	Pulmonary Tissue Specimens Collection	Class II			Exempted ²		H2 2023	
		Single-use Biopsy Needle	Pulmonary Tissue Specimens Collection	Class II			Exempted ²		H2 2023	
	Multiple Medical Specialties	Laparoscopic Surgery Trocar	Working Channel Establishment	Class IIa Class II	 		Clinical Evaluation ¹		Feb 2017	To be commercialized
		Single-use Stone Retrieval Basket	Stone Retrieval	Class IIa Class II	 		Clinical Evaluation ¹		Feb 2017	Oct 2020
							Clinical Evaluation ¹		Aug 2015	Nov 2015
		Single-use Guidewire	Instruments Guidance	Class IIa Class II	 		Clinical Evaluation ¹		Feb 2017	Mar 2020
		Inflation Device	Intra-balloon Pressure Measurement	Class II	 		Clinical Evaluation ¹		Jun 2019	Jun 2020
							Clinical Evaluation ¹		Jun 2013	Jun 2014

★ Approved  Application process in China  Overseas application process  Core Products

Notes:

- Exempt from clinical trials in China if we can demonstrate to regulatory authorities that our product, in non-clinical trial evaluations, has comparable safety and efficacy compared to products that target the same indication and adopt the same technology.
- Exempt from clinical trials and non-clinical trial evaluations pursuant to the Catalog of Medical Devices Exempted from Clinical Evaluation (《免於臨床評價醫療器械目錄》) issued by the NMPA on September 16, 2021.
- Exempt from clinical trials in the EU if we can demonstrate the safety and performance through a combination of nonclinical data and clinical data that already exists on the device or by analogy with published data generated on an equivalent device that has the same intended use under the Medical Devices Regulation (EU) 2017/745 (MDR).
- Exempt from clinical trials in the U.S. if we can demonstrate there are comparable products that have same intended use and are listed under the same product classification in the U.S.
- Clinical trial requirements of individual products are assessed on a case-by-case basis in Japan.
- Active medical devices using plasma energy.
- Active medical devices using high-frequency electric energy.
- As the second generation of this product has been approved in January 2023, we have decided to de-register the first generation of our negative pressure drainage device, which had been submitted to the NMPA as of the Latest Practicable Date.

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Active Medical Devices

We commenced the development of active medical devices in 2017 to expand our coverage of non-vascular interventional surgery medical devices. We obtained registration approvals for our first active medical device, the single-use high-frequency sphincterotome in China and the EU in 2017. Later in 2022, we obtained registration approval for our single-use hot biopsy forceps and our two Core Products, including the single-use electrosurgical snare and the plasma radio frequency generator (NW-100) in China. Through our subsidiary Neowing Medical, we have also dedicated significant R&D efforts to develop innovative plasma electrosurgery devices and expand our active medical device portfolio to other medical specialties such as urology and general surgery. As of the Latest Practicable Date, we had five active medical devices approved in China and/or the EU and five under development for various non-vascular interventional surgeries using plasma energy or high-frequency electric power for gastroenterology, urology and general surgery. A majority of our active medical devices, including our Core Products, a single-use electrosurgical snare and a plasma radio frequency generator (NW-100), aim to drive the application of plasma electrosurgery in various medical specialties. In 2021 and 2022, our revenue generated from sales of active medical devices, including our single-use high-frequency sphincterotome and single-use hot biopsy forceps, amounted to RMB2.8 million and RMB3.4 million, respectively, and accounted for 1.1% and 1.0% of our total revenue for the respective year.

Our Core Products

Our Core Products use plasma energy during surgeries to enable higher precision, better insulation and reduced damage to surrounding tissues. They are the first plasma electrosurgery medical devices approved for gastroenterological interventional surgeries in China and globally.

Single-use Electrosurgical Snare

Our single-use electrosurgical snare is a flexible medical device designed to be inserted through an endoscope to remove polyps in the gastrointestinal tract in a saline environment. It is specifically designed to be used with our plasma radio frequency generator (NW-100). Our single-use electrosurgical snare was approved by the NMPA as a Class III medical device in August 2022. Our single-use electrosurgical snare has following advantages compared to electrosurgical snares using high-frequency electric power: (i) increased safety by confining the electric current path to the target tissue, and (ii) improved maneuverability and efficiency by facilitating grasping the normal tissue adjacent to the polyp and prevent sliding over the lesion.

From April 2019 to August 2021, we conducted a multi-center, prospective, randomized-controlled and non-inferiority clinical trial to evaluate the safety and efficacy of our single-use electrosurgical snare and plasma radio frequency generator in 220 patients. The

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complete resection rate was 97.20%, which refers to the ability of our single-use electrosurgical snare to completely resect 8-20 mm lesions. Our single-use electrosurgical snare can only be used together with our plasma radiofrequency generator (NW-100). We submitted an application to the NMPA for a Class III medical device certificate for our single-use electrosurgical snare in July 2021. We completed and passed technical review in July 2022 and received a Class III medical devices registration certificate in August 2022. We prepared and submitted our registration materials, which refers to the technical file prepared according to Medical Device Regulation 2017/745 (MDR) Appendix II, to the EU review committee in October 2021 and expect to obtain the approval in the EU in the second half of 2023. For the U.S., we have initiated the non-clinical testing required by the FDA in November 2020 and plan to submit registration materials, which refers to the technical file required FD&C Act for FDA 510(k) application, in the first half of 2024. We expect to obtain the registration approval in the U.S. in the second half of 2024. After receiving the registration certificates, we plan to engage in extensive academic promotion activities with KOLs, surgeons, hospitals and medical associations and further build our sales network to facilitate sales.

Other than our single-use high-frequency sphincterotome which has very limited sales, we do not have and are not developing any high frequency and plasma energy medical devices targeting the same indication. As such, our development of plasma electrosurgical medical devices generally will not result in cannibalization of our high frequency medical devices. For further details, see “Business — Our Product Portfolio — Active Medical Devices — Gastroenterology — Single-use Electrosurgical Snare — Our Core Product.”

WE MAY NOT BE ABLE TO ULTIMATELY MARKET OUR SINGLE-USE ELECTROSURGICAL SNARE SUCCESSFULLY.

Plasma Radio Frequency Generator (NW-100)

Our plasma radio frequency generator (NW-100) is an active electrosurgery medical device that converts electric current into plasma and can be applied in a broad range of major non-vascular interventional surgeries, including EMR, ESD and ERCP. Our plasma radio frequency generator (NW-100) was approved as a Class III medical device by the NMPA in September 2022. It is compatible with our single-use electrosurgical snare, and is specifically designed to be used with our own single-use electrosurgical knife and single-use sphincterotome, which are under development. It can only be used together with other active medical devices using plasma energy, and is specifically designed and approved to be used with our own active consumables only, including our single-use electrosurgical snare, single-use sphincterotome and single-use electrosurgical knife. It is a plug-and-play device, featuring a user-friendly touch screen display where the surgeon can calibrate the energy level and the duration of the operation.

