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### OVERVIEW

We are a China-based company in the neuro-interventional medical device industry, dedicated to providing innovative solutions for physicians and patients. Since our first product approval in 2004, we had, as of the Latest Practicable Date, amassed a total of 30 assets in our portfolio, including ten therapeutic products and three access products approved and commercialized in China and 17 product candidates under development. We boast a comprehensive portfolio of approved therapeutic products covering all of the three major areas of neurovascular disease, namely hemorrhagic stroke, cerebral atherosclerotic stenosis and acute ischemic stroke (AIS). In the field of hemorrhagic stroke, the largest segment of the neuro-interventional medical device industry in China by product sales, we have commercialized products covering key therapeutic categories, including embolization coils, flow-diverting stents and stent grafts, according to CIC. In addition to approvals in China, *NUMEN* and *NUMEN FR*, two of our flagship embolization coil products, have been approved in the United States, the European Union and South Korea. We plan to establish a R&D and production center in the United States to supply the global market and to move forward with our global expansion. China’s neuro-interventional medical device market has been dominated by internationally renowned companies. According to CIC, we are the only Chinese company among the top five players in this market in terms of revenue in 2020, with a market share of approximately 4%.

Stroke is the leading cause of death in China, accounting for over 20% of total mortalities in 2020, with high incidence rates. According to CIC, China had an incidence of 0.8 million hemorrhagic stroke patients, 0.5 million transient ischemic attack (a condition commonly associated with cerebral atherosclerotic stenosis) patients and 1.7 million AIS patients in 2020. The penetration rate of neuro-interventional procedures in the fields of hemorrhagic stroke, cerebral atherosclerotic stenosis and AIS in China has remained relatively low at 9.1%, 1.0% and 2.7%, respectively, in 2020, suggesting significant potential for development. According to CIC, the size of the neuro-interventional medical device industry in China is expected to expand from RMB5.8 billion in 2020 to RMB17.5 billion in 2026, at a CAGR of 20.1%.

Employing neuro-interventional medical devices, endovascular neurosurgeries represent advanced treatment options for neurovascular disease, with minimal invasion and shorter recovery time for patients as compared to traditional open surgery. Specifically:

- *Hemorrhagic stroke.* One major cause of hemorrhagic stroke is intracranial aneurysm, which is primarily treated by embolization coils and flow-diverting stents. Hemorrhagic stroke neuro-interventional devices accounted for 65.2% of China’s neuro-interventional medical device market in 2020 in terms of sales revenue, according to CIC. In 2020, the penetration rate of neuro-interventional procedures for intracranial aneurysm in China was at 9.1%, as compared to 62.3% in the United States.
- *Cerebral atherosclerotic stenosis.* Cerebral atherosclerotic stenosis is a subset and the main form of ischemic stroke, which is primarily treated by bare metal stents, drug-eluting stents (DES) and balloon catheters. By the same parameters, according to CIC, cerebral atherosclerotic stenosis neuro-interventional devices accounted for 12.2% of the market in 2020.
- *Acute ischemic stroke.* AIS occurs when blood flow through a brain artery is blocked by a clot, or mass of thickened blood. A stent retriever is the main neuro-interventional medical

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device for the treatment of AIS. By the same parameters, according to CIC, AIS neuro-interventional devices accounted for 22.6% of the market in 2020.

Our portfolio includes products covering all of the three major areas of neurovascular disease, with the following highlights:

### *Hemorrhagic stroke*

- NUMEN<sup>®</sup> Coil Embolization System (“NUMEN”) and NUMEN FR Coil Detachment System (“NUMEN FR”), which obtained NMPA approval in 2020 and obtained FDA approval in the United States, CE Marking in the European Union and MFDS approval in South Korea in 2021;
- Tubridge<sup>®</sup> Flow-diverting Stent (“Tubridge”), the first neuro-interventional medical device admitted to the Green Path and the first and the only Chinese-developed flow-diverting stent approved by the NMPA;
- Willis<sup>®</sup> Intracranial Stent Graft System (“Willis”), the first and the only intracranial stent graft indicated for the treatment of cerebral vessel diseases in the world; and
- Rebridge<sup>®</sup> Intracranial Visualized Stent (“Rebridge”), the first Chinese-developed full-visualization coil embolization assisting stent that entered clinical trials.

### *Cerebral atherosclerotic stenosis*

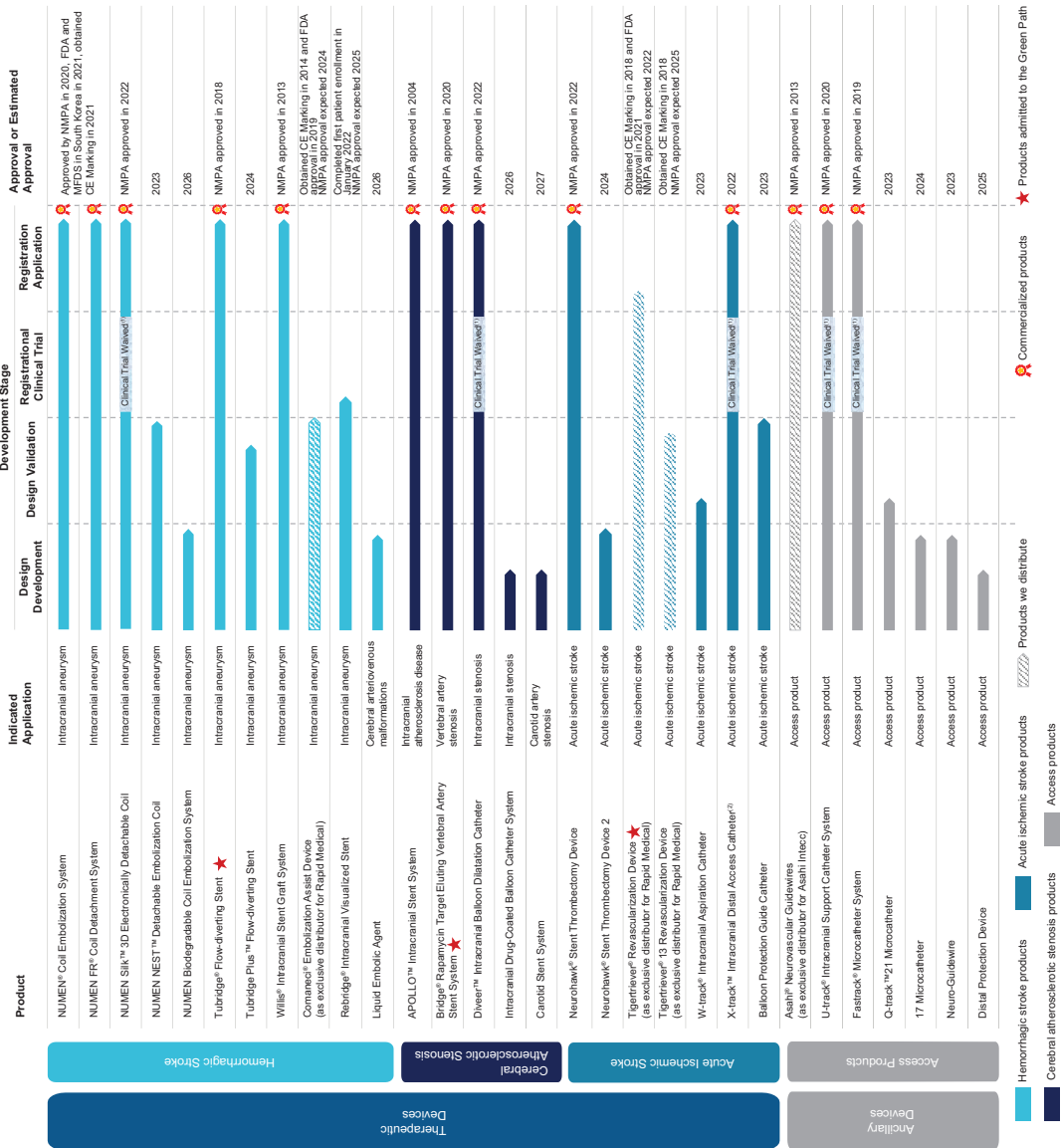
- APOLLO<sup>™</sup> Intracranial Arterial Stent System (“APOLLO”), the world’s first approved stent system to treat intracranial atherosclerotic disease (ICAD); and
- Bridge<sup>®</sup> Rapamycin Target Eluting Vertebral Artery Stent System (“Bridge”), the first vertebral artery DES that was admitted to the Green Path and approved by the NMPA.

### *Acute ischemic stroke*

- Neurohawk<sup>®</sup> Stent Thrombectomy Device (“Neurohawk”), our self-developed stent retriever system with enhanced full visualization, which was approved by the NMPA in February 2022; and
- Tigertriever<sup>™</sup> Revascularization Device (“Tigertriever”), the world’s first adjustable stent retriever with full visualization and developed by our partner Rapid Medical. We have the exclusive right to commercialize *Tigertriever*, *Tigertriever 13* and all follow-up products of *Tigertriever*, which are compatible with procedures in blood vessels of varying diameters, in Greater China. *Tigertriever* was admitted to the Green Path. We submitted *Tigertriever*’s NMPA application in December 2021 and expect to receive approval in the fourth quarter of 2022. According to CIC, *Tigertriever 13* is to date the world’s smallest stent retriever, designated for distal vessel occlusion.

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The following chart summarizes our product portfolio as of the Latest Practicable Date:



Through 18 years of development, we have gained technological expertise and R&D achievements that stand out in China. As of the Latest Practicable Date, we had five approved hemorrhagic stroke products, three approved cerebral atherosclerotic stenosis products and two approved AIS products. As of the same date, we had three products that had been admitted to the NMPA’s innovative medical device special review and approval procedure (known as the “Green Path”), which is a selective program under which the NMPA provides support throughout the registration process and grants priority review to qualified medical device candidates, and four self-developed products that had obtained 16 national or regional awards. As of the Latest Practicable Date, we had 102 registered patents in China, including 32 invention patents, and 142 patents under application, including 110 invention patents. In addition, we had 30 patents registered and 58 patents under application in 10 other countries as of the Latest Practicable Date. According to CIC, we ranked first among Chinese neuro-interventional medical device companies in China in terms of registered patents. Our distinctive physician-engineer collaboration model (醫工結合) throughout our R&D process allows us to gain practical insight from key opinion leaders and real-time needs from patients.

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Through our collaborations with physicians, we aim to develop a complete portfolio of neurovascular interventional solutions for physicians and patients.

As the largest Chinese neuro-interventional medical device company in China with a market share of approximately 4%, we have a proven record of commercialization as demonstrated by our comprehensive portfolio of commercialized products covering the major hospitals in the field of neuro-intervention. As of December 31, 2019, 2020 and 2021, we had penetrated into approximately 1,500, 1,800 and 2,200 hospitals, respectively, among which approximately 1,000, 1,150 and 1,300 were Class III hospitals, and 500, 650 and 900 were Class I and Class II hospitals, respectively. We had penetrated into approximately 2,400 hospitals, among which over 1,400 are Class III hospitals as of the Latest Practicable Date. According to CIC, our products had penetrated all of the top 100 hospitals as monthly ranked by China’s National Stroke Center in 2021. We have established customized commercialization strategies targeting specific market segments. In first- and second-tier cities, we focus on enhancing our brand awareness and penetrating into major hospitals through organizing and participating influential conferences in neuro-intervention industry, building long-term relationship with key opinion leaders and providing training to physicians. Given that hemorrhagic stroke surgeries are more prevalent in first- and second-tier cities, for distributors covering these markets, we select those who have solid experience in distributing hemorrhagic stroke products and strong connections with leading hospitals in hemorrhagic stroke surgeries. In lower-tier cities and counties, we promote our products through our Eagle & Swallows (神雕飛燕) program, through which we introduce knowledge about neuro-intervention, organize training on neuro-interventional procedures, provide follow-up consulting, and offer routine guidance to local physicians and patients. Accordingly, as surgeries for acute ischemic stroke and cerebral atherosclerotic stenosis are more prevalent in lower-tier cities and counties, for distributors covering these markets, we select those who have rich experience and extensive hospital connections in these surgical areas.

We maintain and follow a global vision. Some of our flagship products have been approved in overseas markets for sale. Our *NUMEN* and *NUMEN FR* obtained FDA approval in the United States, CE Marking in the European Union and MFDS approval in South Korea in 2021. In addition, we collaborate with global leading neuro-interventional medical device companies to enrich our product portfolio and expand our sales network. In 2019, we established a strategic relationship with Israel-based Rapid Medical, under which we act as the exclusive distributor of Rapid Medical’s flagship products, *Comaneci*, *Tigertriever*, *Tigertriever 13* and all follow-up products, in Greater China. In May 2021, we became Rapid Medical’s largest shareholder through equity investments. In addition, we have cooperated with Japan-based Asahi Intecc and act as the exclusive distributor for its neurovascular guidewires in mainland China since November 2016. Furthermore, we have established local sales teams in Latin America, Asia Pacific and Europe. We also plan to establish an overseas R&D and production center in Irvine, California, the neuro-intervention R&D hub in the United States. Our goal is to establish a local supply chain and production facilities in the United States aiming to supply the global market with overseas production and to move forward with our global expansion.

We recorded robust financial growth during the Track Record Period. Our revenue increased from RMB183.7 million in 2019 to RMB 221.9 million in 2020 and further to RMB382.8 million in 2021.

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### COMPETITIVE STRENGTHS

We believe the following strengths contribute to our success:

#### **Largest Chinese neuro-interventional medical device company with comprehensive product portfolio.**

As the largest Chinese player in the neuro-interventional medical device industry in China, we have been promoting the development of this high potential industry through our innovative products. As early as 2004, *APOLLO* was approved by the NMPA and became the world’s first approved stent system to treat ICAD, a disease caused by cerebral atherosclerotic stenosis. Over the 18 years since then, we have grown into the largest Chinese neuro-interventional medical device company, in terms of revenue in 2020, according to CIC. As of the Latest Practicable Date, we had ten therapeutic products approved in China, including two coil embolization systems, one coil detachment system, one flow-diverting stent, one stent graft, one intracranial artery stent, one vertebral artery drug-eluting stent (DES), one stent retriever, one intracranial balloon dilatation catheter and one intracranial distal access catheter. These approved therapeutic products cover all of the three major areas of neurovascular disease, namely hemorrhagic stroke, cerebral atherosclerotic stenosis and AIS. As of the same date, we also had three access products approved by the NMPA, including two self-developed products and one product of Asahi Intecc that we distribute in mainland China. We boast a comprehensive portfolio of products and product candidates covering all of the three major areas of neurovascular disease—hemorrhagic stroke, cerebral atherosclerotic stenosis and AIS—that are approved or in the registration approval stage.

- *Hemorrhagic stroke.* In the field of hemorrhagic stroke, the largest segment of the neuro-interventional medical device industry in China by product sales, we have commercialized products covering key therapeutic categories in this segment, including embolization coils, flow-diverting stents and stent grafts, according to CIC. Our commercialized products include *NUMEN*, *NUMEN FR*, *Tubridge* and *Willis*. According to CIC, *Tubridge* was the first neuro-interventional medical device admitted to the Green Path, and was the first and remains the only Chinese-developed flow-diverting stent approved by the NMPA. *Willis* was the first and remains the only intracranial stent graft to treat cerebral vessel diseases approved in the world. We also have products approved in overseas markets. *NUMEN* and *NUMEN FR* have been approved in the United States, the European Union and South Korea.
- *Cerebral atherosclerotic stenosis.* According to CIC, *APOLLO* was the world’s first approved stent system to treat ICAD. In addition, *Bridge* was the first vertebral artery DES that was admitted to the Green Path and approved by the NMPA.
- *AIS.* Through self-development and strategic cooperation, we have received NMPA approval for *Neurohawk* and *X-track* and progressed into the registration approval stage of *Tigertriever*, covering varying vessel diameters. According to CIC, we are the only Chinese company who has stent retrievers that are compatible with procedures in varying sizes of blood vessels.
- *Access products.* We have a variety of access products to accommodate the treatment of neurovascular disease. Our approved access products include Fastrack Microcatheter

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System and U-track Intracranial Support Catheter System, as well as Asahi guidewires, for which we have acted as its exclusive distributor in mainland China since November 2016.