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Our plasma radio frequency generator (NW-100) has following advantages compared to generators using high-frequency electric power: (i) reduced damage to surrounding tissue by directly turning a solid into a gas, (ii) low surgical smoke by avoiding the formation of soot particles, (iii) better operating result, and (iv) reduced the need for inpatient care. Our plasma radio frequency generator (NW-100) is the first plasma electrosurgery generator approved for non-vascular interventional surgeries in gastroenterology in China and globally.

Since August 2017, we commenced the development of our single-use electrosurgical snare and conducted pre-clinical studies including prototype testing, manufacturing process validation, *in vitro* testing, *in vivo* testing and product optimization. From April 2019 to August 2021, we conducted a multi-center, prospective, randomized-controlled and non-inferiority clinical trial to evaluate the safety and efficacy of our single-use electrosurgical snare and plasma radio frequency generator. We submitted an application to the NMPA for a Class III medical device certificate for our plasma radio frequency generator (NW-100) in August 2021. In November 2021, NMPA issued a round of technical clarifications and supplemental material requests in the ordinary course of reviewing our application. We formally submitted responses to the NMPA’s comments in July 2022 and received a Class III medical device registration certificate from the NMPA in September 2022 stating that our plasma radio frequency generator (NW-100) can only be used with active consumables manufactured by us for the endoscopic cutting of gastrointestinal tract tissues in a saline environment. We are concurrently preparing applications for, and expect to obtain approval in the EU in the second half of 2023. We initiated the non-clinical testing required by the FDA in November 2020 and plan to submit registration materials in the first half of 2024. We expect to obtain the registration approval in the U.S. in the second half of 2024. We are also expanding the applications of our plasma radio frequency generator (NW-100) to be used with other consumable products for a broader range of non-vascular interventional surgeries, such as ESD and ERCP, and are currently conducting further registration clinical trials required by the NMPA for these applications. We plan to conduct post-approval clinical trials focusing on the thermal damage caused to the surrounding tissues, the degree of carbonization and crusting of the lesion edges and the frequency of intraoperative bleeding and perforation events to further demonstrate the advantages of plasma electrosurgeries compared with high-frequency electrosurgeries to facilitate the marketing process of the Core Products.

For further details, see “Business — Our Product Portfolio — Active Medical Devices — Gastroenterology — Plasma Radio Frequency Generator (NW-100) — Our Core Product.”

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WE MAY NOT BE ABLE TO ULTIMATELY MARKET OUR PLASMA RADIO FREQUENCY GENERATOR (NW-100) SUCCESSFULLY.

Other Active Medical Devices

In addition to our Core Products, we have developed and continue to develop a number of active medical devices for different medical specialties. For gastroenterology, our single-use high-frequency sphincterotome was approved in China in April 2017 and in the EU in February 2017. Our single-use hot biopsy forceps are exempt from the clinical trial requirements in China and were approved in China in January 2022. We have initiated clinical trials for our single-use sphincterotome and single-use electrosurgical knife in 2021 and 2019, respectively. We expect our single-use sphincterotome to be approved in the EU in the second half of 2023, in the U.S. in the second half of 2025 and in China in the second half of 2025. We expect our single-use electrosurgical knife to be approved in the EU in the second half of 2023, in China in the first half of 2024, and in the U.S. in the first half of 2025.

For urology, we are developing two types of active medical devices to be used in transurethral plasmakinetic prostatectomy (TUPKP) and transurethral plasmakinetic enucleation of prostate (TUKEP), consisting of single-use resection electrodes and plasma radio frequency generator (NW-200). Our plasma radio frequency generator (NW-200) can only be used together with other active medical devices using plasma energy, and is designed and will be approved to be used with our own active consumables. Our single-use resection electrodes are exempt from the clinical trial and non-clinical trial evaluation requirements in China, and our plasma radio frequency generator (NW-200) may be exempt from clinical trial requirements if we can demonstrate its safety and efficacy in non-clinical trial evaluations. Our single-use resection electrodes have been approved in China in June 2023 and we expect the product to be approved in the EU and the U.S. in the second half of 2023 and the first half of 2025, respectively, and plasma radio frequency generator (NW-200) to be approved in the EU, China and the U.S. in the second half of 2023, the second half of 2024 and the first half of 2025, respectively.

We are also developing high-frequency electrosurgical electrodes and a high-frequency electrosurgical instrument for resection and coagulation for general surgery interventional surgeries. For further details, see “Business — Our Product Portfolio — Active Medical Devices.”

Endoscopes

Endoscopes are optical medical devices that are inserted into body cavities either through natural orifices or through small incisions, to observe internal organs or tissues and provide working channels for other surgical instruments in non-vascular interventional surgeries. In 2014, we began to develop our endoscope portfolio with a number of R&D programs ongoing in parallel

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and in 2017, we successfully obtained approval for our first two endoscope products, the single-use ureterorenoscope (1.0) and video processor (1.0), in the EU, for which we also obtained registration approvals in the U.S. in 2018 and for the video processor (1.0) in China in 2019. More notably, our accumulated R&D efforts since 2014 led to 23 registration approvals for nine endoscopes from 2017 to 2023, including products such as single-use ureterorenoscope (2.0), single-use choledochoscope and video processor (2.0).

We had a comprehensive single-use endoscope portfolio, serving all major medical specialties that perform non-vascular interventional surgery with, as of the Latest Practicable Date, nine products approved in China, the U.S., the EU and/or Japan and five in the pipeline. In particular, we have built a robust portfolio of endoscopes for non-vascular interventional surgeries in urology globally and in China. From urology, we have continued to expand and deepen our endoscope portfolio to serve all major medical specialties that perform non-vascular interventional surgery. We have developed our endoscopes using algorithm-optimized CMOS image sensors, which are crucial to high visual quality, and achieved numerous industry firsts, including the first approved single-use ureterorenoscope with an image resolution that reached 400*400 pixels and the first approved single-use cystoscope and single-use bronchoscope with an image resolution that reached 800*800 pixels globally. Moreover, we are the first in the world to enhance our single-use endoscopes with technologies like a full snake spine structure to achieve comparable maneuverability as reusable endoscopes, complementing surgeons’ operating preferences. Our revenue from sales of endoscopes amounted to RMB109.9 million and RMB183.9 million in 2021 and 2022, respectively, accounting for 43.1% and 54.0% of our total revenue for the respective year. For further details, see “Business — Our Product Portfolio — Endoscopes.”

Non-active Consumables

We commenced our business with the development of non-active consumables since 2009, which are single-use instruments that are used in conjunction with endoscopes and active medical devices in non-vascular interventional surgeries. Our non-active consumables are highly compatible and synergistic with our own product portfolio and most of the major international and domestic endoscope brands on the market. Our non-active consumables portfolio primarily covers five major product types used in non-vascular interventional surgeries, namely, guidewires, balloon catheters, retrieval baskets, occlusion catheters and sheath tubing. We obtained our first registration approval for non-active consumables in 2010. From 2017 to 2023, we obtained 30 registration approvals for 22 non-active consumables in China, the U.S. and/or the EU and two under development. In 2021 and 2022, our revenue generated from sales of non-active consumables amounted to RMB142.5 million and RMB153.5 million, respectively, and accounted for 55.8% and 45.0% of our total revenue for the respective year. The ramp-up of revenue generated from sales of non-active consumables was not only attributable to our established market reputation after years of commercialization of these non-active consumables, but also as a result of

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increasing approval and sales of our endoscopes as we created synergies among products and business lines. For further details, see “Business — Our Product Portfolio — Non-active Consumables.”

ADDRESSABLE MARKETS AND COMPETITIVE LANDSCAPE

Active medical devices, endoscopes and non-active consumables are the most common medical devices used in non-vascular interventional surgeries. With improvements in health awareness, higher incidence of non-vascular diseases, technological advancements in non-vascular interventional surgeries and rising preference of non-vascular interventional surgeries over open surgeries, the number of non-vascular interventional surgeries performed globally has grown steadily from 77.1 million in 2016 to 125.1 million in 2022 at a CAGR of 8.4%, and is expected to reach 256.2 million in 2030 at a CAGR of 9.4% from 2022. The number of non-vascular interventional surgeries performed in China has grown from 21.1 million in 2016 to 37.6 million in 2022 at a CAGR of 10.1% and is expected to continue its strong growth and reach 89.0 million in 2030 at a CAGR of 11.4% from 2022. With the fast growing prevalence of non-vascular interventional surgeries, the global market size for endoscopes used in non-vascular interventional surgeries is expected to reach US\$32.1 billion in 2030 at a CAGR of 8.1% from 2022, of which, the market size for single-use endoscopes is expected to reach US\$7.3 billion growing at a CAGR of 26.3% from 2022. The market size of single-use endoscopes used in non-vascular interventional surgeries in China is expected to grow from RMB623.3 million in 2022 to RMB11,497.4 million in 2030 at a CAGR of 44.0%. The global market size for plasma electrosurgery medical devices is expected to reach US\$13.1 billion in 2030 at a CAGR of 14.6% from 2022 and the market size for plasma electrosurgery medical devices in China is expected to reach RMB17.0 billion in 2030, growing at a CAGR of 21.6% from 2022. The market size for the global non-vascular interventional surgery non-active consumables is expected to reach US\$57.1 billion in 2030 at a CAGR of 7.2% from 2022.

As of the Latest Practicable Date, we were able to offer integrated solutions of endoscopes, active medical devices and non-active consumables for non-vascular interventional surgeries. The chart below illustrates details of major domestic and international manufacturers of medical devices used in non-vascular interventional surgeries as of the Latest Practicable Date. For details, see “Industry Overview — Overview of Non-Vascular Interventional Surgery Market”.

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Company name	Active medical devices		Endoscopes			Non-active consumables
	Active consumables	Energy generators	Single-use endoscopes		Reusable endoscopes	
	Approved	Approved	Approved	In pipeline	Approved	Approved
(Domestic) 	●	●	●		●	●
(Domestic) Micro tech	●	●	●			●
(Domestic) Shenda	●	●		⊕	●	●
(Domestic) Aohua	●			⊕	●	●
(International) Boston scientific	●	●	●			●
(International) Olympus	●	●	●		●	●
(International) Karl Storz	●	●	●		●	●
(International) Richard Wolf	●	●	●		●	●
(International) Stryker	●	●			●	●
(International) Smith & Nephew	●	●			●	●

● : approved in FDA or NMPA ⊕ : in pipeline

Source: NMPA, FDA and CIC Report

In particular, our Core Products are active medical devices indicated for interventional surgeries in gastroenterology. Currently, there are many plasma medical devices approved in different specialties, such as ENT; sports medicine; urology; spine and others. Major plasma medical device companies include Smith & Nephew, Karl Storz, Medtronic, J&J, Olympus, Richard Wolf, among others. Our Core Products only target a small sub-segment in the entire plasma medical devices market, namely the plasma electrosurgery medical device market. As of the Latest Practicable Date, except for our single-use electrosurgical snare and plasma radio frequency generator (NW-100), there were no plasma radio frequency generators and active consumables indicated for gastroenterologic interventional surgeries approved in China and there was one single-use electrosurgical snare and one plasma radio frequency generator (developed by Xi'an surgical medical) currently under development in China. Our single-use electrosurgical snare and our plasma radio frequency generator (NW-100) are the first plasma electrosurgery medical devices approved for gastroenterologic interventional surgeries in China and globally. For details, see “Industry Overview — Overview of Non-Vascular Interventional Surgery Market”.

Non-vascular interventional surgery medical device markets in China and globally are intensely competitive and rapidly evolving. We face fierce competition from many companies, including large multi-national and domestic medical device companies that have commercialized or are commercializing or pursuing the development of non-vascular interventional surgery medical devices. For details, see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Commercialization and Distribution of Our Products.” The barriers to enter into this market primarily include the ability to provide integrated non-vascular interventional surgical solutions, having multi-disciplinary and proprietary technology capabilities, establishing brand awareness and end-user recognition, the ability to navigate and comply with stringent regulations, and establishing broad distribution channels, manufacturing capabilities and a stable supply chain. We believe we have established strong competitive advantages with our highly synergistic and

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comprehensive portfolio, and R&D-driven innovation, which we expect to enable us to maintain our market leading position and capture future opportunities. For details, see “Business — Our Product Portfolio” and “Industry Overview” in this document.

OUR TECHNOLOGIES

We have developed four core technology competencies, namely, our active medical device, single-use endoscope, non-active consumable and raw material design technologies, each serving as the foundation to a key segment of our product R&D. Leveraging our well-rounded technological competencies, we are able to continuously develop and commercialize all major medical devices used in non-vascular interventional surgeries to address unmet clinical needs. For further details, see “Business — Our Technologies.”

COMPETITIVE STRENGTHS

We believe the following strengths have contributed to our success and differentiated us from our competitors: (i) we are a provider of integrated non-vascular interventional surgical solutions in China, (ii) we offer a comprehensive single-use endoscope portfolio with strong operating performance and vast market potential, (iii) we are developing a suite of active medical devices, led by our Core Products, driving the application of plasma electrosurgery in non-vascular interventional surgeries, (iv) we have a robust and synergistic portfolio of non-active consumables with broad indication coverage, crucial to our cost efficiency and future revenue growth, (v) we operate a fully-integrated platform with robust R&D, commercial-scale manufacturing, regulatory affairs and market-tested global commercialization capabilities with our products sold in over 65 countries and regions across five continents, and (vi) we are led by a visionary and experienced management team with support from leading healthcare investors.