In 2019, 2020 and 2021, our revenue increased rapidly at a CAGR of 44.4%, reaching RMB382.8 million in 2021. According to CIC, we are the largest Chinese neuro-interventional medical device company in terms of revenue in 2020.

### **Strong R&D capability and effective R&D model creating multiple technological breakthroughs in China and worldwide.**

Leveraging our position in China’s neuro-interventional medical device industry, we have built strong R&D capability and an effective R&D model. As of the Latest Practicable Date, we had a total of 30 commercialized products and product candidates in our portfolio, including 3 products that had been admitted to the Green Path. In particular, our self-developed *Tubridge* was the first neuro-interventional medical device and *Bridge* was the first vertebral artery DES admitted to the Green Path, according to CIC. In addition, all of our six approved therapeutic products have been developed by ourselves, two of which have obtained FDA approval, CE Marking and MFDS approval.

Some of our self-developed products achieved technological breakthroughs globally and in China. According to CIC, *Willis* was the first and remains the only intracranial stent graft to treat cerebral vessel diseases approved in the world, and *Tubridge* was the first and remains the only Chinese-developed flow-diverting stent approved by the NMPA. Moreover, *APOLLO* was the world’s first approved stent to treat ICAD, and *Bridge* was the first vertebral artery DES that was admitted to Green Path and approved by the NMPA.

Our products have received multiple recognitions globally and in China. *Willis* was one of the innovative stent devices to treat intracranial aneurysm recognized by *Stroke*, a journal published by American Heart Association and American Stroke Association, in 2007. *Willis* also won the First Prize in Science and Technology Award of Shanghai (上海市科技進步一等獎) in 2009 and the Second Prize in National Science and Technology Award (國家科學技術進步獎二等獎) in 2014. *APOLLO* won the Second Prize for Science and Technology Award of Shanghai (上海市科技進步二等獎) in 2009.

We have developed and relied on a distinctive physician-engineer collaboration model (醫工結合) throughout our R&D process. We cooperate with a wide range of physicians in various forms and depths. In the early stage of product research and development, we obtain and consider physicians’ practical needs in product design. Further into the R&D process, we establish an interactive mechanism with physicians to advance product development. Through close communication with experts in the clinic, we convert treatment ideas into therapeutic solutions in the laboratory.

- *Tubridge*. The design concept of *Tubridge* can be traced back to the time when there was no optimal treatment in China for the treatment of large and giant intracranial aneurysms, and physicians resorted to layering multiple coil embolization systems and stents, which could lead to lower rate of success and high surgical costs. Our development of *Tubridge* represented an early hemodynamics (the dynamics of blood flow) study in China. Between 2012 and 2016, we completed the first prospective, multi-center and randomized controlled trial (RCT) in China’s neuro-interventional medical device industry. The primary endpoint of the RCT showed a statistically significantly higher aneurysm complete occlusion rate of

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*Tubridge* than the stent-assisted coiling device used in the control group. *Tubridge* allows physicians to treat a majority of large and giant intracranial aneurysms with one flow-diverting stent, which could save more than 50% in costs, according to CIC.

- *Willis*. We jointly developed *Willis* with Professor Li Minghua from Shanghai Sixth People’s Hospital Affiliated to Shanghai Jiaotong University, who first introduced the theory of parent artery reconstruction of intracranial aneurysm, that is to bypass and cover the orifice of the aneurysms with a covered stent, reconstruct the parent artery wall and redirect the blood to the cerebral artery. Based on this innovative theory, we worked on *Willis*’ design, material and technology seamlessly with Professor Li and launched *Willis* in 2013 (with us owning all intellectual property). *Willis* is the first neuro-interventional therapeutic device that applies the theory of intracranial parent artery reconstruction in practice to treat neurovascular diseases, and it remained as the only intracranial stent graft for the treatment of cerebral vessel diseases in the world, according to CIC. Compared to surgical repair or coil embolization, *Willis* is able to reduce the risk of procedure-related rupture of aneurysms and the related risk of intracranial bleeding.
- *Bridge*. Conventional treatments of vertebral artery stenosis, such as coronary drug-coated balloon stents and intracranial bare-metal stents, have relatively high in-stent restenosis rates. To address this, we developed *Bridge*, a rapamycin target-eluting vertebral artery stent system, which effectively contained the in-stent restenosis rate to 3.7% at the six-month follow-up in its registration clinical trial, which was significantly lower than the in-stent restenosis rate of 15.2% of the other NMPA-approved vertebral stent, according to CIC.

Through 18 years of development, we have built technological expertise and R&D achievements that stand out in China. As of Latest Practicable Date, we had 102 registered patents in China, including 32 invention patents, and 142 patents under application, including 110 invention patent applications. In addition, we had 30 patents registered and 58 patents under application in 10 other countries. According to CIC, we ranked first among Chinese neuro-interventional medical device companies in China in terms of registered patents. We also participated in drafting the industry standards for intracranial arterial stents and intracranial coil embolization systems. We have an experienced in-house R&D team. Mr. Wang Yiqun Bruce, head of our R&D team, has 26 years of experience in international leading medical device companies. The majority of our R&D team members and all core R&D team members have a master’s degree or a doctoral degree.

### **Proven commercialization capabilities with the highest revenue among Chinese neuro-interventional medical device companies.**

As the first domestic entrant to the neuro-interventional medical device industry in China, we have developed proven commercialization capabilities evidenced by our leading position among domestic peers, customized commercialization strategies and an extensive distribution network.

According to CIC, we are the largest Chinese neuro-interventional medical device company in terms of revenue in 2020. Our revenue increased from RMB183.7 million in 2019 to RMB382.8 million in 2021, at a CAGR of 44.4%. Some of our flagship products have predominant market shares in China. According to CIC, *Willis* has a market share of 100% in intracranial stent graft market, and

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*Tubridge* and *APOLLO* has a market share of approximately 44% and 47% in flow-diverting stent market and intracranial stent market, respectively, all in terms of sales volume in China’s neuro-interventional medical device market in 2020.

We had penetrated into approximately 2,400 hospitals, among which over 1,400 are Class III hospitals as of the Latest Practicable Date. According to CIC, our products had penetrated into all of the top 100 hospitals in China as monthly ranked by China’s National Stroke Center in 2021.

We have established differentiated commercialization strategies for first- and second-tier cities on the one hand and lower-tier cities and counties on the other hand.

- In first- and second-tier cities, we focus on enhancing our brand awareness and penetrating into major hospitals through organizing and participating in influential conferences in the neuro-intervention industry, building long-term relationship with key opinion leaders and providing training to physicians. We are an active participant in various major conferences in the neuro-intervention industry in China, including the annual Oriental Conference of Interventional Neurovasculology (東方腦血管大會), the Annual Conference of Chinese Interventional Neuroradiology Society of Chinese Stroke Association (中國卒中協會神經介入分會學術年會) and the Western Stroke Interventional Conference (西部卒中介入會議). We have established a teaching and training model, under which experienced physicians provide training to physicians who are new to our products. These physicians, once experienced in using our products, will in turn be invited to train newcomers to further improve our brand awareness. We also offer skill training programs to young physicians to help them improve technical skills and broaden understanding of neuro-interventional surgery.
- In lower-tier cities and counties, we promote our products through our Eagle & Swallows (神雕飛燕) program. Stroke treatment is time-sensitive. The PRC government started an initiative in 2018 to establish a full coverage of stroke treatment nationally, aiming to allow patients to receive treatment within one hour of disease onset. The number of stroke treatment centers in lower-tier cities and counties is expected to rapidly increase, and the historically less developed markets will become increasingly important. Through our Eagle & Swallows (神雕飛燕) program, we introduce knowledge about neuro-intervention, organize training on neuro-interventional procedures, provide follow-up consulting and routine guidance to physicians and patients. As of the Latest Practicable Date, we had penetrated into approximately 130 lower-tier cities and counties.

We have an internal sales and marketing team of approximately 100 employees, with an average industry experience of more than 8 years. In addition, we have established cooperation with more than 200 distributors and sub-distributors, covering all provinces in the PRC. We have maintained long-term relationships with our distributors, some of which have had more than 10 years of cooperation with us.

### **Increasing global visibility with strategic partnerships for further expansion**

We are committed to becoming a global leader in the neuro-interventional medical device market. We are gradually gaining access for our products into the top 10 countries in terms of neuro-



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interventional procedures, including the United States, Japan, South Korea and Brazil. As the first step of our overseas expansion, *NUMEN* and *NUMEN FR* received FDA approval in the United States, CE Marking in the European Union and MFDS approval in South Korea in 2021. We also performed the first overseas coil embolization placement procedure using *NUMEN* and *NUMEN FR* in Chile in August 2021.

As part of our globalization process, we have established a series of localized sales organizations with in-depth understanding of local markets and resources of sales channels. We have leaders of sales and marketing team in Brazil, Japan and United Kingdom, who work collaboratively to expand our global sales network and enhance our market presence.

In addition, to enhance our brand awareness in the United States and globally, we seek to localize our R&D, supply chain and production. We plan to establish a R&D and production center in Irvine, California, the neuro-intervention R&D hub in the United States. We believe that our presence in the United States will help us compete with top U.S. neuro-interventional medical device companies in the areas of talent, brand, supply chain and production capability. Our goal is to establish a local supply chain and production facilities in the United States aiming to supply the global market with overseas production and to move forward with our global expansion.

We cooperate with leading international companies to expand our product portfolio and sales network, with the aim of achieving a more diversified portfolio of products for all of the three major areas of neurovascular disease. In 2019, we established a strategic relationship with Rapid Medical, to which we believe we are complementary in terms of products and resources. As part of this cooperation, we are the exclusive distributor of Rapid Medical’s flagship products, *Comaneci*, *Tigertriever* and *Tigertriever 13*, and all follow-up products, in Greater China, which further enhances our footprint in hemorrhagic stroke and AIS. We also plan to leverage Rapid Medical’s sales network in the United States as we progress our overseas plans for *NUMEN* and *NUMEN FR*. In November 2016, we entered into a distribution agreement with Asahi Intecc, under which we act as the exclusive distributor of its global leading neurovascular guidewires in mainland China. Relying on our sales network in mainland China, the sales of Asahi guidewires have grown rapidly since we began to act as its exclusive distributor.

### **Efficient management of supply chain to ensure top quality and large-scale production**

As an established medical device company with a comprehensive portfolio of commercialized products and products under development, we believe one of our key strengths is our ability to effectively manage our supply chain, manufacturing capacity and quality assurance systems.

We have established a robust supplier evaluation system to ensure satisfactory performance of the suppliers and to secure stable supplies of quality equipment, materials and services. Relying on our long-term cooperation and continuous growing demands, we have established stable relationship with these suppliers, including several industry top suppliers in the global medical device market.

We have achieved scalable production in China. During the Track Record Period, we conducted manufacturing activities primarily at our manufacturing facility located in our leased properties in Zhoupu, Shanghai, with an aggregate GFA of approximately 2,300 sq.m. To expand our manufacturing capability as the market demand continues to grow, we constructed another

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manufacturing facility in our leased properties in Zhangjiang, Shanghai, with an aggregate GFA of approximately 7,000 sq.m. We obtained the production permit for this facility in May 2022. As of the Latest Practicable Date, we manufactured our commercialized stent, coil and catheter products at these facilities with an annual production capacity of approximately 110,000 units. We expect to increase our designed annual capacity to approximately 350,000 units per year in 2025. In addition, we possess key proprietary technology and knowledge of our specialized machinery, which enables us to adjust product design in accordance with our specific manufacturing requirements, iterate and upgrade our product portfolio and improve cost efficiency.

We believe product quality is the lifeline of a neuro-interventional medical device company. We strive to pursue innovation and to provide patients with safe and reliable products to help them improve their quality of life. We uphold product quality as our core value and have established a corporate culture to consistently manufacture high-quality products. To achieve this goal, we have formed a digital product quality control system covering the entire production process, allowing us to trace every step in our product design, development, manufacturing and after-sale service and monitoring. We have also established a central testing laboratory in accordance with ISO13485 that could meet the testing and verification demands at each stage within the product life cycle. We have received product quality recognition and certifications in China and globally. We were recognized as a Grade A Product Quality Enterprise by Shanghai Food and Drug Administration consecutively from 2016 to 2020. In 2015, we obtained the ISO13485 Medical Device Quality Management System Certification. Since then, we have obtained quality system certification in the European Union, Brazil, Argentina and South Korea. We also expect to receive quality system certifications in Japan in 2022.

### **Visionary and experienced management team and strong synergy with controlling shareholder MicroPort**

We have a visionary management team with rich experience and expertise covering the full spectrum of research and development, manufacturing and commercialization of neuro-interventional medical devices. Mr. Peng Bo, our chairman, has over 20 years of experience in the medical device industry and also serves as the chief marketing officer of MicroPort. Mr. Xie Zhiyong, our president, has over 20 years of experience in the neuro-intervention industry. Mr. Xie has been recognized as a Leading Talent of Shanghai (上海市領軍人才) and Zhangjiang Professional of Excellence (張江卓越人才). Mr. Xie has two research projects that won the Second Prize for National Science and Technology Award (國家科學技術進步獎二等獎) and more than 100 registered patents. Mr. Wang Yiqun Bruce, our executive vice president and director of our engineering and technology department, has 26 years of neuro-intervention industry experience, including 17 years with Boston Scientific Corporation, and is a member of the prestigious Shanghai Foreign Elite Talent Introduction Program (上海市高層次引進人才). Mr. Wang has 16 patents registered in the United States and 13 patents registered in China. Mr. Duan Lei, our vice president of sales and promotion of neuro-interventional solutions, is well connected with key opinion leaders in the neuro-intervention industry and has more than 15 years of medical device industry experience. Led by Mr. Duan, we have maintained rapid sales growth as evidenced by our robust financial growth during the Track Record Period.

Since our inception, we have received strong support from our Shareholders and achieved great synergy with our Controlling Shareholder, MicroPort. MicroPort is a leading medical device company focused on innovating, manufacturing and marketing high-end medical devices globally, which has

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been listed on the Main Board since 2010. Benefiting from the market recognition of the “MicroPort” brand, we have successfully penetrated into the major hospitals in the field of neuro-intervention. Inspired by the global R&D, manufacturing and sales service network of MicroPort, our team has accumulated vast experience in this field.

### OUR STRATEGIES

Our mission is to provide accessible, top-quality and comprehensive solutions for stroke patients. We plan to implement the following strategies to achieve this mission:

#### **Promote universal and affordable neuro-interventional solutions to patients**

According to CIC, the number of stroke patients and the penetration rate of neuro-interventional procedures continue to rise worldwide. In China, the penetration rate of neuro-interventional procedures in the fields of hemorrhagic stroke, cerebral atherosclerotic stenosis and AIS has remained relatively low as compared to that of the developed countries. Additionally, with the rapid increase in the number of approved Chinese-developed neuro-interventional medical devices, there is significant increasing potential for the market share of Chinese-developed neuro-interventional medical devices.

As the pioneer in the market, we will use our proven commercialization capability and strategy to gain market share and provide universal neuro-interventional solutions. To widen the breadth of our market coverage, we will continue to promote our products in lower-tier cities and counties through our Eagle & Swallows (神雕飛燕) program. We will proactively seek to meet the market demand for Chinese-developed products and further strengthen our position in the neuro-intervention industry in China.

We aim to offer advanced and affordable neuro-interventional products in all of the three major areas of neurovascular disease, allowing patients to receive neuro-interventional procedures at a relatively lower price. While our products are more affordable, our products retain comparable quality as similar products from international companies. We will continue to expand our commercial offering while ensuring affordable neurovascular solutions to the wider public.

#### **Continue to enhance our innovation capability, expand product portfolio and achieve complete solution for neurovascular disease**

We have established a comprehensive R&D system to continuously enhance our innovation capability and R&D efficiency. Our physician-engineer collaboration model (醫工結合) covers the entire R&D process, allowing us to make timely innovative adjustments to solve problems in neurovascular disease treatment.

We will also continue to expand the depth and breadth of our product pipeline to achieve full product coverage of the neurovascular therapeutic area. We expect to commercialize *NUMEN Silk* 3D electronically detachable coil, *Diveer* intracranial balloon dilatation catheter and *Tigertriever* revascularization device in 2022. We expect to have around 30 commercialized products by 2026.