BUSINESS STRATEGIES

We intend to capitalize on our competitive strengths by pursuing the following business strategies: (i) continue to enrich our non-vascular interventional surgical solutions by leveraging our robust in-house R&D capabilities to cover all major surgery types in all major medical specialties, (ii) strengthen our comprehensive platform comprising R&D, clinical trial and regulatory affairs and manufacturing to achieve continuous innovation and long-term growth, (iii) enhance market penetration, especially single-use products, by increasing sales and marketing efforts in China and overseas and commercializing new products. We view China and overseas markets to be of equal importance, (iv) expand our global footprint and advance our global strategy by further growing our sales network, registering more products in China and overseas

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and developing platform capabilities, such as overseas R&D centers, supply chains and service centers, and (v) selectively pursue strategic investments and acquisitions to integrate valuable assets and leading technologies. For further details, see “Business — Business Strategies.”

RESEARCH AND DEVELOPMENT

Research and development efforts are critical to our continued business growth. We are devoted to developing new products and upgrading existing products, with a focus on addressing clinical pain points and fulfilling clinical needs at lower costs. In 2021 and 2022, we incurred research and development costs of RMB290.9 million and RMB141.7 million, respectively, a significant portion of which was attributed to share-based compensation expenses. The research and development costs for each year of 2021 and 2022 accounted for 47.8% and 50.2% of our total operational expenses, namely the total of selling and distribution expenses, research and development costs and administrative expenses. For the same periods, our research and development costs in relation to our Core Products amounted to RMB8.1 million and RMB9.4 million, respectively, accounting for 17.7% and 14.0%, respectively, of our total research and development costs excluding the share-based compensation in relation to equity incentives to R&D staff and our research and development costs attributable to our plasma electrosurgical devices, which included our research and development costs for Core Products, amounted to RMB13.0 million and RMB15.2 million, respectively, accounting for 28.6% and 22.7%, respectively, of our total research and development costs excluding the share-based compensation in relation to equity incentives to R&D staff. Fluctuations in our research and development costs for Core Products primarily reflect their development progress. While the percentage attributable to Core Products was not significant during the Track Record Period, it is due to a number of factors, including the fact that the Core Products began R&D prior to the Track Record Period, we granted significant equity to R&D staff instead of cash (which cannot be allocated accurately to the Core Products), and we have a large pipeline of products compared to many peers, and therefore the amounts allocated to each product would appear lower. We did not capitalize any research and development expenditures during the Track Record Period. Our R&D team consisted of more than 110 members as of the Latest Practicable Date. Our R&D team comprises renowned R&D professionals with a full spectrum of expertise across medical device development, material science, biomedical engineering, mechanical and automation engineering, with experience from globally leading MNCs and large domestic medical device companies, such as Boston Scientific, Henkel and Kinetic Medical. For further details, please see “Business — Research and Development.”

Relationship with CROs and SMOs

We collaborate with CROs and SMOs to support our pre-clinical studies and clinical trials. The CROs are primarily responsible for providing facilities, equipment, consumables and technical support, preparing study reports and assisting us in completing certain steps of the clinical trial.

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We also engage SMOs to support researchers, ensure the quality of our pre-clinical studies or clinical trials and supervise compliance with relevant regulatory requirements throughout the execution of the pre-clinical studies or clinical trials at trial sites. CRCs will be designated by the SMOs to make non-medical judgments to ensure the smooth operation of our pre-clinical studies and clinical trials. Under the agreements we sign with the CROs, SMOs and CRCs, we own all intellectual property and trial results, and the CROs, SMOs and CRCs must maintain strict confidentiality with respect to the information they acquire during clinical trials.

SALES AND DISTRIBUTION

Through our sales network, our sales cover all provinces in China and over 65 countries and regions across five continents. In China, our products have penetrated over 1,500 hospitals, including over 400 Class III hospitals and over 1,100 Class II hospitals. The following table sets forth our revenue and sales volume by geographic market for the years indicated.

	Year Ended December 31,							
	2021				2022			
	Revenue		Sales Volume		Revenue		Sales Volume	
			Unit in				Unit in	
	RMB'000	%	thousands	%	RMB'000	%	thousands	%
Mainland China								
— Endoscopes	37,013	14.5	16,991	4.8	53,722	15.8	31,393	6.8
— Non-active consumables . . .	141,487	55.4	299,078	84.0	151,072	44.3	349,999	76.2
— Active medical devices	2,823	1.1	4,839	1.4	3,355	1.0	5,977	1.3
	<u>181,323</u>	<u>71.0</u>	<u>320,908</u>	<u>90.2</u>	<u>208,149</u>	<u>61.1</u>	<u>387,369</u>	<u>84.3</u>
Other countries/regions ⁽¹⁾								
— Endoscopes	72,877	28.6	30,587	8.6	130,184	38.2	60,965	13.3
— Non-active consumables . . .	1,046	0.4	4,235	1.2	2,434	0.7	10,988	2.4
— Active medical devices	—	—	—	—	—	—	—	—
	<u>73,923</u>	<u>29.0</u>	<u>34,822</u>	<u>9.8</u>	<u>132,618</u>	<u>38.9</u>	<u>71,953</u>	<u>15.7</u>
Total	<u>255,246</u>	<u>100.0</u>	<u>355,730</u>	<u>100.0</u>	<u>340,767</u>	<u>100.0</u>	<u>459,322</u>	<u>100.0</u>

Note:

- (1) Other countries/regions mainly include the U.S. and various countries and regions in the EU, the Middle East, Central Asia and Southeast Asia.

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We sell our products through a network of distributors, which is in line with industry practice. Our distributors in turn sell our products directly to end customers, such as hospitals. We believe that our distribution model enables us to leverage the distributors’ customer bases while controlling costs. In general, we are able to efficiently manage and control our network of distributors and have great visibility over market demand. We may also from time to time authorize our distributors to appoint certain sub-distributors within their respective sales region. Through engaging certain sub-distributors, we are able to serve more primary hospitals, and to reduce the logistics expenses incurred during the distribution process.

The following table sets forth the change in numbers of our distributors that purchased our products in the periods indicated.

	Year Ended December 31,	
	2021	2022
Domestic		
Domestic distributors as of the beginning of the period	351	459
Increase in domestic distributors ⁽¹⁾	233	361
Decrease in domestic distributors ⁽²⁾	125	117
Net increase in domestic distributors	108	244
Domestic distributors as of the end of the period	459	703
Overseas		
Overseas distributors as of the beginning of the period	52	60
Increase in overseas distributors ⁽¹⁾	11	18
Decrease in overseas distributors ⁽²⁾	3	3
Net increase in overseas distributors	8	15
Overseas distributors as of the end of the period	60	75

Notes:

- (1) The increase in distributors represents those distributors that made purchases from us in the period indicated but did not purchase from us in the period immediately preceding the period indicated.
- (2) The decrease in distributors represents those distributors that made purchases from us in the period immediately preceding the period indicated but did not purchase from us in the period indicated.