- *Continue to strengthen our product portfolio for hemorrhagic stroke.* We plan to develop the next-generation coil embolization systems and flow-diverting stents to offer a total solution for a wide range of intracranial aneurysm procedures. In the next five years, we intend to achieve the most comprehensive product pipeline for the treatment of intracranial aneurysm globally.

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- *Solidify our leading position in cerebral atherosclerotic stenosis.* We will continue to invest in the development of self-expandable and drug-coated intracranial stents as well as vertebral artery drug-eluting balloon catheters. We expect to achieve higher efficacy, improved safety and better treatment results in the area of cerebral atherosclerotic stenosis.
- *Increase our investment in AIS products.* We will continue the research and development of stent retrievers and aspiration products in the field of AIS. For stent retrievers, we expect to commercialize our self-developed *Neurohawk* and Rapid Medical’s *Tigertriever* upon obtaining their NMPA approvals in 2022. We will then have stent retrievers compatible with procedures in varying sizes of blood vessels. For aspiration products, we will increase investments in the development of aspiration catheters, balloon guiding catheters and distal access technology. In 2023, we expect to commercialize multiple products in the field of AIS, establishing a comprehensive layout for the treatment of AIS.
- *Enhance our access product portfolio.* We intend to expand our access product portfolio by developing products that are compatible with therapeutic products for hemorrhagic stroke, cerebral atherosclerotic stenosis and AIS.

### **Comprehensive global strategy to expand our international layout**

With an eye on the international market, we actively seek to continue the establishment and expansion of our global presence. We intend to expand our product portfolio and global sales network, and achieve a more diversified portfolio of products for all major neurovascular disease areas in the global market. We plan to continue advancing the registration of our innovative products overseas. We also plan to further expand our international team to cover the top 10 countries in terms of neuro-interventional procedures. Relying on our localized team members, we aim to provide physicians and patients from all over the world with advanced treatment, training on neuro-interventional procedures, and a comprehensive product portfolio. Through our continuing efforts, we aim to enhance our brand awareness and product recognition in the global market.

To achieve international recognition of our product and brand, we intend to establish R&D and production centers overseas. For instance, we plan to establish an overseas R&D and production center in Irvine, California, the hub of neuro-intervention of R&D in the United States, within two years to supply the global market. Our goal is to create quality products in accordance with international standards and connect with physicians worldwide to understand their clinical needs in neuro-interventional procedures. We will also establish a global procurement and supply chain network to build resources in different locations, to reduce cost, improve production capacity and enhance product quality in turn.

To accelerate our globalization strategy, we will continue to integrate resources from our cooperation partners and to seek support from our Controlling Shareholder, MicroPort. We intend to expand our product portfolio and global sales network through our cooperation partners. Furthermore, benefiting from the market recognition of the “MicroPort” brand, we believe we are well positioned to promote our products to physicians and hospitals globally.

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### **Continue to improve our operating efficiency, enlarge production scale and enhance economies of scale**

We have built an efficient, integrated and all-round operation platform. As we continue to expand our business, we intend to further improve operating efficiency, enlarge production scale and enhance economies of scale.

We will continue to optimize our all-round operating system, consisting of procurement, quality control, manufacturing and training systems. We plan to establish and maintain a global supply chain. Benefiting from the complementary effect of domestic and international resources, we are able to effectively control cost and enhance operating efficiency. In addition, we will continue to adhere to a standardized quality control system in the entire production process and upgrade our manufacturing technologies. We aim to ensure consistent high-quality and stable capacity under large-scale production. Through our training system, we aim to familiarize our employees with the all-round operating system to improve efficiency and ensure quality control.

We plan to continuously improve our production capacity and efficiency by expanding our manufacturing facility and the scale of our production team to meet the demands of the market. In doing so, we believe we will benefit from economies of scale and achieve lower procurement and production costs. With our continuous expansion, we aim to provide affordable neuro-interventional solutions to a wider general public.

### **Continue to cooperate with enterprises in the neuro-intervention industry worldwide**

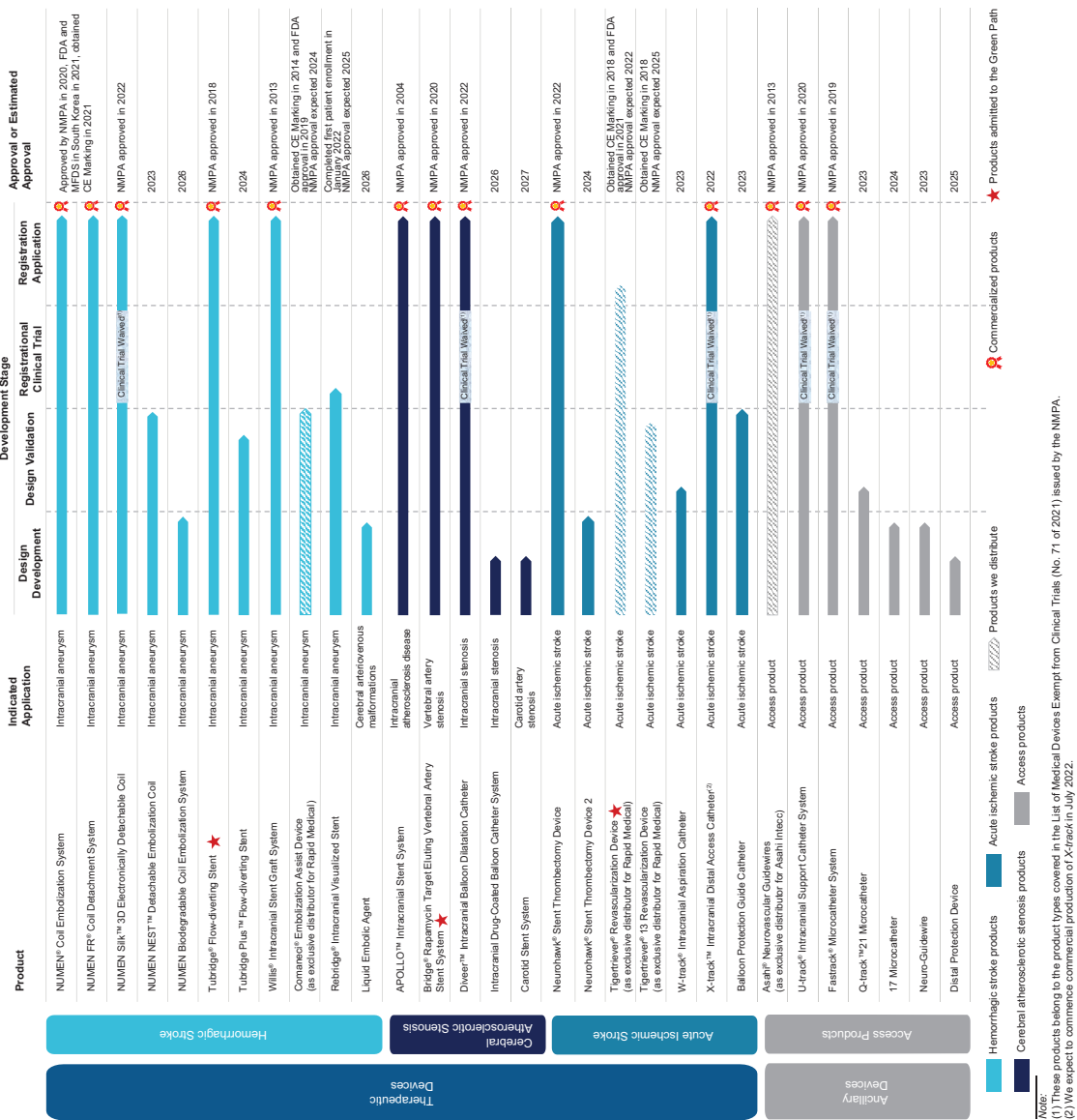
We have entered into various forms of cooperation with leading international companies. Leveraging our position in the neuro-intervention industry in China and our global brand influence, we believe we are the preferred partner for international companies in China.

We aim to expand our product line and strengthen synergies among products through cross-border collaborations. We will closely follow and monitor cutting-edge technologies in the global neuro-intervention industry by focusing on highly innovative companies in the industry with breakthrough technologies and innovative products that are complementary to our product portfolio. We plan to establish cooperation with these companies through strategic acquisition, equity investments, distribution arrangements, registration cooperation or a combination of these methods. Our goal is to reinforce our influence in the global neurovascular marketplace.

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### OUR PRODUCT PORTFOLIO

Since our first product approval in 2004, we have amassed a total of 30 commercialized products and product candidates in our portfolio. We boast a comprehensive portfolio of approved products covering all of the three major areas in neurovascular diseases, namely hemorrhagic stroke, cerebral atherosclerotic stenosis and acute ischemic stroke (AIS). As of the Latest Practicable Date, we had ten therapeutic products and three access products approved in China. All of our commercialized therapeutic products are classified as Class III medical devices under NMPA regulations. As of the same date, we also had 17 product candidates under development. The following chart summarizes our product portfolio as of the Latest Practicable Date:



### Hemorrhagic Stroke Products

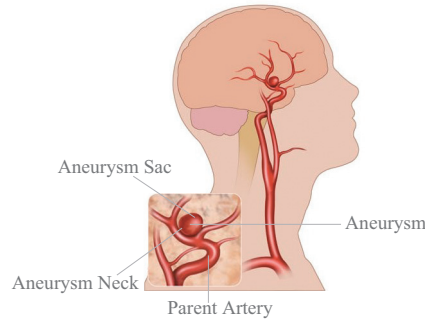
A hemorrhagic stroke happens when an artery in the brain leaks or ruptures. Hemorrhagic stroke is most commonly caused by high blood pressure or intracranial aneurysm, which are balloon-like bulges in an artery that can stretch and burst. If an intracranial aneurysm ruptures, the blood floods around brain tissues and it quickly becomes life-threatening. Therefore, intracranial aneurysms are

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known as “ticking timebombs in the head.” Even if an intracranial aneurysm remains unruptured, it still presses on brain tissues nearby and potentially causes pain around the eye, changes in vision or numbness on one side of the face. Below is an illustrative diagram of an intracranial aneurysm:



Traditionally, the only available treatment for intracranial aneurysm was surgical clipping, which requires the patient to have a craniectomy, an open procedure that removes part of the skull. The physician then places a clip through an incision in the skull to seal off the aneurysm neck. In the last three decades, minimally invasive treatments for intracranial aneurysm have evolved tremendously, and various treatment options have been developed.

The first minimally invasive treatment was coil embolization, which closes off the aneurysm sac by filling the aneurysm with coils. This prevents the aneurysm from further expanding and rupturing. Coils can also be used in conjunction with assisting devices like stents, especially for aneurysms with wide necks or unusual shapes. The stent supports the coils and prevents them from migrating into the parent artery, the artery from which the aneurysm has developed, whilst at the same time encouraging packing density and suspension of blood flow in the aneurysm. Stent grafts are expandable stents covered by a membrane, which fit within the artery wall tightly and therefore prevent blood flow from entering the aneurysm. A relatively new treatment is flow diversion. Flow-diverting stent aims to decrease blood flow within the aneurysm and redirect the blood to the parent artery. It also promotes endothelial tissue formation along the surface of the stent, which subsequently closes off the aneurysm neck and permanently closes the aneurysm from systemic blood circulation. Flow-diverting stent is specifically indicated for large aneurysms (between 10 and 25 mm in diameter) or giant aneurysms (greater than 25 mm in diameter). For large or giant aneurysms, flow-diverting stent provides better coverage for aneurysm necks, and therefore has a higher rate of success and lower recurrence rate compared to traditional treatments.

We have developed a comprehensive product portfolio covering all treatment options discussed above. Our products portfolio for intracranial aneurysm include (i) *NUMEN*<sup>®</sup> Coil Embolization System; (ii) *NUMEN FR*<sup>®</sup> Coil Detachment System; (iii) *Tubridge*<sup>®</sup> Flow-diverting Stent; (iv) *Willis*<sup>®</sup> Intracranial Stent Graft System; (v) *Comaneci*<sup>®</sup> Embolization Assist Device; and (vi) *Rebridge*<sup>®</sup> Intracranial Visualized Stent. We are also developing a liquid embolic agent for treating cerebral arteriovenous malformations (cerebral AVM), a condition where abnormal connections form between the arteries and veins in the brain.

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### Commercialized Products

#### *NUMEN® Coil Embolization System (“NUMEN”)*

*NUMEN* (meaning “god with divine power” in Latin) is a coil embolization system used to treat intracranial aneurysm. In a procedure with *NUMEN*, several coils are placed densely within the target aneurysm to close off blood inflow, preventing the aneurysm from further expanding and bursting. After the embolization, a thrombus, or blood clot, also gradually forms inside the aneurysm and endothelial cells start to cover the aneurysm neck. This further stops blood from flowing into the aneurysm and effectively cures it.

*NUMEN* permits stable framing, smooth filling and finishing, with superb conformability to shapes of aneurysms. Its three models, *MicroFrame*, *MicroFill* and *MicroFinish*, have 177 specifications with different diameters, lengths and softness levels, providing physicians with a full range of embolization options to ensure the safety and efficacy in all stages of the coiling procedure.

*NUMEN* is classified as a Class III medical device under NMPA regulations and was approved and commercialized in China in September 2020. It also obtained FDA approval, CE Marking and MFDS approval in South Korea in 2021. In August 2021, the first overseas coil embolization procedure with *NUMEN* was completed in Chile, marking *NUMEN*'s initial entrance to the overseas market.

We have been continuously developing upgraded versions of *NUMEN*. *NUMEN Silk* was approved by the NMPA in February 2022. We plan to submit the registration application for *NUMEN NEST* in the first quarter of 2023 and expect to obtain NMPA approval in the fourth quarter of 2023. *NUMEN Biodegradable* is currently in the design development stage, and we expect to obtain NMPA approval in 2026.

#### *Product Structure*

*NUMEN* coils are made of thin and soft platinum tungsten alloy wires, which are deployed through a microcatheter when placed in the aneurysm sac. The physician detaches a coil after it is properly placed. *NUMEN* is used together with its detachment device, *NUMEN FR*, which also obtained FDA approval, CE Marking and MFDS approval along with *NUMEN*. *NUMEN FR* uses an electrolytic detachment mechanism, which features a fast, smooth and convenient detaching process. See “—*NUMEN FR*® *Detachment System*” below for details.

#### *Features and Competitive Advantages*

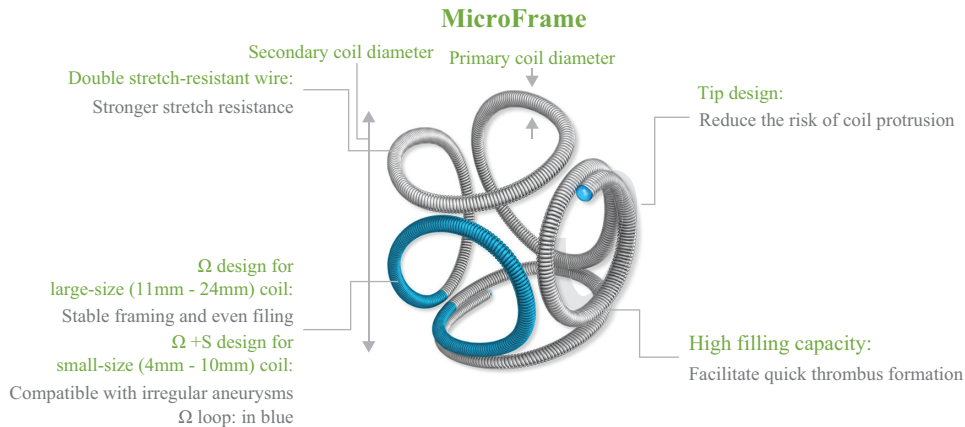
*NUMEN* has three models, *MicroFrame*, *MicroFill* and *MicroFinish*. Each of the three models has further variations with different diameters, lengths and softness levels, aiming to provide physicians with a full range of embolization options, helping ensure the safety and efficacy in all stages of the coiling procedure, namely, framing, filling and finishing stages. The framing stage aims to build up a stable and supportive basket in the aneurysm, and the framing coil usually has the same or slightly smaller diameter as the aneurysm. In the filling stage, filling coils, which are shorter and smaller than the framing coil, are packed densely inside the framing coil. Then, in the finishing stage, the physician places finishing coils, which are much softer than framing coils and filling coils, in the remaining spaces in the aneurysm.



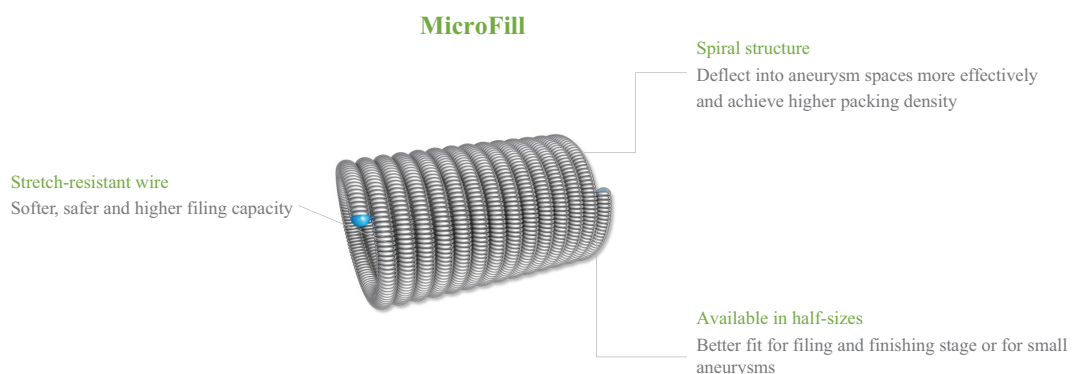
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We believe the three models of *NUMEN* have the following features and benefits:

- *MicroFrame* provides stable framing and dense coverage for the aneurysm neck. *MicroFrame* uses double stretch-resistant wires, which have stronger stretch resistance. Also, the tip design of the *MicroFrame* minimizes the risk of coil protrusion (*i.e.*, a coil falling out of the aneurysm neck) and provides a stable anchor to the aneurysm wall. *MicroFrame*'s high filling capacity facilitates quick thrombus formation, which is critical for treating aneurysms.



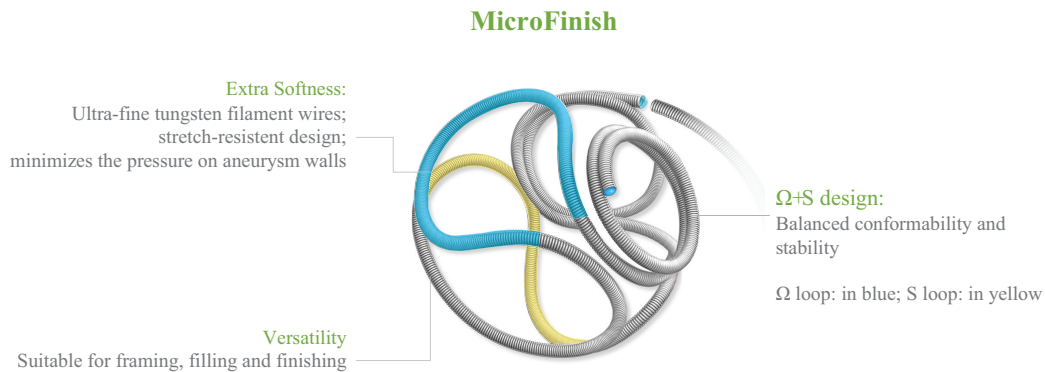
- *MicroFill* is specifically designed for high-density filling. Its spiral design allows it to fill in remaining spaces in aneurysms more efficiently. *MicroFill* is also available in half sizes, making it a better fit for the filing or finishing stage or small aneurysms. Its stretch-resistant wires allow it to be safer and have superior durability. These features enable *MicroFill* to achieve better packing density, greater conformability and reduced compartmentalization. Compartmentalization is an effect where coils divide aneurysm space into several smaller spaces without uniform distribution within the aneurysm. This is primarily a result of the coils' poor conformability and undermines the procedure's ability to reach the desired packing density.



- *MicroFinish* is made of ultra-fine tungsten filament wires. These properties help the coils achieve extra softness and minimizes the pressure on aneurysm walls. *MicroFinish*'s  $\Omega+S$  design allows it to have a good balance between stability and conformability.  $\Omega$  loops (in blue in the diagram below) allows the coil to have a stable configuration, whereas S loops (in yellow in the diagram below) fill the open spaces in the aneurysm sac. Thanks to its

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softness and stability, *MicroFinish* is well-balanced for framing, filling and finishing, covering all stages of the coiling procedure.



### *Upgraded Generations of NUMEN*

#### NUMEN Silk™ 3D Electronically Detachable Coil (“*NUMEN Silk*”)

*NUMEN Silk* features greater smoothness in coil filing stage and finishing stage. The smoothness of the distal-end of the delivery wire utilized in *NUMEN Silk* improves the microcatheter’s stability. *NUMEN Silk* also minimizes the kick-back of the microcatheter in the finishing stage, therefore reducing the risk of aneurysm rupture and improving intraoperative safety.

#### NUMEN NEST™ Detachable Embolization Coil (“*NUMEN NEST*”)

*NUMEN NEST* has a greater primary coil diameter than other NUMEN models. This feature allows *NUMEN NEST* to achieve the desired packing density with fewer coils, which leads to higher filling capacity and greater cost efficiency.

#### NUMEN Biodegradable Coil Embolization System (“*NUMEN Biodegradable*”)

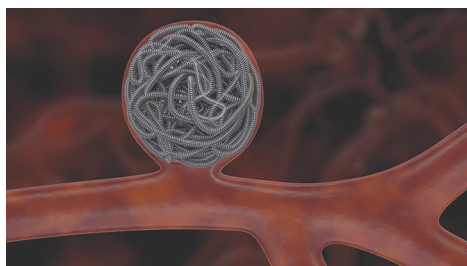
*NUMEN Biodegradable* utilizes innovative biodegradable materials, and can be substantially absorbed during the patient’s healing process. *NUMEN Biodegradable* is expected to be used mostly together with coil-assisting stents or flow-diverting stents, which reduces the likelihood of “mass effect,” where the brain tissue surrounding a large or giant aneurysm is compressed and injured due to space being taken up by the aneurysm.

### *Operation Procedure*

At the beginning of a coil embolization procedure, the physician inserts a flexible micro-guidewire and a microcatheter through the femoral artery in the groin. The physician steers the microcatheter through blood vessels and uses fluoroscopy which makes the blood vessels visible through real-time X-ray.

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Once the microcatheter reaches the target brain vessel, the physician guides it to enter the aneurysm. The coil advances into the aneurysm through the microcatheter. The microcatheter allows the physician to deploy, position or reposition the coil until it is properly placed and then detached. Multiple coils are packed inside the aneurysm sac to occlude, or close up, the aneurysm. Below is an illustrative diagram of an aneurysm after a coil embolization procedure:



Over time as the coils slow down blood flow inside the aneurysm, blood clots begin to form inside the aneurysm, and endothelial cells start to cover the aneurysm neck. This further stops blood from flowing into the aneurysm and effectively cures it.

### *Summary of Clinical Trial Results*

Between August 2017 and December 2019, we completed a registrational clinical trial, Coil Application Trial in China, or the “CATCH” study, which investigated the safety and efficacy of *NUMEN* in the treatment of intracranial aneurysms in comparison against an established coil embolization product. CATCH was a prospective, randomized, controlled, open-label, non-inferiority trial conducted in ten centers across China, with a total of 350 subjects enrolled and randomized. The primary efficacy endpoint of the trial, successful aneurysm occlusion rate at six months, was 91.18% for the *NUMEN* group as compared to 91.85% for the control group ( $p = 0.8419$ ), which demonstrated that *NUMEN* was non-inferior to the control group product for the efficacy of aneurysm occlusion. *NUMEN* also demonstrated a good safety profile. The overall mortality rates during the 30-day follow-up period was 1.19% and 1.81% for the *NUMEN* group and control group ( $p=0.6837$ ), respectively, showing no significant difference between the two groups. The serious adverse event (SAE) occurrence rate during a 12-month follow-up period was 12.50% and 17.47% for the *NUMEN* group and control group, respectively, also showing no statistically significant difference ( $p = 0.2222$ ).

### *Development History and Development Plan*

*NUMEN* was approved by the NMPA in September 2020 and commenced commercialization in China in the same month. It also obtained CE Marking, FDA approval and MFDS approval in South Korea in May 2021, September 2021 and September 2021, respectively. In August 2021, the first overseas coil embolization procedure with *NUMEN* was completed in Chile, marking *NUMEN*'s entrance to the overseas market.

We have been continuously developing upgraded versions of *NUMEN*. *NUMEN Silk* was approved by the NMPA in February 2022. We plan to submit the registration application for *NUMEN NEST* in the first quarter of 2023 and obtain NMPA approval in the fourth quarter of 2023. *NUMEN Biodegradable* is currently in the design development stage, and we expect to obtain NMPA approval in 2026.

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### Market Opportunity and Competition

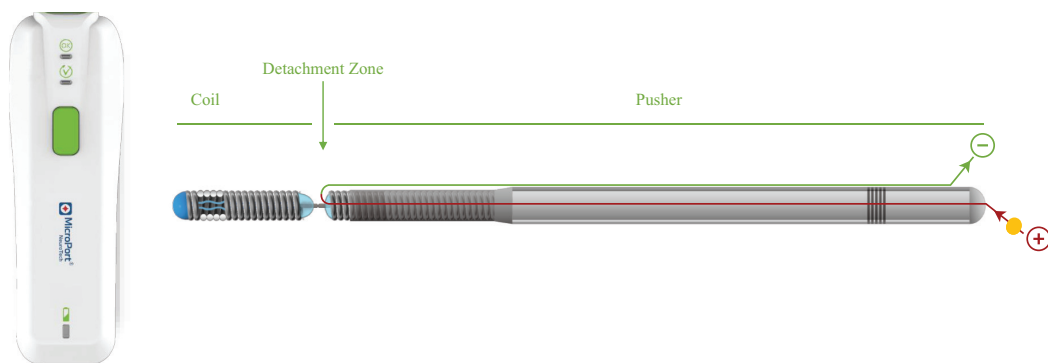
Intracranial coil embolization has become widely accepted and is often the first-line treatment for intracranial aneurysm. The number of intracranial coil embolization procedures in China increased from approximately 28,300 in 2015 to 70,100 in 2020 and is estimated to further increase to approximately 205,400 in 2026, at a CAGR of 21.8% from 2020 to 2026, according to CIC.

As of the Latest Practicable Date, there were 38 intracranial coil embolization devices developed by a number of companies approved by the NMPA, as shown in the following table:

<u>Company</u>	<u>Number of approved embolization coils</u>
Medtronic	8
MicroVention	8
Johnson & Johnson	5
Stryker Neurovascular	5
Achieva Medical	3
Our Company	2
TJWY Medical	2
Wallaby Medical	2
SealMed	1
Zylox-Tonbridge Medical	1
Visee Medical	1
<b>Total</b>	<b>38</b>

### *NUMEN FR*<sup>®</sup> Coil Detachment System (“*NUMEN FR*”)

*NUMEN FR* is the detachment system used together with *NUMEN*. After having properly placed the embolization coil, a physician detaches the coil from the delivery wire by pressing a button on *NUMEN FR*. Below is an illustrative diagram of *NUMEN FR* and the coil detachment zone:



Coil detachment systems commonly employ electrolytic, hydraulic, mechanical or electrothermal mechanisms. *NUMEN FR* utilizes the electrolytic detachment mechanism. The detachment segment disengages when a current is passed through it over time. In CATCH study, the registrational clinical trial for *NUMEN* and *NUMEN FR*, *NUMEN FR* demonstrated a high detachment success rate of 98.91% (820 out of 829). For details of CATCH study, see “—*NUMEN*<sup>®</sup> Coil Embolization System (“*NUMEN*”)—Summary of Clinical Trial Results.” *NUMEN FR* is classified as a Class III medical device under NMPA regulations and was approved and commercialized in China

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in July 2020. Together with *NUMEN*, *NUMEN FR* was approved in the United States, the European Union and South Korea in 2021.

### *Tubridge*<sup>®</sup> *Flow-diverting Stent* (“*Tubridge*”)

*Tubridge* is a flow-diverting stent that treats intracranial aneurysm as an endovascular scaffold to alter the flow between the parent artery and the aneurysm. *Tubridge* is specifically indicated for large and giant aneurysms, where coil embolization, the more traditional treatment, has a lower rate of success and higher recurrence rate due to the complexity and size of the aneurysms. Also, *Tubridge* allows physicians to treat large and giant intracranial aneurysms with a single device, which could save more than 50% in costs as compared with coil embolization procedures where multiple embolic coils and stents are needed, according to CIC. Further, because *Tubridge* eliminates the need to enter the aneurysm sac, it significantly reduces the risk of intraoperative rupture and is therefore safer.

*Tubridge*'s mechanism of action can be divided into three stages: hemodynamic (the dynamics of blood flow) stage, thrombus formation stage and endothelialization stage. The hemodynamic stage happens immediately after the placement of *Tubridge*, as the coverage of the aneurysm neck with stent mesh disrupts blood flow and reduces pressure within the aneurysm. This significantly reduces the velocity of blood flow inside the aneurysm and, as a result, a stable thrombus forms over days to weeks. Furthermore, in the endothelialization stage, the stent acts a scaffold for endothelial cells to form along it, which facilitates permanent exclusion of the aneurysm from blood circulation and ultimately reconstructs the artery.

*Tubridge* is classified as a Class III medical device under NMPA regulations. It was recognized as an innovative medical device by the NMPA, or entered the Green Path, in 2016, and was approved by the NMPA in March 2018. According to CIC, *Tubridge* was the first neuro-interventional medical device that entered the Green Path, and was also the first and remains the only Chinese-developed flow-diverting stent approved by the NMPA. The clinical trial for *Tubridge* was the first randomized controlled trial (RCT) of neuro-interventional devices in China, according to CIC. The next-generation product, *Tubridge Plus*, is in the design validation stage and is expected to obtain NMPA approval in 2024.

### *Product Structure*

#### Tubridge

*Tubridge* consists of a braided nickel-titanium stent and a delivery system, which deploys the stent to the target artery through a combination of pushing and unsheathing techniques. The nickel-titanium braided wires allow the mesh to be highly flexible and conformable to the artery wall, which is critical given the large variations in the arterial diameter over the length of the stent. In addition to nickel-titanium wires, the mesh is also comprised of two platinum-iridium wires which serve as radiopaque markers to locate the stent under angiography, imaging through X-ray to check blood vessels. Given the need to place the stent accurately, *Tubridge* can be repositioned and redeployed.

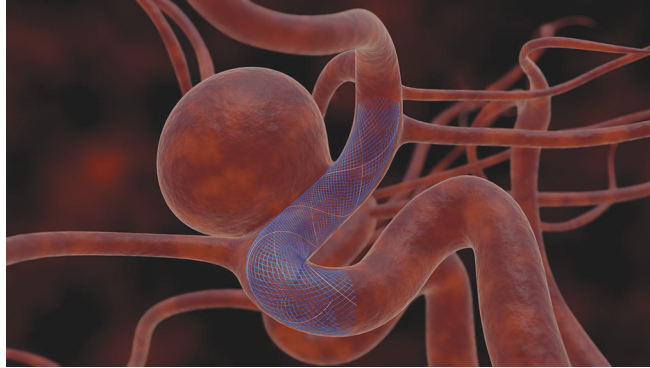
*Tubridge*'s mesh stent covers the aneurysm neck, which significantly reduces the velocity of blood flow inside the aneurysm and, as a result, a stable thrombus forms over days to weeks. Further, the stent also acts a scaffold for endothelial cells to form along it, which facilitates permanent exclusion of the aneurysm from blood circulation and ultimately reconstructs the artery. *Tubridge* has

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43 specifications with different lengths and diameters, including several large-size specifications, which are able to provide physicians with a full range of options for vascular reconstruction. Below is an illustrative diagram of *Tubridge*'s stent placed in the parent artery:



### Tubridge Plus™ Flow-diverting Stent (“*Tubridge Plus*”)

We are currently developing the next-generation product, *Tubridge Plus*, which aims to improve the smoothness in delivery and stent radiopacity (visibility under angiography). Such upgrades are expected to enhance the safety of procedures with *Tubridge Plus* as they facilitate the accurate placement of the stent. As a result, the needs for repositioning or adjusting the stent are likely to be reduced.