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During the Track Record Period, the new distributors we had in each period were primarily due to the growth of our business and expansion of our sales network. The decrease in the number of distributors from period to period primarily reflected the consolidation among our distributors and our strategic adjustments to optimize our distribution network as we terminated our cooperation with distributors if they failed to pass our annual review on sales performances.

We select our distributors based on their experience in the medical device industry, particularly in non-vascular interventional surgery medical devices and their business qualifications. We manage our distributors in various aspects including prevention of cannibalization, inventory management and control, anti-corruption and anti-bribery, and management of sub-distributors. In order to avoid cannibalization of sales among our distributors, we adopt measures including setting geographic and product type restrictions, setting our termination right and closely monitoring end customers. For details, see “Business — Sales and Distribution.”

PRICING

We generally sell our products at uniform ex-factory prices to our distributors in China. We take into account a number of factors in determining our ex-factory prices, which primarily include our costs and expenses, patient affordability, the pricing of competitive products and the competitive landscape. In China, hospitals hold respective bidding/tender processes to procure medical devices, such as our products. The bidding price refers to the highest price a manufacturer is allowed to set at bidding and the retail price may be equal to or lower than the bidding price. The retail price are determined by commercial negotiation between hospitals, manufacturers, and/or their distributors. To accommodate to the DRG systems, we also offer integrated solutions of endoscopes, active medical devices and non-active consumables, which, we believe, make us the provider-of-choice to hospitals, enabling them to better manage costs. In the overseas market, we can control the prices of products sold to distributors through negotiations. For the retail prices of our commercialized products, we will set lowest selling price for each product, but the final retail price is determined between the distributors and customers in arms-length negotiations. The distributors may agree to a retail price with a premium or discount considering the competitiveness and market for each product, but we do not have access to the final retail prices of its products sold overseas. We may periodically offer volume discounts to our distributors if they procure sizable orders of our products. We may also offer product rebates to our distributors if the purchase amount by our distributors exceeds a threshold in new geographic regions or for new products.

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OUR CUSTOMERS

During the Track Record Period, our customers were primarily distributors. For each year ended December 31, 2021 and 2022, the aggregate sales to our five largest customers were RMB68.3 million and RMB126.6 million, representing 26.7% and 37.1% of our revenue, respectively. Sales to our largest customer for each year ended December 31, 2021 and 2022 were RMB34.0 million and RMB69.3 million, representing 13.3% and 20.3% of our revenue, respectively. See “Business — Our Customers.”

RAW MATERIAL AND SUPPLIERS

The principal raw materials for our products include medical polymer materials, medical-grade metal materials, injection-molded parts, electronic parts, CMOS chips and packaging materials. We purchased most of our raw materials in China during the Track Record Period. In 2021 and 2022, we incurred raw material costs of RMB51.1 million and RMB71.0 million, respectively, representing 55.1% and 54.9% of our cost of sales during the same years, respectively.

During the Track Record Period, our suppliers mainly included (i) suppliers of raw materials and equipment, (ii) lessors of our leased properties, and (iii) service providers in relation to promotion service and customs declaration service. For each year ended December 31, 2021 and 2022, the aggregate purchases from our five largest suppliers were RMB45.5 million and RMB68.8 million, representing 25.2% and 26.3% of our total purchases, respectively. Purchases from our largest supplier for each year ended December 31, 2021 and 2022 were RMB12.5 million and RMB33.6 million, representing 6.9% and 12.8% of our total purchases, respectively. See “Business — Raw Material and Suppliers — Our Suppliers.”

OUR CONTROLLING SHAREHOLDER

As of the Latest Practicable Date, Mr. Yan, through his direct ownership, and indirectly through his interests in Ningbo Zhongyu, Shanghai Qingqing, WISDOM I, WISDOM II, WISDOM III, WISDOM IV and Nuoyitai, as well as the powers of attorney conferred upon him by Mr. CHAI Zhaogang, Mr. YUAN Zheng and Mr. ZHOU Yuan, was entitled to exercise or control the exercise of the voting rights attaching to approximately 63.4% of the total issued Shares of our Company. Such powers of attorney will be terminated upon [REDACTED]. Immediately following the completion of the [REDACTED] (assuming that the [REDACTED] is not exercised), Mr. Yan will be entitled to exercise or control the exercise of the voting rights attaching to [REDACTED]% of the total issued Shares of our Company and will continue to be our Controlling Shareholder upon completion of the [REDACTED]. For details, see “Relationship with Our Controlling Shareholder” in this document.

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PRE-[REDACTED] INVESTMENTS

Since the establishment of our Company, we have had six rounds of Pre-[REDACTED] Investments, raising an aggregate amount of [REDACTED] of RMB315 million. Our Pre-[REDACTED] Investors include Sophisticated Investors, namely Temasek and Hillhouse, which will be respectively interested in approximately [REDACTED]% and [REDACTED]% of the total issued share capital of our Company upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised). Pursuant to applicable PRC laws, the Pre-[REDACTED] Investors shall not dispose of any of the Shares held by them within 12 months following the [REDACTED]. For details of our Pre-[REDACTED] Investments, see “History, Reorganization and Corporate Structure — Pre-[REDACTED] Investments” in this document.

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we had registered 295 patents and patent applications, including 177 issued patents and 66 patent applications in China, as well as 19 issued patents and 33 patent applications in countries or regions outside the PRC. All of these patents and patent applications are solely or jointly owned by us. Among these patents and patent applications, seven patents and five patent applications are related to our two Core Products. See “Business — Intellectual Property.” Our Directors confirm that during the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings in respect of, and we had not received notice of any material claims of infringement or misappropriation of, any intellectual property rights that are threatened or pending, in which we may be a claimant or a respondent. For risks relating to intellectual property rights, see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights.”

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SUMMARY OF KEY FINANCIAL INFORMATION

Description of Certain Key Items of the Consolidated Statement of Profit or Loss and Other Comprehensive Income

	Year Ended December 31,			
	2021		2022	
	(RMB'000, except for percentages)			
Revenue	255,246	100.0%	340,767	100.0%
Cost of sales	(92,754)	(36.3)%	(129,381)	(38.0)%
Gross profit.	162,492	63.7%	211,386	62.0%
Loss before tax	(694,197)	(272.0)%	(217,695)	(63.9)%
Loss for the year.	(694,665)	(272.2)%	(221,117)	(64.9)%
Attributable to:				
Owners of the parent	(699,103)	(273.9)%	(220,784)	(64.8)%
Non-controlling interests	4,438	1.7%	(333)	(0.1)%

Non-IFRS Measures

To supplement our consolidated financial statements, which are presented in accordance with the IFRS, we also use adjusted net profit and other adjusted figures as non-IFRS measures, which are not required by, or presented in accordance with, the IFRS. We believe that such non-IFRS measures are reflections of our operating results by eliminating the potential impact of certain items.