### *Operation Procedure*

A physician begins the *Tubridge* placement procedure by inserting a guiding catheter through the femoral artery. Led by a guidewire, the catheter is threaded to the target brain artery. The physician then removes the guidewire and inserts a microcatheter through the catheter. The microcatheter, carrying the flow-diverting stent, is navigated past the aneurysm neck before being unsheathed. This unsheathing action releases the flow-diverting stent and deploys it in the parent artery across the aneurysm neck. The flow-diverting stent slows blood flow entering the aneurysm causing flow stagnation within the aneurysm, and thrombus forms within the aneurysm as a result. In the meantime, endothelial cells begin to grow along the stent and cover the aneurysm neck. This eventually leads the aneurysm to be separated from the parent artery, therefore, resulting in aneurysm occlusion.

### *Features and Competitive Advantages*

We believe *Tubridge* has the following features and benefits:

- *The first and only Chinese-developed flow-diverting stent.* *Tubridge* was the first neuro-interventional medical device that entered the Green Path, and was also the first and remains the only Chinese-developed flow-diverting stent approved by the NMPA, according to CIC.
- *Flexibility and conformability.* Consisted of 48/64 (representing small/large size) braided nickel-titanium wires, the mesh of *Tubridge* is highly flexible and conformable to the artery wall, which is critical given the large variations in the arterial diameter over the length of the stent.

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- *Innovative mechanism of action: flow diversion.* *Tubridge’s* mesh stent covers the aneurysm neck, which significantly reduces the velocity of blood flow inside the aneurysm and, as a result, a stable thrombus forms over days to weeks. Further, the stent also acts a scaffold for endothelial cells to form along it, which facilitates permanent occlusion of the aneurysm from blood circulation and ultimately reconstructs the artery.
- *43 specifications providing a full range of options.* *Tubridge* has 43 specifications with different lengths and diameters, including several large-size specifications, which provide physicians with a full range of options for vascular reconstruction.

### *Summary of Clinical Trial Results*

Between 2012 and 2016, we completed a clinical trial (the “PARAT” study) comparing *Tubridge’s* safety and efficacy in treating large or giant aneurysms against a well-established stent-assisted coiling device. Stent-assisted coiling is a more traditional technique as compared with the flow diversion technique.

The PARAT study was a prospective, multicenter, randomized clinical trial conducted in 15 hospitals in China. A total of 144 patients completed the procedures, including 82 patients undergone *Tubridge* placement procedure and 62 patients treated with stent-assisted coiling. The primary endpoint was complete aneurysm occlusion at the 6-month follow-up review. In its 6-month follow-up review, the aneurysm complete occlusion rate for the *Tubridge* group and the stent-assisted coiling group was 75.3% and 24.5%, respectively. Such results demonstrated that *Tubridge* had a statistically significantly higher aneurysm complete occlusion rate than the stent-assisted coiling device (95% confidence interval,  $p < 0.001$ ). The adverse event (AE) occurrence rate at the one-year follow-up was 56.10% and 53.23% for the *Tubridge* group and the control group, respectively. The AEs primarily included headache, vomiting and fever, and were not device-related. There was no statistically significant difference in the AE occurrence rate between the groups at the 30-day, 90-day or one-year follow-up. The overall rate of death or stroke related to target vessels at the one-year follow-up was 17.07% and 14.52% for the *Tubridge* group and the control group, respectively, also showing no statistically significant difference between the groups ( $p = 0.678$ ). The PARAT study was the first randomized controlled trial (RCT) of neuro-interventional devices in China, according to CIC.

### *Development History and Development Plan*

The development of *Tubridge* represented an early hemodynamics research project in China, according to CIC, and was sponsored under the National Technology Support Scheme (國家科技支撐計畫) in 2012. Between 2012 and 2016, we completed the PARAT study comparing *Tubridge’s* safety and efficacy in treating large or giant aneurysms against a well-established stent-assisted coiling device.

*Tubridge* entered the Green Path in 2016, and was approved by the NMPA in March 2018. According to CIC, *Tubridge* was the first neuro-interventional medical device that entered the Green Path, and was also the first and remains the only Chinese-developed flow-diverting stent approved by the NMPA.

*Tubridge Plus*, our next-generation product, is in the design validation stage and will commence the registrational clinical trial in the second quarter of 2022, and is expected to obtain the approval in 2024.

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### *Market Opportunity and Competition*

Flow diversion is the most recently developed treatment for intracranial aneurysm. Compared with traditional treatments such as coil embolization, flow diversion alters the blood flow away from the aneurysm and reduces the need to place coils inside the aneurysm sac, thereby reducing the risk of intraoperative rupture or failures due to coil migration.

Although the flow diversion technique is relatively new, its penetration is expected to grow rapidly. The number of procedures performed with flow-diverting stents in China is expected to increase from approximately 4,500 in 2020 to 38,900 in 2026 at a CAGR of 43.5%, and the penetration rate is expected to increase from 0.5% in 2020 to 5.0% in 2026. The following table sets forth the flow-diverting stents approved in China as of the Latest Practicable Date, according to CIC. *Tubridge* obtained a market share of approximately 44% in 2020 in China in terms of sales volume.

<u>Product</u>	<u>Company</u>	<u>NMPA First Approval Time</u>
Pipeline Flex Embolization Device	Medtronic	December 2017
<i>Tubridge</i>	Our Company	March 2018
Surpass Streamline Flow Diverter	Stryker Neurovascular	June 2020

### ***Willis® Intracranial Stent Graft System (“Willis”)***

*Willis* is a stent graft indicated for treating intracranial aneurysm. It is made of a thin metal mesh (the stent) covered by a thin polytetrafluoroethylene (ePTFE) membrane (the graft). Delivered by a balloon catheter, the stent graft is opened inside the parent artery when the balloon is inflated. The stent graft blocks blood flow away from the aneurysm and prevents it from rupturing, causing it to gradually shrink along with thrombus formation.

According to CIC, *Willis* was the first and remains the only intracranial stent graft for treating cerebral vessel diseases in the world. It is also the first medical device that applies the theory of intracranial parent artery reconstruction in practice. Leveraging the stent graft’s high flexibility and conformability, *Willis* achieves a high rate of aneurysm exclusion after the stent placement and a low rate of endoleak, which is defined as the persistent perfusion of the space between the stent and the parent artery and represents one of the most common failures of endovascular repair.

*Willis* is classified as a Class III medical device under NMPA regulations and was approved by the NMPA in 2013. Our research project on *Willis* won the Second Prize for National Science and Technology Award (國家科學技術進步獎二等獎) in 2014.

### *Product Structure*

*Willis* consists of a stent, an ePTFE membrane and a low-pressure balloon catheter. The stent, available in various diameters and lengths, is made of a cobalt-chromium alloy, which is radiopaque under angiography, which in turn facilitates accurate placement. The sinusoidal (or sine-curve) design of the stent also provides better balance among strength, flexibility and conformability. The membrane is extremely thin and highly expandable. The membrane’s strength and flexibility help reduce the likelihood of incomplete coverage of the aneurysm neck, stent migration and membrane rupture, which are all common causes of failure of endovascular repair. The balloon catheter delivers the stent graft to the parent artery. The balloon is able to expand gradually under low pressure, which minimizes the pressure on the wall of the parent artery and reduces the risk of artery rupture. *Willis*

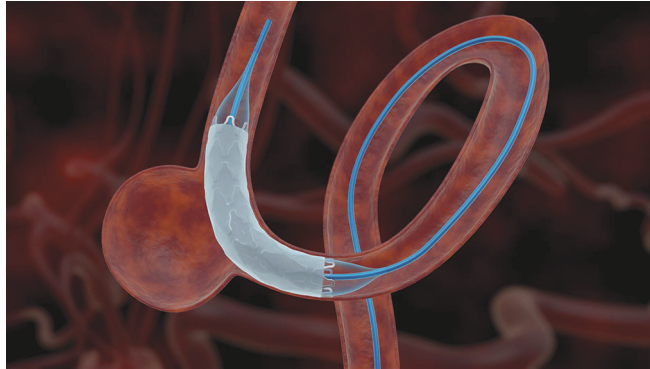


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has also variations for arteries with different diameters. Below is an illustrative diagram of *Willis* placed in the parent artery:



### *Operation Procedure*

A physician first inserts the guidewire into the femoral artery and navigates it to the parent artery in the brain. Guided by the guidewire, the stent graft system is threaded up and placed across the aneurysm neck. Then the balloon is inflated to open up the stent and to eliminate the space between the stent graft and the artery wall, ensuring that the stent is opposed to the vessel wall in place. The physician then deflates the balloon and retrieves the catheter from the body. This procedure excludes the aneurysm from blood circulation and, consequently, causes the aneurysm to shrink and be cured.

### *Features and Competitive Advantages*

We believe *Willis* has the following features and benefits:

- *The first and only intracranial stent graft for cerebral vessel diseases in the world.* According to CIC, *Willis* was the first and remains the only intracranial stent graft for treating cerebral vessel diseases in the world. It is also the first medical device that applies the theory of intracranial parent artery reconstruction in practice. *Willis* also provides viable solutions for complex neurovascular diseases, including dissecting aneurysms, blood blister-like aneurysms, pseudo-aneurysms and carotid-cavernous fistulae.
- *Stent with sinusoidal design and highly expandable ePTFE membrane.* The sinusoidal (or sine-curve) design of the stent provides a better balance among strength, flexibility and conformability. The ePTFE membrane is extremely thin and highly expandable. The membrane's strength and flexibility help reduce the likelihood of incomplete coverage of the aneurysm neck, stent migration and membrane rupture.
- *Low-pressure expandable balloon catheter.* *Willis* is equipped with a low-pressure expandable balloon catheter specifically designed for neuro-interventional procedure. The balloon expands gradually under low pressure, which minimizes the pressure on the wall of the parent artery and reduces the risk of artery rupture.

### *Development History*

*Willis* is classified as a Class III medical device under NMPA regulations and was approved by the NMPA in 2013. Our research project on *Willis* won the Second Prize for National Science and

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Technology Award in 2014. Our earlier research on *Willis* was also awarded First Prize for Science and Technology Award of the Ministry of Education (教育部科技進步一等獎) in 2012 and First Prize for Science and Technology Award of Shanghai (上海市科技進步一等獎) in 2009. *Willis* was one of the innovative stent devices for intracranial aneurysm in 2007 recognized by *Stroke*, a journal published by American Heart Association and American Stroke Association.

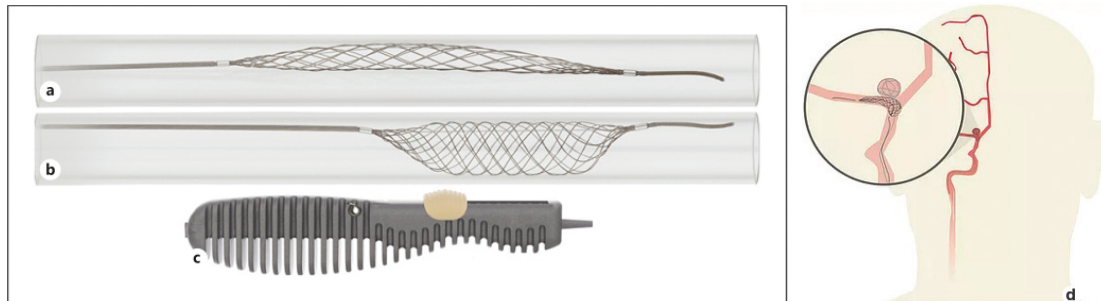
### *Market Opportunity and Competition*

Stent graft is an alternative treatment option for treating intracranial aneurysm. According to CIC, as of the Latest Practicable Date, *Willis* was the first and remained the only intracranial stent graft for treating cerebral vessel diseases in the world.

### *Product Candidates under Development*

#### ***Comaneci***<sup>®</sup> *Embolization Assist Device* (“*Comaneci*”)

*Comaneci* is a temporary coil embolization assisting stent developed by Rapid Medical. An assisting stent is particularly useful for the coil embolization of wide-neck or unusually shaped aneurysms. The stent serves as a scaffold to prevent the coils from falling out of the aneurysm sac, inadvertently blocking the artery. Such temporary stenting procedure also serves as a platform to increase packing density. *Comaneci* is a temporary assisting stent, which is retrieved by the physician after the procedure. This eliminates the need for patients to take medications, which are normally needed for permanent assisting stents. *Comaneci* also features its adjustability in size. Using a slider on the handle, a physician controls the movement of the main wire in the stent, which further controls the stent to inflate or deflate. Below are illustrative diagrams of *Comaneci*:



#### *Notes:*

- a. The deflated stent of *Comaneci* after being unsheathed from the microcatheter.
- b. The inflated stent controlled by the physician through the slider on the handle.
- c. The handle of the *Comaneci* with its yellow adjustable slider on top.
- d. The stent placed in the parent artery.

Delivered by a microcatheter, the *Comaneci* stent is deployed across the aneurysm neck. Once the stent is in place, another microcatheter carrying the embolization coils is placed in the aneurysm sac. With the stent temporarily deployed and open, the coils are then released through the coiling microcatheter into the aneurysm sac. The physician then slowly retracts the stent and checks the stability of the coils inside the aneurysm sac. After the checking is complete, the physician withdraws the embolization microcatheter, and then re-sheaths the stent in the stent microcatheter and retrieves both the stent and the stent microcatheter.

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*Comaneci* received CE Marking in 2014 and was approved by the FDA in 2019. It also received FDA Breakthrough Device designation, a program designed to facilitate the development and registration of medical devices offering more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, in February 2022, to treat cerebral vasospasm (a condition where the blood vessels in the brain become narrow, thus reducing blood flow to the brain and causing subsequent death of brain tissue) after hemorrhagic stroke. We were engaged as the exclusive distributor in Greater China for *Comaneci*. See “—Collaborations—Rapid Medical” for details. We are assisting Rapid Medical to conduct preparatory work for registering *Comaneci* with the NMPA. *Comaneci* is expected to be approved by the NMPA in 2024.

### ***Rebridge***<sup>®</sup> ***Intracranial Visualized Stent*** (“***Rebridge***”)

*Rebridge* is a coil embolization assisting stent in the design validation stage. *Rebridge* features full radiopacity and densely braided mesh. The wires that are braided into the stent are made of radiopaque alloy. Compared with other stents that only have several radiopaque wires serving as marker wires, all wires of *Rebridge* are radiopaque, allowing physicians to visualize the stent deployment to achieve optimal placement. Radiopaque strands along the entire stent body also enable physicians to visualize the stent expansion. *Rebridge* is also densely braided. The high metal coverage and small pore size provide stronger and consistent support to the embolization coils, in particular, those smaller coils used in the finishing stage. *Rebridge* are also designed in several models to accommodate arteries with different diameters, but all models of *Rebridge* remain to be low-profile and can be delivered with the same delivery system.

*Rebridge* is the first Chinese-developed full-visualization coil embolization assisting stent that entered clinical trials, according to CIC. We commenced a controlled, multi-center, randomized trial to evaluate *Rebridge*’s safety and efficacy. The first patient enrollment for *Rebridge*’s registrational clinical trial was completed in January 2022, and the trial is expected to be completed in the fourth quarter of 2024. We expect to obtain NMPA approval in 2025.

### ***Liquid Embolic Agent***

We are conducting preclinical design development for a liquid embolic agent to treat cerebral arteriovenous malformations (cerebral AVM). Cerebral AVM is an abnormal connection between the arteries and veins in the brain that usually forms by birth. Arteries in the brain connect directly to nearby veins without having the normal capillaries, or tiny blood vessels, between them.

Our *Liquid Embolic Agent* intends to provide a minimally invasive, endovascular treatment for cerebral AVM. *Liquid Embolic Agent* is primarily composed of ethylene vinyl alcohol, a chemical substance that can embolize blood vessels. Ethylene vinyl alcohol is dissolved in dimethyl sulfoxide, a solvent, and mixed with radiopaque substance. The liquid is delivered to the target vessel through a microcatheter. It then begins to form a skin and solidifies over time from the outside to the inside, achieving embolization of the target area of the vessel. For smaller AVMs, the embolization is intended to completely obliterate the malformation; for larger AVMs, the embolization reduces the AVM size and enhances the safety for further surgery.

*Liquid Embolic Agent* is currently under preclinical design development. We plan to commence a clinical trial in 2024 and expect to obtain NMPA approval in 2026.

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### Cerebral Atherosclerotic Stenosis Products

Cerebral atherosclerotic stenosis occurs when blood flow to the brain is restricted by narrowed arteries due to plaque buildup inside the vessel. Cerebral atherosclerotic stenosis can be further divided into intracranial stenosis, vertebral artery stenosis and carotid artery stenosis. The prevalence of cerebral atherosclerotic stenosis in Chinese population increased from 15.6 million patients in 2015 to 17.1 million patients in 2020, and is estimated to further increase to 18.8 million patients in 2026 at a CAGR of 1.6% from 2020 to 2026.

Because cerebral atherosclerotic stenosis is commonly seen among people aged above 40, it is expected that an increasing number of people in China will suffer from this condition in the future, considering the aging population trend in China. In addition, a further growth in the neuro-interventional device market is driven by the higher risk of cerebral atherosclerotic stenosis observed among young generations in China, primarily due to an increasing prevalence of coexisting traditional stroke risk factors and health risk behaviors including hypertension, diabetes, obesity, lipid disorders and tobacco use.

Selection of a treatment for cerebral atherosclerotic stenosis depends on factors such as the size of the blockage and the patient’s risk for a first stroke or recurrent strokes. For smaller blockages, medications and recommendations of lifestyle changes may be used to minimize risk factors, such as high cholesterol and high blood pressure. Surgery may be recommended when there is a large blockage and high risk for stroke, involving the use of a balloon, a stent or a drug-coated/eluting device (typically a drug-coated balloon or drug-eluting stent) to stretch and open the blocked artery. Depending on the anatomical location of the blockage, stents for treating cerebral atherosclerotic stenosis are further categorized into intracranial stents, vertebral stents and carotid stents.

We have developed a comprehensive product portfolio to treat cerebral atherosclerotic stenosis. Our products and product candidates include (i) *APOLLO*<sup>TM</sup> intracranial stent system; (ii) *Bridge*<sup>®</sup> rapamycin target eluting vertebral artery stent system; (iii) *Diveer*<sup>TM</sup> intracranial balloon dilatation catheter; (iv) an intracranial drug-coated balloon catheter system; and (v) a carotid stent system.

### Commercialized Products

#### *APOLLO*<sup>TM</sup> Intracranial Stent System (“APOLLO”)

*APOLLO* is designed to treat patients suffering from intracranial atherosclerotic disease (ICAD). *APOLLO* consists of a balloon-expandable stent and a delivery catheter, with the stent being delivered to the lesion to push plaque back against the artery walls and keep the artery open. *APOLLO* was approved by the NMPA in 2004. According to CIC, *APOLLO* was the world’s first approved stent system to treat ICAD. *APOLLO* was designated a National Key New Product (國家重點新產品) by the Ministry of Science and Technology of PRC in 2011 and won the Second Prize for Science and Technology Award of Shanghai (上海市科技進步二等獎) in 2009.

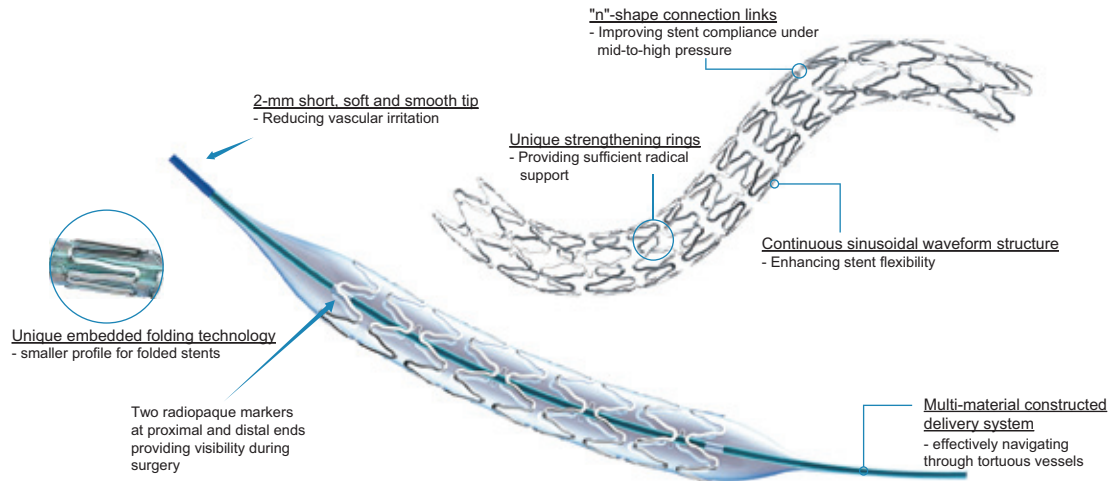
#### *Product Structure*

*APOLLO* comprises a balloon-expandable stent and a delivery catheter with a short tip and a semi-compliant balloon located at the distal end of the catheter. Semi-compliant balloons are commonly used in applications that require mid-to-high pressures but provide more flexibility for easy

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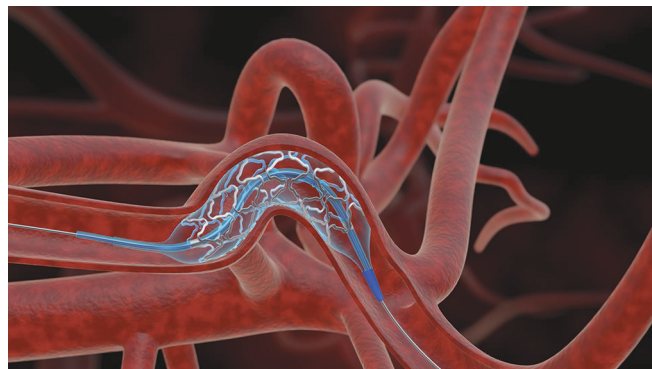
delivery. An inflation tube is located at the proximal end of the delivery catheter and it inflates the balloon when the latter is delivered to the target lesion. The proprietary embedded folding technology ensures lower profile insertion into the body and improves trackability, which is also aided by radiopaque markers at both ends of the stent.

The stent uses laser-cut stainless steel with various diameters and lengths, allowing physicians to choose the appropriate stent to meet each patient’s particular needs. The superior design of *APOLLO* enhances trackability and provides greater flexibility in diseased and narrowed arteries. Below is an illustrative diagram of *APOLLO*:



### Operation Procedure

Intracranial stent placement is an endovascular procedure performed with local anesthesia. Under X-ray guidance using fluoroscopy, a guiding catheter is navigated from the femoral or radial artery to the narrowed cerebral artery. The balloon-expandable stent is advanced to the target lesion. Once in position, the stent opens up as the physician inflates the balloon. The stent is placed in the narrowed area permanently to push plaque back against the artery wall, keeping the artery open and preventing plaque from obstructing blood flow. The guiding catheter and guidewire are removed after the physician confirms that the stented vessel functions properly through angiography. Below is an illustrative diagram of how *APOLLO* opens up and keeps the narrowed vessel open upon placement:



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### *Features and Competitive Advantages*

*APOLLO* was the first Chinese-developed and the world’s first approved balloon-expandable stent for treating ICAD. We believe *APOLLO* has the following features and benefits:

- *Supportive and flexible stent with advanced structure.* *APOLLO* is composed of strengthening rings that are constructed in sinusoidal waveform to provide sufficient radical support while reducing the metal coverage on the vessel wall. Additionally, two “n”-shaped connection links are staggered in 90 degrees axially to connect the strengthening rings, which improves compliance and thus allows the stent to navigate through tortuous intracranial vessels.
- *Unique embedded folding technology.* *APOLLO* employs a unique embedded folding technology so that the stent has a smaller profile when folded, which makes it safer to be delivered through the vessels. The balloon can also be folded to ensure smaller diameter and thus smooth delivery and retracement during the procedure.
- *Multi-material constructed delivery system with soft tip design to achieve minimum invasiveness.* The delivery system of *APOLLO* is constructed of various materials that are connected with precision to enhance navigation through tortuous vessels. The soft and smooth tip design of the delivery system further reduces irritation to the vessels during the procedure.

### *Summary of Clinical Trial Results*

Between 2013 and 2015, we completed a registrational clinical trial (the “AIRE-CHINA” study) comparing *APOLLO*’s safety and efficacy in treating severe symptomatic ICAS against a well-established balloon predilation and self-expanding stent. The AIRE-CHINA study was a prospective single-arm registry study with a total of 300 patients enrolled. The primary efficacy endpoint was the rate of stroke, transient ischemic attack (TIA) and death within 30 days after implantation. In its 30-day follow-up review, the rate of stroke, TIA and death for the *APOLLO* group and the control group was 4.4% and 4.3%, respectively, which also suggests a low occurrence rate of AE (stroke, TIA and death). Within one year, there was no difference in the probability of primary outcomes (stroke, TIA and death) between patients in the *APOLLO* group and patients in the control group.

### *Development History*

The R&D work for *APOLLO* started in 2003, where preclinical work included market research, product design and data verification. We applied regulatory registration of *APOLLO* as a Class III medical device and obtained the NMPA approval in 2004. *APOLLO* was designated a National Key New Product in 2011 and won the Second Prize for Science and Technology Award of Shanghai in 2009.

### *Market Opportunity and Competition*

The cerebral atherosclerotic stenosis neuro-interventional device market in China is at an early stage of development. The number of cerebral atherosclerotic stenosis neuro-interventional procedures in China increased from approximately 13,300 in 2015 to approximately 39,000 in 2020 and is

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estimated to further increase to approximately 149,400 in 2026, at a CAGR of 24.5% from 2020 to 2026. Particularly, the number of cerebral and vertebral stenting procedures in China increased from approximately 11,500 in 2015 to approximately 33,900 in 2020 and is estimated to further increase to approximately 103,600 in 2026, at a CAGR of 20.5% from 2020 to 2026. Considering the market potential, domestic players are becoming increasingly important by making affordable alternatives available to patients with unmet medical needs and generally improve the penetration rate of stenting procedures. One of the key distinguishing factors for competing in this market is the ability to develop advanced products with improved safety and efficacy features.

According to CIC, there were three NMPA-approved cerebral stent devices (including DES) for treating cerebral atherosclerotic stenosis as of the Latest Practicable Date, summarized in the following table. According to CIC, our *APOLLO* has a market share of approximately 47.0% in the intracranial stent market, in terms of 2020 sales volume.

<u>Product</u>	<u>Company</u>	<u>NMPA First Approval Time</u>
<i>APOLLO</i>	Our Company	November 2004
Wingspan Stent System	Stryker Neurovascular	November 2006
Intracranial DES (顱內藥物洗脫支架系統)	Sino Medical Sciences Technology Inc. (賽諾醫療)	July 2021

### ***Bridge***<sup>®</sup> *Rapamycin Target Eluting Vertebral Artery Stent System* (“**Bridge**”)

*Bridge* is designed to treat patients suffering from symptomatic vertebral artery stenosis, which is the narrowing and blockage of the vertebral arteries that induce symptoms such as ischemic stroke. *Bridge* is a balloon-expandable stent with rapamycin coated inside the grooves on the stent surface facing the vessel wall. Rapamycin is an anti-proliferation drug commonly used in stenting procedures to reduce the incidence of neointimal hyperplasia, *i.e.*, the thickening of a vascular wall that can cause the vessel to become blocked or obstructed again after stent placement. *Bridge* is designed to deliver the drug-eluting stent to the lesion and push plaque back against the artery walls while slowly delivering rapamycin to the target area. *Bridge* was recognized as an innovative medical device (創新醫療器械), or entered the Green Path, in 2018. We obtained NMPA approval for *Bridge* in December 2020. According to CIC, *Bridge* was the first vertebral artery DES that was admitted to the Green Path and approved by the NMPA.

#### *Product Structure*

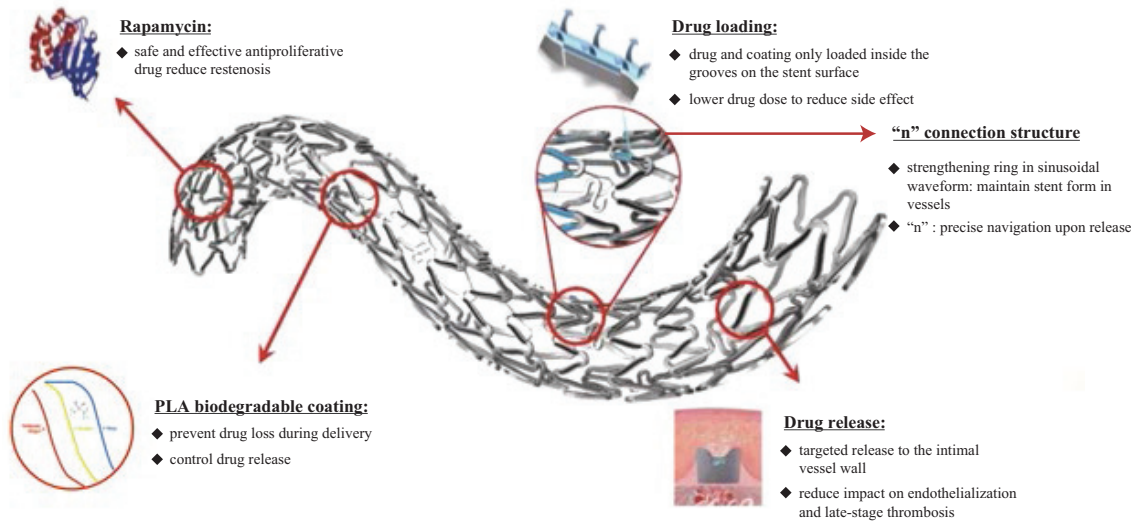
*Bridge* is a balloon-expandable drug-eluting stent constructed of a cobalt-chromium alloy with various diameters and lengths, and coated with rapamycin. Cobalt-chromium alloy stents are thinner, stronger and more flexible than stainless steel stents, and, as a result, provide higher efficacy. Rapamycin has been proven to be safe and effective in preventing in-stent restenosis and inflammation around the stent.

*Bridge* features a unique drug delivery design. The drug is loaded inside the tiny grooves on the stent surface facing the vessel wall, with a targeted release to the narrowed area of the blood vessel. Such design helps reduce the amount of drug released and improve safety by minimizing the impact on patient, including allowing for faster re-endothelialization (new endothelial cell growth, which

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helps form a thick walled layer lining the blood vessels) along the stent construct as it becomes embedded and incorporated in the blood vessel. Below is an illustrative diagram of *Bridge*:

### Unique drug loading design of *Bridge*



### Operation Procedure

Vertebral artery stenting is similar to intracranial stenting for atherosclerosis, *e.g.*, the procedure in which our *APOLLO* stent is used. The balloon-expandable drug-eluting stent is advanced to the lesion over a guidewire and released as the balloon inflates. The loaded rapamycin elutes from the stent gradually and is released to the vessel wall. For further details, see “—*APOLLO*—Operation Procedure.”

### Features and Competitive Advantages

*Bridge* was the first target DES for treating vertebral artery stenosis that was admitted to the Green Path and approved by the NMPA in China. We believe *Bridge* has the following features and benefits:

- **Targeted drug release.** *Bridge* employs an advanced engraving technique to support the targeted release of anti-proliferative drug from the stent to the vessel walls.
- **Lower dose of drug load and release for safer results.** The biodegradable coating consisting of rapamycin and polylactic acid (PLA) is only stored in the tiny grooves on the stent surface facing the vessel wall, rendering relatively lower drug dose, proper drug release dynamics and safer results with low neurotoxicity.
- **Improved follow-up efficacy.** Our clinical trial results showed that the in-stent restenosis rate for *Bridge* was only 3.7% at six-months after surgery, which is significantly lower than the in-stent restenosis rate of 15.2% of the other NMPA-approved vertebral stent, according to CIC.