Adjusted net profit for the year (Non-IFRS Measure) was calculated by taking total loss for the year and adding back (i) share-based compensation expenses, (ii) fair value loss on financial liabilities at FVTPL, and (iii) [REDACTED]. Our management considered the share-based compensation payment expenses as a non-cash item. In addition, the fair value loss on financial liabilities at FVTPL was in relation to certain special rights we granted to certain Pre-[REDACTED] [REDACTED], as all the special rights will be terminated before the [REDACTED]. [REDACTED], was an item that arises from activities relating to the [REDACTED].

Adjusted net profit for the year (Non-IFRS Measure) is not a measure required by or presented in accordance with IFRS. We believe this non-IFRS measure facilitates comparisons of operating performance from period to period, and thus providing useful information to [REDACTED] and others in understanding and evaluating our consolidated results of operations in the same manner as they help our management. However, the use of this non-IFRS measure has limitations as an analytical tool, and you should not consider it in isolation from, or as substitute

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for analysis of, our results of operations or financial condition as reported under the IFRS. Our presentation of such adjusted figures may not be comparable to a similarly titled measure presented by other companies.

The following table reconciles our adjusted net profit for the year (non-IFRS measure) with our loss for the year, which is the most directly comparable financial measure calculated and presented in accordance with IFRS:

	Year Ended December 31,	
	2021	2022
	(RMB'000)	
Loss for the year	(694,665)	(221,117)
Added:		
Share-based compensation expenses	478,267	129,911
Fair value loss on financial liabilities at FVTPL	250,681	152,807
[REDACTED]	12,168	15,630
Adjusted net profit for the year (Non-IFRS Measure)	46,451	77,231

We are a growing R&D-driven company. Our revenue increased from RMB255.2 million in 2021 to RMB340.8 million in 2022, primarily attributable to the increase in revenue from our sales of endoscopes and non-active consumables in line with an increase by 29.2% in sales volume of the aforementioned products. In particular, our revenue from sales of endoscopes increased by 67.4% due to significant sales volume increases of our single-use ureterorenoscope and single-use cystoscope as a result of rising market demands and our expanded sales network. Our revenue from sales of non-active consumables increased by 7.7% primarily due to an increase in sales volume of our non-vascular luminal guidewire, single-use stone retrieval basket and ureteral access sheath.

While we have generated revenue from commercialized products, we incurred a net loss historically and in 2021 and 2022 mainly due to our commitment of substantial financial resources to build our business foundation, our products and R&D, manufacturing and sales and marketing capabilities. Our net loss in 2021 and 2022 was also attributable to non-cash expenses such as share-based compensation in relation to equity incentives to R&D and other staff and fair value loss on financial liabilities at FVTPL in relation to the grant of special right. For details, see “Financial Information — Description of Certain Key Items of the Consolidated Statement of Profit or Loss and Other Comprehensive Income — Fair Value Loss on Financial Liabilities at FVTPL.” We may continue to incur losses for the foreseeable future, and the losses may increase as we expand our development of, and seek regulatory approvals for, our product candidates, and commercialize our products.

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In view of our net loss throughout the Track Record Period, we plan to improve such position by (i) rapidly advancing our pipeline products towards commercialization; (ii) implementing our commercialization strategy to ramp up product sales and generate more revenue; and (iii) adopting comprehensive measures to effectively control our cost and operating expenses leveraging synergies across our operations.

Description of Certain Consolidated Statement of Financial Position Items

	As of December 31,	
	2021	2022
	(RMB'000)	
Total non-current assets	169,395	211,683
Total current assets	271,359	314,599
Total current liabilities	101,164	1,798,531
Net current assets/(liabilities)	170,195	(1,483,932)
Total non-current liabilities	1,550,944	30,811
Net liabilities	1,211,354	1,303,060
Total deficiency in equity attributable to		
owners of the parent	(1,217,046)	(1,303,060)
Non-controlling interests	5,692	—

We recorded net current assets of RMB170.2 million as of December 31, 2021 and net current liabilities of RMB1,483.9 million as of December 31, 2022. The fluctuation was primarily in relation to the reclassification of our Series A, Series B and Series C Shares from non-current liabilities as of December 31, 2021 to current liabilities as of December 31, 2022, as we are not required to redeem the aforementioned shares if we fail to complete the [REDACTED] until December 31, 2023.

We recorded net liabilities of RMB1,211.4 million as of December 31, 2021, primarily due to (i) the recognition of financial liabilities at FVTPL of RMB1,265.0 million relating the issuance of Shares to certain Pre-[REDACTED] Investors in October 2021; (ii) the comprehensive loss of RMB694.7 million; and (iii) acquisition of non-controlling interests of RMB123.8 million. The increase of net liabilities were partially offset by (i) equity settled share-based payment of RMB478.3 million recognized as a result the equity interests we granted to our directors, employees and external consultants in July 2021. In July 2021, we granted a total of 10,840,724 Shares to Mr. Yan, 101 employees and two consultants. Generally speaking, we granted shares to employees in major functional departments of our Group, including the R&D, administrative, sales and marketing department and manufacturing and quality control departments, among others, who have, in our opinion made significant contributions to our business. In addition, in view of the significant role that Mr. Yan plays in key aspects of our operations, we granted a total of 6,429,472

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Shares to Mr. Yan in July 2021. In July 2021, we also granted a total of 4,411,252 shares to 23 administrative staff, 12 sales and marketing staff, 19 manufacturing and quality control staff, 47 R&D members and two consultants. We recognized share-based compensation expenses of RMB478.3 million and RMB129.9 million for the years ended December 31, 2021 and 2022. For details, see note 31 to the Accountants’ Report set out in Appendix I of this document; and (ii) capital contribution from shareholders of RMB260.4 million in relation to our Pre-[REDACTED] Investments.

Our net liabilities increased from RMB1,211.4 million in 2021 to RMB1,303.1 million as of December 31, 2022, primarily due to the comprehensive loss of RMB221.1 million recognized in 2022. Such increase was partially offset by equity settled share-based payment of RMB129.9 million recognized as a result the equity interests we granted to our directors, employees and external consultants in July 2021. The fair value of the shares held by certain Pre-[REDACTED] Investors are recognized as financial liability carried at FVTPL and debited to equity simultaneously. We do not expect to record any further fair value changes after [REDACTED] as such Shares held by these Pre-[REDACTED] Investors will be re-designated from liabilities to equity as a result of the termination of the special rights before the completion of the [REDACTED]. We expect our financial position will significantly improve upon [REDACTED] and our net liabilities position as of December 31, 2022 would turn into a net assets position as a result of the re-designation. For details, see note 28 to the Accountants’ Report set out in Appendix I of this document.

Cash Flows

	Year Ended December 31,	
	2021	2022
	<i>(RMB’000)</i>	
Net cash flows from operating activities	60,206	15,254
Net cash flows used in investing activities	(70,660)	(54,499)
Net cash flows from/(used in) financing activities.	135,264	(2,168)
Net increase/(decrease) in cash and cash equivalents.	124,810	(41,413)
Cash and cash equivalents at beginning of year	42,832	168,042
Cash and cash equivalents at end of year	168,042	134,126

During the year ended December 31, 2021 and 2022, we had net cash flows from operating activities of RMB60.2 million and RMB15.3 million, respectively.