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### *Summary of Clinical Trial Results*

We had conducted a prospective, multicenter, single-arm clinical trial in China between 2014 and 2018 to evaluate the safety and efficacy of *Bridge*. The trial was conducted in 6 centers with 101 subjects enrolled. The primary efficacy endpoint is the rate of in-stent restenosis (defined as stenosis greater than 50% of the vessel lumen diameter in a previously stented segment) of subjects, which was assessed through digital subtraction angiography (DSA) performed at six months after surgery. The trial showed that the in-stent restenosis rate for *Bridge* was only 3.7% at six-months after surgery, which was significantly lower than the in-stent restenosis rate of 15.2% of the other NMPA-approved vertebral stent, according to CIC. And there was no occurrence of serious AE related to the trial devices during or after the clinical trial.

### *Development History and Development Plan*

The R&D work for *Bridge* started in 2012. *Bridge* entered the Green Path in March 2018. *Bridge* is classified as a Class III medical device and was approved by the NMPA in December 2020. According to CIC, *Bridge* was the first vertebral DES admitted to the Green Path. We then commenced sales of *Bridge* in China in 2021.

We are currently conducting preclinical design development for a large-size *Bridge* (*Bridge* 4.5/5.0) and plan to commence a clinical trial in 2023. We expect to obtain NMPA approval in 2025.

### *Market Opportunity and Competition*

The conventional treatments of vertebral artery stenosis primarily include coronary stents and intracranial bare-metal stents. These treatments have relatively high restenosis rates resulting from the formation of neointimal hyperplasia, a condition caused by the proliferation of vascular wall cells in response to the stent implantation. In line with the overall growth of the cerebral atherosclerotic stenosis neuro-interventional devices market in China, demand for efficient, safe and reliable vertebral artery stent solutions is growing. The rationale for using drug-eluting stents is to inhibit the occurrence of vascular restenosis, which improves the safety and efficacy of stenting procedures in treating vertebral artery stenosis. According to CIC, there were two NMPA-approved vertebral drug-eluting stents for treating vertebral artery stenosis as of the Latest Practicable Date, summarized in the following table:

<u>Product</u>	<u>Company</u>	<u>NMPA First Approval Time</u>
Rapamycin Vertebral Artery DES (雷帕霉素藥物洗脫椎動脈支架系統)	Alain Biotechnology Co. Ltd. (Beijing) (雅倫生物科技)	July 2020
<i>Bridge</i>	Our Company	December 2020

### *Diveer™ Intracranial Balloon Dilatation Catheter (“Diveer”)*

*Diveer* is used in interventional procedures for intracranial stenosis, which, when placed in the lesion, compresses the plaque through balloon dilatation and at the same time widens the lumen of the artery and keeps it open. We commenced product development for *Diveer* in March 2020 and completed type testing for *Diveer* to the required technical standards in May 2021. We applied for the NMPA approval in June 2021 and received NMPA approval in January 2022.

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### ***Product Candidates under Development***

#### ***Intracranial Drug-Coated Balloon (DCB) Catheter System***

Our intracranial DCB catheter system is used in interventional procedures for intracranial stenosis, which, in addition to opening up the artery through balloon dilatation, also delivers an anti-proliferative drug to the lesion to prevent neointimal hyperplasia. As of the Latest Practicable Date, there was no intracranial DCB approved for marketing in China. We have commenced product development for our intracranial DCB catheter system and expect to receive NMPA approval in 2026.

#### ***Carotid Stent System***

Our carotid stent system is used in interventional procedures for carotid artery stenosis, which is a procedure similar to stent implantation for ICAD, *e.g.*, the procedure using our *APOLLO*. See “—*APOLLO*—Operation Procedure.” We have commenced product development for our carotid stent system since September 2021 and expect to receive NMPA approval in 2027.

### **Acute Ischemic Stroke Products**

Acute ischemic stroke is characterized by a sudden loss of blood circulation to an area in the brain, resulting in corresponding loss of neurological function. AIS occurs when blood flow to a brain artery is obstructed by a clot, which is a mass of thickened blood. A typical cause of AIS is intracranial atherosclerosis. In China, there were 1.7 million patients of AIS in 2020, according to CIC.

AIS treatment is time-sensitive. According to CIC, it is crucial to provide proper treatment to AIS patients within 24 hours from symptom onset. The best treatment time for AIS is four to six hours since symptom onset. Before 2004, intravenous thrombolysis was the only approved treatment for AIS. The application of intravenous thrombolysis is recommended to be used within three hours from symptom onset. Because intravenous thrombolysis causes low recanalization rate, mechanical thrombectomy, in particular stent-retrieving thrombectomy, has become the first-line treatment for AIS. Using fluoroscopy or continuous X-ray, the physician guides the stent retriever through the patient’s vessel to locate and extract the clot. Stent-retrieving thrombectomy is used within 24 hours from symptom onset. As a relatively new approach to treat AIS, aspiration thrombectomy is a neuro-interventional procedure using negative pressure to pull out the clot through an aspiration catheter. It can be conducted independently or in conjunction with stent-retrieving thrombectomy.

We are developing a comprehensive product portfolio to treat AIS. Our product solutions include (i) *Neurohawk*<sup>®</sup> stent thrombectomy device; (ii) *Tigertriever*<sup>®</sup> revascularization device; (iii) *W-track*<sup>®</sup> intracranial aspiration catheter; (iv) *X-track*<sup>™</sup> intracranial distal access catheter; and (v) balloon protection guide catheter.

### **Commercialized Products**

#### ***Neurohawk*<sup>®</sup> Stent Thrombectomy Device**

##### *Overview*

Our *Neurohawk* is a stent retriever used in minimally invasive thrombectomy procedures to remove clots in blood vessels. By placing the expandable stent into the target blood vessel, physicians

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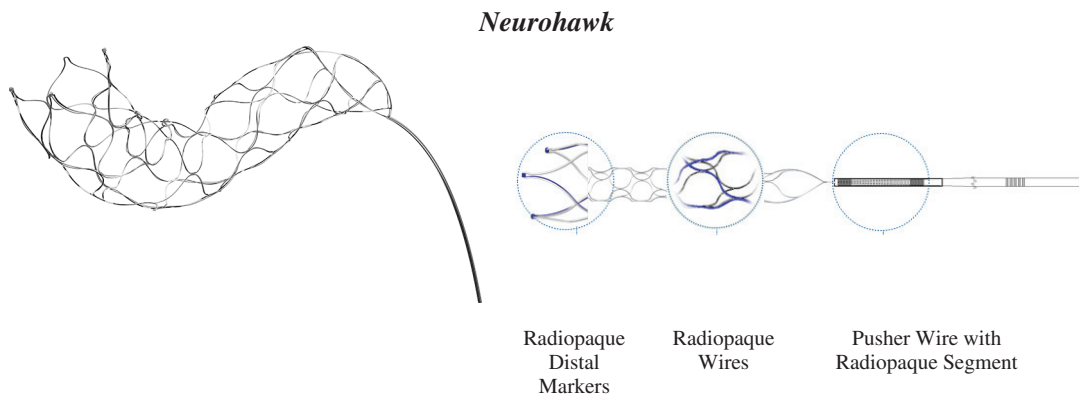
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can capture the clot and remove it by retrieving the stent. *Neurohawk* is our self-developed stent retriever system with full visualization.

*Neurohawk* is classified as a Class III medical device by the NMPA. We commenced a clinical trial for *Neurohawk* in March 2018 and completed it in February 2021. We submitted a registration application to NMPA in March 2021 and obtained NMPA approval in February 2022.

### *Product Structure*

*Neurohawk* comprises a self-expanding stent and a pusher wire, which is compressed inside an introducer sheath. The stent is able to expand and catch the clot when released after being deployed in the target blood vessel. *Neurohawk* can maintain ideal apposition with vessel wall by expanding and compressing the stent. *Neurohawk* is equipped with enhanced full visualization with three radiopaque markers on the distal end and three radiopaque wires in the main part of the stent. The stent can be seen under fluoroscopy, which enables physicians to place and retrieve the device confidently.



We have developed two models with different diameters for *Neurohawk*, allowing physicians to choose the stent retriever according to the blood vessel diameter. *Neurohawk* AIS4025 is suitable for stent-retrieving thrombectomy in blood vessel with a diameter of 2 to 3 mm, such as the M1 segments of the middle cerebral artery. *Neurohawk* AIS6030 is suitable for stent-retrieving thrombectomy in blood vessels with a diameter of 3 to 5 mm, such as the internal carotid artery. Both models of *Neurohawk* can be delivered through a 0.021 inch microcatheter.

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### *Operation Procedure*

During a thrombectomy procedure, the physician first locates the blockage using advanced neuro-imaging technology. The physician then inserts a combination of access and delivery catheters in femoral artery, to get access to the intended vascular site under fluoroscopic guidance, then introduce a microcatheter inside the guiding catheter to reach the occluded segment and pass through the clot. The stent retriever is then inserted into the microcatheter and delivered to the occluded segment. The physician uses the delivery wire to hold the stent position and withdraws the microcatheter to unsheath the stent, letting it open and expand outward to capture the clot. As the device can be seen in its entirety under fluoroscopy, the physician can monitor the position of stent to ensure that it is fully open. The physician then draws back the stent retriever with the captured clot.

### *Features and Competitive Advantages*

*Neurohawk* is our self-developed stent retriever system with full visualization. We believe *Neurohawk* has the following features and benefits:

- *Promotion of clot retrieval and stent wall opposition.* *Neurohawk* is structured with three-dimensional spiral and staggered meshes, which allow *Neurohawk* to better capture large, tough or fragile clots. Physicians may also expand and compress the stent to optimize wall apposition to blood vessel relying on *Neurohawk's* sound radial resistance force.
- *Enhanced full visualization.* *Neurohawk* is equipped with radiopaque markers on the distal end and radiopaque wires in the main part of the stent to provide full visualization. The radiopaque markers are embedded on the distal end and in the main body of the stent, and in the pusher wire. The radiopaque markers allow the physicians to determine the nature of the clot and apply appropriate techniques to remove the clot.

### *Summary of Clinical Trial Results*

Between 2018 and 2021, we completed a clinical trial (the “CAPTURE” study) to evaluate the safety and efficacy of *Neurohawk* by primarily comparing the recanalization rate between patients undergoing stent retrieving thrombectomy procedures using *Neurohawk* and *Solitaire FR* revascularization device (Medtronic). The CAPTURE study was a prospective, multi-center, randomized and non-inferiority clinical trial with a total of 239 patients enrolled.

The primary efficacy endpoint is the recanalization rate (mTICI $\geq$ 2b) with stent thrombectomy procedures. The recanalization rate was 88.70% of the *Neurohawk* group and 90.60% of the *Solitaire FR* group. *Neurohawk* demonstrated non-inferiority in respect of efficacy as compared with *Solitaire FR*. The second efficacy endpoints of the clinical trial include time for recanalization, NIHSS score at 30 $\pm$ 6 hours and ratio of patients with 90 $\pm$ 14 days post treatment mRS score not exceeding 2 (inclusive). There was no statistically difference in the secondary endpoints between the two study groups.

The safety endpoints of the clinical trial are the rate of symptomatic intracranial hemorrhage (sICH) at 30 $\pm$ 6 hours and all-cause mortality rate at 90 $\pm$ 14 days. There is no statistically significant difference in both safety endpoints between the two study groups.

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### *Development History and Development Plan*

Our development of *Neurohawk* started in 2015. We commenced a clinical trial for *Neurohawk* in March 2018 and completed it in February 2021. We submitted a registration application to NMPA in March 2021 and obtained NMPA approval in February 2022.

We are currently developing *Neurohawk 2* with different working length for wider applicability. We expect to submit registration application to NMPA and obtain approval in 2024.

### *Market Opportunity and Competition*

See “—*Tigertriever*<sup>®</sup> Revascularization Device—Market Opportunity and Competition.”

### *Aspiration Catheters*

#### *X-track*<sup>™</sup> intracranial distal access catheter (“*X-track*”)

*X-track* distal access catheter is used in neuro-interventional procedures to facilitate the delivery of stent to reach the distal point in target blood vessels. *X-track* removes the clot through direct aspiration together with stent retriever thrombectomy. *X-track* is a single-lumen catheter, the body of which is built of three layers, including an inner tube, a reinforcement layer and an outer layer. The proximal end of the single-lumen catheter is connected to a connector and a strain relief tube. *X-track* is equipped with an guide sheath and a shaping mandrel. To facilitate the advancement of *X-track* in neuro-interventional procedures, *X-track* has a semi-rigid proximal shaft and a flexible distal shaft with a radiopaque marker.

*X-track* is designed for the introduction of a wide range of neuro-interventional therapeutic devices. The physician first places *X-track*, together with microcatheter and micro guidewire, into a guide sheath. The physician then inserts the microcatheter and micro guidewire to the proximal end of *X-track*, and advances the assembly of microcatheter, micro guidewire and *X-track* to the target vessel. Once *X-track* reaches the target location, the physician removes the micro guidewire and insert the therapeutic device through *X-track*.

We commenced R&D for *X-track* in August 2017. We submitted an NMPA registration in July 2021 and obtained NMPA approval in April 2022. We expect to commence commercial production of *X-track* in July 2022.

### *Product Candidates under Development*

#### *Tigertriever*<sup>®</sup> Revascularization Device

##### *Overview*

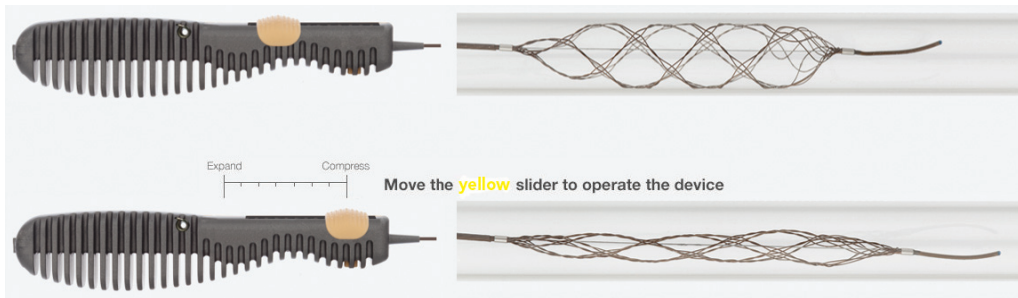
Developed by Rapid Medical, *Tigertriever* is the world’s first adjustable stent retriever with full visualization, according to CIC. *Tigertriever* is classified as a Class III medical device by the NMPA. *Tigertriever* received FDA registration in the United States in March 2021 and CE Marking in the European Union in May 2018. The *Tigertriever* product family are compatible with procedures performed in blood vessels of varying diameters. We were engaged as the exclusive distributor in Greater China for *Tigertriever*, *Tigertriever 13* and all follow-up products of *Tigertriever*. The

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*Tigertriever* is delivered through a 0.021 or a 0.017 inch microcatheter and is usually used for occlusion in large cerebral arteries, middle cerebral arteries and middle anterior cerebral arteries. *Tigertriever 13* is delivered through a 0.013 inch microcatheter and is mainly used for occlusion in distal small and middle cerebral arteries. *Tigertriever 13*, designed for distal vessel occlusion, is the world’s smallest stent retriever to date. The *Tigertriever* product family allows physicians to treat AIS in the majority of cerebral arteries, while the conventional stent retrievers are generally delivered through a 0.021 inch microcatheter for large cerebral arteries.

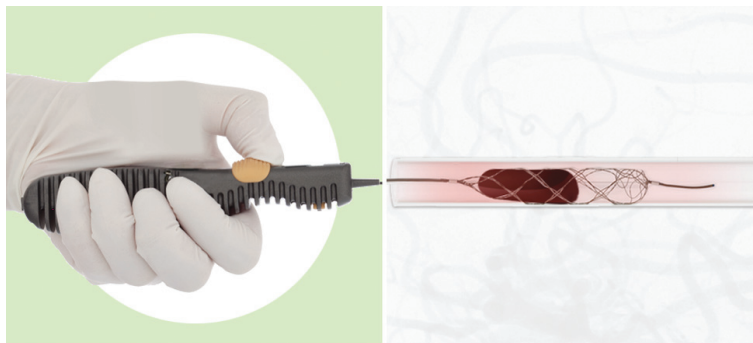
### *Product Structure*

*Tigertriever* consists of a braided nickel-titanium stent, a core wire and an expansion control handle. The braided nickel-titanium stent retriever is collapsible, nondetachable and fully retrievable. The stent construction is expanded by pulling a core wire, which is connected to the distal end of the mesh. The proximal end of the core wire is connected to a slider in the handle, through which physicians may expand and compress the stent at any time during the procedure. Being the world’s first adjustable stent retriever with full visualization, *Tigertriever* is also equipped with full length radiopacity, allowing physicians to observe and feel the stent retriever under fluoroscopy.