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Our Directors are of the opinion that, taking into account (i) the financial resources available to our Group, including cash and cash equivalents of RMB134.1 million as of December 31, 2022, cash flows from operating activities and the estimated [REDACTED] from the [REDACTED], and (ii) our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development costs, administrative expenses, finance costs and other expenses for at least the next 12 months from the date of this document.

Our cash burn rate refers to our average monthly (i) capital expenditures, (ii) lease payments, and (iii) operating expenses (excluding non-cash items). Our operating expenses (excluding non-cash items) consisted of research and development costs, administrative expenses, and selling and distribution expenses, and excluded share-based compensation expenses, and depreciation and amortization. Assuming that the average cash burn rate going forward of two times the level in 2021, we estimate that our cash and cash equivalents as of December 31, 2022 and the estimated [REDACTED] (based on the low end of the indicative [REDACTED]) from the [REDACTED] will be able to maintain our financial viability for 40 months. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development status and expect to raise our next round of financing, if needed, with a minimum buffer of 12 months.

Key Financial Ratios

In 2021 and 2022, our gross profit margin was 63.7% and 62.0%, respectively. For details, see “Financial Information — Results of Operations.”

Our current ratio decreased from 2.7 as of December 31, 2021 to 0.2 as of December 31, 2022, mainly due to the reclassification of our Series A, Series B and Series C Shares from non-current liabilities as of December 31, 2021 to current liabilities as of December 31, 2022.

DIVIDEND

No dividend was paid or declared by our Company during the Track Record Period. The determination of whether to pay a dividend and in which amount is based on factors the Board may deem relevant. Any dividend distribution will also be subject to the approval of the Shareholders in the Shareholder’s meeting. Under the PRC law and the Articles of Association, the general reserve requires annual appropriations of 10% of after-tax profits at each year-end until the balance reaches 50% of the relevant PRC entity’s registered capital. In view of our accumulated losses, as advised by our PRC Legal Advisors, according to the relevant PRC laws and regulations and the Articles of Association, we shall not declare or pay dividend until the accumulated losses are covered by our after-tax profits and sufficient statutory common reserve are drawn in accordance with the relevant laws and regulations.

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We do not have a specific dividend policy or a predetermined dividend payout ratio. The determination to pay dividends in the future will be made at the direction of our Board and will be based on our profits, cash flows, financial condition, capital requirements and other conditions that our Board deems relevant. The payment of dividends may be limited by other legal restrictions and agreements that we may enter into in the future.

FUTURE PLANS AND USE OF [REDACTED]

We estimate that we will receive [REDACTED] from the [REDACTED] of approximately [REDACTED] million, after deducting [REDACTED] commissions, fees and estimated expenses payable by us in connection with the [REDACTED], and assuming an [REDACTED] of [REDACTED] per Share, which is the mid-point of the indicative [REDACTED] range stated in this document. We intend to apply these [REDACTED] for the following purposes: (i) approximately [REDACTED], or [REDACTED] million, will be allocated to optimize, develop and promote our Core Products, namely, our single-use electrosurgical snare and our plasma radio frequency generator (NW-100); (ii) approximately [REDACTED], or [REDACTED], will be allocated to the research and development, clinical trials and commercialization of our other 19 pipeline products, (iii) approximately [REDACTED], or [REDACTED], will be used to fund our potential acquisition and in-licensing opportunities, and (iv) approximately [REDACTED], or [REDACTED], will be used for our working capital and general corporate purposes. See “Future Plans and Use of [REDACTED].”

RISK FACTORS

We are seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. These risks are set out in “Risk Factors” in this document. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies such as ours, including the following: (i) our historical operating results may not be representative of future performance. We may incur net losses for the foreseeable future, and you may lose substantially all your [REDACTED] in us given the high risks involved in the medical device business; (ii) we had net liabilities during the Track Record Period. We cannot assure you that we will not experience net liabilities in the future, which could expose us to liquidity risks; (iii) we may fail to successfully develop, obtain regulatory approval for, or commercialize our product candidates in a timely manner, or at all; (iv) we are subject to intense competition from domestic and international competitors or substitutes, and we may be unable to maintain or enhance our market share in this industry for a variety of reasons; (v) 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; (vi) if we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from

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developing or commercializing our product candidates; (vii) if we determine our intangible assets, including goodwill, to be impaired, our results of operations and financial condition may be adversely affected.

[REDACTED]

Our [REDACTED] mainly include [REDACTED] commission, professional fees and other fees incurred in connection with the [REDACTED]. [REDACTED] to be borne by us are estimated to be approximately [REDACTED] million (assuming an [REDACTED] of [REDACTED] per H Share, which is the mid-point of the indicative [REDACTED] range stated in this document and assuming that the [REDACTED] is not exercised), which includes (i) the [REDACTED] expenses of approximately [REDACTED] million; (ii) [REDACTED] expenses of approximately [REDACTED] million, which consist of fees and expenses of legal advisors and the reporting accountant of approximately [REDACTED] million and other fees and expenses of approximately [REDACTED] million. In 2021 and 2022, [REDACTED] charged to our consolidated statements of profit or loss and other comprehensive income were [REDACTED] and [REDACTED], respectively. We expect that the remaining [REDACTED] of approximately [REDACTED] million will be charged to our consolidated statements of profit or loss and other comprehensive income after the Track Record Period, and approximately [REDACTED] million will be deducted from equity upon the [REDACTED]. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate. Our [REDACTED] as a percentage of gross [REDACTED] is [REDACTED], assuming an [REDACTED] of [REDACTED] per H Share, which is the mid-point of the indicative [REDACTED] range stated in this document and assuming that the [REDACTED] is not exercised.

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[REDACTED] STATISTICS

The statistics in the following table are based on the assumptions that [REDACTED] H Shares will be issued pursuant to the [REDACTED], Unlisted Shares will be converted into H Shares and the [REDACTED] is not exercised:

	Based on an [REDACTED] of [REDACTED] per Share	Based on an [REDACTED] of [REDACTED] per Share
[REDACTED] of our Shares ⁽¹⁾	[REDACTED] million	[REDACTED] million
[REDACTED] of our H Shares ⁽²⁾	[REDACTED] million	[REDACTED] million
Unaudited [REDACTED] adjusted consolidated net tangible assets per share ⁽³⁾⁽⁴⁾	[REDACTED]	[REDACTED]

Notes:

- (1) The calculation of [REDACTED] is based on [REDACTED] expected to be in issue immediately upon completion of the [REDACTED].
- (2) The calculation of the [REDACTED] of our H Shares is based on the [REDACTED] H Shares, comprising [REDACTED] H Shares to be issued under the [REDACTED] and [REDACTED] H Shares to be converted from Unlisted Shares, expected to be in issue immediately upon completion of the [REDACTED].
- (3) The unaudited [REDACTED] net tangible assets per Share is arrived on the basis that [REDACTED] Shares were expected to be issued immediately after completion of the [REDACTED]. In addition, the number of Shares used for the computation of unaudited [REDACTED] net tangible assets per Share also takes no account of any Shares which may be fall to be issued upon the exercise of the [REDACTED]. For the purpose of this unaudited [REDACTED] statement of adjusted net tangible assets attributable to owners of the Company, the balances stated in RMB are converted into HK\$ at the rate of RMB1.00 to [REDACTED].
- (4) No adjustment has been made to the unaudited [REDACTED] adjusted consolidated net tangible assets to reflect any trading results or other transactions of the Group entered into subsequent to December 31, 2022.

RECENT DEVELOPMENT AND NO MATERIAL ADVERSE CHANGE

Impact of COVID-19 Outbreak

Since December 2019, a novel strain of coronavirus or COVID-19, has become widespread in China and around the world. To contain the virus’ spread, China and many other countries have taken various restrictive measures, such as lockdowns, quarantines, closure of work places, travel

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restrictions and home office policies. In response to Delta and Omicron variants outbreak (the “**Recurrence**”) in 2021, the Chinese government has implemented emergency measures in certain cities or regions, including Shanghai, including travel restrictions, mandatory cessations of business operations, mandatory quarantines, and limitations on social and public gatherings and lockdowns of cities or regions. These measures have, to a certain extent, affected our research and development, procurement, manufacturing, logistics and offline sales activities in the first half of 2022 from February 2022 to May 2022.

For example, as our manufacturing facilities are primarily located in Shanghai, we had to temporarily suspend operations for three months. Despite the three-month suspension, for the full year of 2022 overall, the suspension did not have a material adverse impact on the Company’s operations. In addition, our ongoing clinical trials and the regulatory approval of the Core Products were slightly delayed, but there was no early termination or necessitated removal of enrolled patients and such delay is not expected to have an overall impact on the product development timeline. While many non-vascular interventional surgeries were postponed or canceled and the demand for our products temporarily decreased during the three months as resources were allocated to COVID-19, since June 2022, many hospitals returned to normal business operations as the COVID-19-related restrictive measures gradually lifted. To the best knowledge of our Directors, there has been no material breach of sales agreements with our distributors as of the Latest Practicable Date and the suspension did not have a material adverse impact on us.

As the COVID-19 related restrictive measures gradually lifted since June 2022 and in December 2022, many of the restrictive measures previously adopted by the PRC government at various levels to control the spread of the COVID-19 virus have been revoked or replaced with more flexible measures. In particular, since December 2022, the PRC government has started to relax substantially all of its restrictive measures nationwide. Many regions experienced a temporary surge in infection cases. The surge in COVID-19 infections since December 2022 has not materially impacted our business operations and financial performance as almost all of our employees were infected and they have already recovered and returned to office within approximately two weeks of infection. We have mobilized internal and external resources and leveraged our operating capabilities to minimize the adverse effect on our business caused by the COVID-19 outbreak and the Recurrence.

Our revenue increased by 33.5% from RMB255.2 million in 2021 to RMB340.8 million in 2022. During the Track Record Period and up to the Latest Practicable Date, there was no early termination or removal of enrolled patients in our clinical trials due to the COVID-19 pandemic. However, the future impact of COVID-19 and the Recurrence globally is still uncertain, our business operations, planned regulatory process and commercialization globally may continue to be subject to the impact of the COVID-19 pandemic and the Recurrence.

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We cannot guarantee you that the COVID-19 pandemic and the Recurrence will not further escalate or have a continued material adverse effect on our results of operations, financial position or prospects. For more details, see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Operations — Our operations and business plans may be adversely affected by natural disasters, health epidemics and pandemics, civil and social disruption and other outbreaks, in particular the COVID-19 outbreak.”

Commercialization of our Core Products

We define commercialization as the time when we receive orders from our customers. Our plasma radio frequency generator (NW-100) was commercialized in December 2022, with sales of two NW-100 to a hospital in Beijing through a distributor. To date, the hospital, the distributor and us were still finalizing the installation plan and we expect to have our two NW-100s installed by the first half of 2023. As the plasma radio frequency generator (NW-100) has not been installed yet, the hospital did not purchase the single-use electrosurgical snare together with the plasma radio frequency generator (NW-100). After the installation of the NW-100s, the hospital will purchase single-use electrosurgical snares from us through a distributor. We commence the commercialization of our single-use electrosurgical snare in June 2023.

Expected Net Loss

We may continue to incur a net loss in the coming years, primarily attributable to the significant operating expenses as a result of the expansion of research and development activities, our commercialization efforts, as well as fair value loss on financial liabilities at FVTPL. We expect to record net losses for the year ending December 31, 2023, primarily because (i) we have continued to incur significant costs and expenses, including share-based compensation, as we furthered our research and development, sales and marketing, and business development efforts, (ii) we have continued to incur fair value loss on financial liabilities on FVTPL, and (iii) we will incur [REDACTED] in 2023.

Recent Laws, Rules and Regulations

On February 17, 2023, the CSRC released the Overseas Listing Trial Measures, together with five interpretative guidelines thereof, which will become effective on March 31, 2023 (the “**Implementation Date**”). The Overseas Listing Trial Measures stipulated that domestic companies that seek to issue securities overseas, both directly and indirectly, shall complete the filing procedures and report relevant information to the CSRC. On the same date, the CSRC also released the Notice on the Arrangements for the Filing Management of Overseas Listing of Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which stipulated that prior to the Implementation Date, the CSRC would carry on its works on a normal basis pursuant

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to relevant regulations for the accepted applications for administrative approval for the overseas securities listing, under which circumstance if such companies could not obtain administrative approval prior to the Implementation Date, these companies shall complete the filing procedures with the CSRC. As advised by our PRC Legal Advisors, as we have obtained an approval letter dated March 20, 2023 from the CSRC for the [REDACTED] and such approval will be valid for a year, we do not expect the Overseas Listing Trial Measures to have any impact on the [REDACTED]. For details, see “Regulatory Overview.”

Silicon Valley Bank Incident

On March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. According to the FDIC, all insured depositors of SVB will have full access to their insured deposits no later than the morning of Monday, March 13, 2023. The FDIC will pay uninsured depositors an advance dividend within the next week. Uninsured depositors will receive a receivership certificate for the remaining amount of their uninsured funds. As the FDIC sells the assets of SVB, future dividend payments may be made to uninsured depositors.

We have no business dealings with SVB, nor has deposited any funds with SVB as of the Latest Practicable Date. We will continue to monitor our capital risk management to ensure the safety of our bank deposits.

No Material Adverse Change

Our Directors confirm that, up to the date of this document, there has been no material adverse change in our financial or trading position since December 31, 2022 (being the date on which the latest audited consolidated financial information of our Group was prepared) and there is no event since December 31, 2022 which would materially affect the information shown in our consolidated financial statements included in the Accountants’ Report in Appendix I in this document.