### *Operation Procedure*

For a procedure with *Tigertriever*, the physician delivers the stent retriever through a microcatheter. When the mesh of the stent retriever reaches the occluded segment, the physician will move the slider on the control handle to expand and compress the mesh to capture the clot. As the wires of the mesh are completely radiopaque, the device can be seen in its entirety under fluoroscopy. The physician can expand and contract the mesh to conform properly to the diameter of the affected vessel wall. The physician then pulls back the stent retriever with the captured clot.



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### *Features and Competitive Advantages*

*Tigertriever* is world’s first adjustable stent retriever with full visualization. We believe *Tigertriever* has the following features and benefits:

- *Smooth penetration.* *Tigertriever* is a braided nickel-titanium stent that utilizes a distinctive braided technology. With a large pore size mesh, *Tigertriever* has a stable structure for smooth penetration.
- *Unparalleled visibility.* *Tigertriever* is equipped with visible wires that enable full length radiopacity. This allows physicians to observe and feel the stent retriever interacting under fluoroscopy.
- *Adjustable radial force to improve apposition.* During the entire procedure, physicians may manually adjust the radial force through the slider in the handle, to improve apposition to vessel wall and minimize vessel injuries.

### *Development History and Development Plan*

In the United States, clinical trials for *Tigertriever* commenced in May 2018 and completed clinical trial in March 2020. *Tigertriever* received FDA approval in March 2021 and CE Marking in the European Union in May 2018.

In China, *Tigertriever* was admitted to the Green Path in May 2020. We are assisting Rapid Medical to conduct preparatory work for registering *Tigertriever* with the NMPA. We submitted *Tigertriever*’s NMPA application in December 2021 and expect to receive approval in the fourth quarter of 2022. We plan to assist Rapid Medical to submit *Tigertriever 13*’s NMPA application in 2024 and expect to receive approval in 2025.

### *Market Opportunity and Competition*

Mechanical thrombectomy has become the first-line treatment for acute ischemic stroke, and stent retriever thrombectomy is the most widely used approach. The number of stent retriever thrombectomy procedures (including standalone stent retriever thrombectomy procedures and stent retriever thrombectomy procedures combined with aspiration thrombectomy procedure) increased from 3,500 in 2015 to 37,800 in 2020, at a CAGR of 61.3% and is expected to further increase to 271,400 in 2026, at a CAGR of 38.9%. The penetration rate for stent retriever thrombectomy procedures (including standalone stent retriever thrombectomy procedures and stent retriever thrombectomy procedures combined with aspiration thrombectomy procedure) increased from 0.2% in 2015 to 2.2% in 2020, and is expected to increase to 15.3% in 2026.

According to CIC, thrombectomy stent procedures performed in small- and medium-sized blood vessels accounted for approximately 15.0% of all thrombectomy stent procedures in 2020. We expect the market size of the thrombectomy stent procedures performed in small- and medium-sized blood vessels is expected to increase from RMB70.0 million in 2020 to RMB420.0 million in 2026, representing a CAGR of 34.3%.

As of the Latest Practicable Date, there were 16 stent retrievers approved by NMPA, including products developed by both Chinese companies and international companies. We submitted an NMPA

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registration application of *Neurohawk* in March 2021 and received approval in the first quarter of 2022. In addition, *Tigertriever* was admitted to the Green Path in May 2020. We submitted *Tigertriever*'s NMPA application in December 2021 and we expect to receive approval in the fourth quarter of 2022. We are the exclusive distributor for *Tigertriever*, *Tigertriever 13* and all follow-up products of *Tigertriever* in Greater China. The following table sets forth these approved stent retrievers:

<u>Company</u>	<u>Number of approved stent retriever</u>	<u>First approved time by NMPA</u>
Medtronic	3	April 2015
Stryker Neurovascular	2	December 2015
Johnson & Johnson	2	November 2018
Acandis GmbH	1	January 2016
Jiangsu Ni Ke	1	May 2018
Shanghai Heartcare	1	August 2020
Zylox-Tonbridge Medical	1	September 2020
Skynor Medical	1	May 2021
Ruikangtong Scientific	1	July 2021
Our Company	1	February 2022
Achieva Medical	1	February 2022
NeuroCare Medical	1	February 2022
<b>Total</b>	<b>16</b>	

### *Aspiration Catheters*

We are also developing W-track<sup>®</sup> intracranial aspiration catheters and balloon protection guide catheters to treat AIS.

#### *W-track<sup>®</sup> Intracranial aspiration catheter (“W-track”)*

*W-track* is an intracranial aspiration catheter used for clot aspiration. *W-track* is a single-lumen catheter, the body of which is composed of an inner tube, a reinforcement layer and an outer tube. The proximal end of the single-lumen catheter is connected to a connector and a strain relief. It is also equipped with a guide sheath, a shaping mandrel and an hemostatic valve. To facilitate the delivery of *W-track* in neuro-interventional procedures, *W-track* has a semi-rigid proximal shaft and a flexible distal shaft with a radiopaque marker.

*W-track* is indicated for the introduction of neuro-interventional therapeutic devices into target vessels or the removal of clot from target blood vessels. The physician first places *W-track*, together with microcatheter and micro guidewire, into guide sheath or a sheath connecting to the hemostasis valve. This is to prevent backflow of blood during insertion of catheter. The physician then inserts the microcatheter and micro guidewire into the proximal end of *W-track*, and advances the assembly of microcatheter, micro guidewire and *W-track* to the target blood vessel. Once *W-track* reaches the target location, the physician removes the microcatheter and the micro guidewire. This type of intracranial device is often referred to as an intermediate catheter. It can be used as an access platform for any type of neuro-interventional procedure or exclusively for thrombus aspiration and clot removal.



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We believe *W-track* has the following features and competitive advantages:

- *Smooth delivery.* *W-track* has a multi-segment transition design to allow its smooth delivery. Between its inner tube and outer tube, the reinforcement layer is constructed in double-wire braided structure with stainless steel, which enhances the stability of aspiration catheter while maintaining flexibility of the tubes. With such design, *W-track* can reach the target occlusion quickly and smoothly, in particular in tortuous intracranial vessels.
- *Enhanced durability.* *W-track* is composed of reinforced stainless steel wires, which lowers the risks of collapse or damage.
- *Efficient aspiration capacity.* *W-track* has large aspiration lumen allowing physicians to remove clot efficiently.

We commenced R&D for *W-track* in May 2021. We expect to submit an NMPA registration application in third quarter of 2022 and receive approval in 2023.

### *Market Opportunity and Competition*

The number of aspiration thrombectomy procedures (including standalone aspiration thrombectomy procedures and aspiration thrombectomy procedures combined with stent retriever thrombectomy procedures) increased from 2,000 in 2015 to 22,500 in 2020, at a CAGR of 63.1%, and is expected to further increase to 171,600 in 2026, at a CAGR of 40.2%, according to CIC. The penetration rate of aspiration thrombectomy procedures (including standalone aspiration thrombectomy procedures and aspiration thrombectomy procedures combined with stent retriever thrombectomy procedures) increased from 0.1% in 2015 to 1.3% in 2020, and is expected to increase to 9.7% in 2026, according to CIC.

As of the Latest Practicable Date, there were eight aspiration catheters approved by the NMPA. The following table sets forth these approved aspiration catheters:

<u>Company</u>	<u>Number of approved aspiration catheter</u>	<u>First approved time by NMPA</u>
Penumbra	3	May 2018
Hemo Bioengineering	1	May 2021
MicroVention	1	July 2021
Weiming Medical	1	April 2022
Yijie Medical	1	April 2022
Achieva Medical	1	May 2022
<b>Total</b>	<b>8</b>	

### *Balloon protection guide catheter*

Our balloon protection guide catheter is a dual-lumen catheter, which is comprised of an inner tube, an outer tube, a balloon, a connector and a strain relief. The balloon protection guide catheter is equipped with two guide sheaths, one dilater, one inner pipe and one rotating hemostasis valve (RHV). The balloon protection guide catheter is indicated for use in facilitating the insertion and the guidance of an intravascular catheter into a selected blood vessel in the neuro vascular systems. The

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balloon provides temporary vascular occlusion during the angiographic procedures and neuro-interventional procedures.

For procedures with a balloon protection guide catheter, the physician first inserts the inner pipe into the balloon protection guide catheter through the lumen and flushes the inner pipe with heparinized saline. Through the guide sheath, the physician introduces and navigates the balloon protection guide catheter to the target vessel. The balloon protection guide catheter can provide proximal flow arrest when the physician performs the clot retrieval procedure with stent retrievers or aspiration catheters in the target vessel. Before removing the stent retrievers or aspiration catheters, the physician inflates the balloon with inflation media, which is consist of half heparinized saline and half contrast, by a 2 ml dilator. Upon completion of the clot retrieval procedure, the physician deflates the balloon using the 2 ml dilator and remove the balloon protection guide catheter.

We commenced R&D for the balloon protection guide catheter in May 2021. We expect to submit an NMPA registration in the fourth quarter of 2022 and receive approval in the second quarter of 2023.

### Access Products

#### Commercialized Products

##### *Asahi® Neurovascular Guidewires (“Asahi guidewires”)*

Asahi Intecc is an industry leader in guidewire manufacturing, with Asahi guidewires being one of the global leading neurovascular guidewires, according to CIC. Asahi guidewires are designed to selectively guide and carry catheters as well as other interventional devices within the neurovascular blood vessels. Asahi guidewires feature a unique multi-stranded coil design at the tip, enhancing torque response, elongation resistance and flexibility. Asahi guidewires were approved by the NMPA in August 2013 and we have been engaged as the exclusive distributor for Asahi guidewires in mainland China since November 2016.

##### *U-track® Intracranial Support Catheter System (“U-track”)*

*U-track* is designed for distal navigation and supporting precise delivery of a variety of neurovascular interventional devices during a neurovascular surgery. We obtained NMPA approval for *U-track* in December 2020.

We believe *U-track* has the following features and competitive advantages:

- *Eleven-transition design and three-layer structure for better navigability and stability.* *U-track* features an eleven-transition design and consists of three layers, including a polytetrafluoroethylene (PTFE) inner tube, a stainless steel coil middle tube and a polymer outer protective layer, which ensure that the catheter can reach the target lesion with better navigability and stability in tortuous vessels.
- *Minimum invasiveness.* *U-track* has a rounded tip design, which causes minimum damage to the vessels during a procedure.
- *Better addressing physicians’ needs.* With a larger inner dimension and various accessories, *U-track* is compatible with different procedures and better meets physicians’

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needs. Additionally, *U-track* is able to navigate through tortuous vessels and lesions without requiring further shaping handling by the physician because of our pre-shaped angle design, which effectively saves operation time.

### ***Fastrack*<sup>®</sup> Microcatheter System (“Fastrack”)**

*Fastrack* is designed for distal navigation and supporting precise delivery of intracranial interventional devices, specifically our *Tubridge*, during a neurovascular surgery. *Fastrack* features a stainless steel-braided proximal end, a distal end with reinforced nickel-titanium coils and double radiopaque markers, ensuring effective support and stability in tortuous vessels. In addition, *Fastrack* has a unique nine-transition design that enables a smooth transition from the proximal end to the distal end, therefore permitting better navigation in interventional procedures. We obtained NMPA approval for *Fastrack* in July 2019.

### **Product Candidates under Development**

As of the Latest Practicable Date, we had four access product candidates in various R&D stages, which further supplements our comprehensive product portfolio. The table below summarizes information on our product candidates:

<u>Name</u>	<u>Designed Features and Applications</u>	<u>Development Plans and Expected Approval Time</u>
Q-track™ 21 Microcatheter	With an inner diameter of 0.021 inch, it is used for the delivery of various stent devices and surgical fluids in neuro-interventional procedures.	Expect to complete type testing; to receive NMPA approval in 2023.
17 Microcatheter	With an inner diameter of 0.017 inch, it is used for the delivery of various devices and surgical fluids in neuro-interventional procedures.	Expect to commence preliminary studies; to receive NMPA approval in 2024.
Neuro-Guidewire	It is used to selectively introduce and position catheters and other interventional devices within arteries in neuro-interventional surgery.	Expect to finish product design and complete type testing; to receive NMPA approval in 2023.
Distal Protection Device	It is specifically designed to support our carotid stent system, which is used to filter and capture atherosclerotic fragments broken off during interventional procedures.	Expect to finish product design and complete type testing; to receive NMPA approval in 2025.

## COLLABORATIONS

As part of our business strategy, we evaluate opportunities to strategically collaborate with other neurovascular device companies through distributorships and investments. We have entered into

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distribution agreements with Asahi Intecc since November 2016 to exclusively distribute their neurovascular guidewires in mainland China. We have also entered into an exclusive distribution agreement with Rapid Medical since October 2019 to distribute their products in Greater China, which collaboration is further strengthened through our strategic investment in Rapid Medical as we prepare for further global expansion of our products.

### **Rapid Medical**

Rapid Medical is a privately held medical device company organized in the State of Israel which develops a range of interventional devices for neurovascular diseases such as ischemic and hemorrhagic stroke. Rapid Medical is a medical technology, or “medtech,” company with cutting edge research and development capabilities, proven record of regulatory approvals and advanced commercialization capabilities. We believe Rapid Medical has products and resources that are complementary to ours. In October 2019, we entered into a distribution agreement with Rapid Medical to be engaged as Rapid Medical’s exclusive distributor to market, promote, distribute and sell *Comaneci*, *Tigertriever*, *Tigertriever 13* and all follow-up products in Greater China. The distribution agreement has a term of ten years, but may be terminated earlier. For example, either party may terminate the agreement immediately if a material breach committed by the other party is not curable or remains uncured for a period of 30 days after such other party has been required in writing to remedy the breach.

Rapid Medical shall use reasonable commercial efforts to obtain NMPA marketing approval for the products with our assistance. The NMPA approval will be owned solely by Rapid Medical. Rapid Medical shall be responsible for necessary costs and expenses associated with obtaining, holding and maintenance of the NMPA approval. We are currently assisting Rapid Medical to register *Tigertriever* with the NMPA. It was admitted to the Green Path in May 2020 and is classified as a Class III medical device by the NMPA. We expect to receive its approval in the fourth quarter of 2022.

After Rapid Medical obtains NMPA approval for these products, we will order the products by means of purchase order, and we will have the right but not the obligation to place the order on a monthly basis. The purchase price is determined pursuant to terms specified in the agreement, which may be reviewed and adjusted through good faith negotiation by both parties from time to time. For each purchase order, we shall make the full payments within sixty calendar days after the date of delivery. We shall use our best efforts to comply with the annual minimum volume requirements as specified in the agreement. If we fail to meet the annual minimum volume requirements, and we have not rectified such failure within a grace period, Rapid Medical is entitled, at its discretion, to either terminate this agreement or cancel our exclusivity distributor status under this agreement.

We are permitted to use Rapid Medical’s trademarks identifying its products distributed in Greater China by us, related services and Rapid Medical’s business solely as required to convey that we are acting as Rapid Medical’s distributor of aforementioned products in Greater China. All of Rapid Medical’s intellectual property, including all updates and new versions, improvements and development thereof, are and shall remain Rapid Medical’s sole and exclusive property.

In addition, we plan to leverage Rapid Medical’s sales network in the United States as we progress our overseas plans. As we expand our coil embolization systems in the United States, we plan to engage Rapid Medical as the distributor for *NUMEN* and *NUMEN FR* in the United States, and these products enhance Rapid Medical in the field of hemorrhagic stroke.

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We also made a strategic investment in Rapid Medical and was the largest shareholder of Rapid Medical, holding approximately 22.28% of the issued share capital of Rapid Medical as of the Latest Practicable Date. See “History, Reorganization and Corporate Structure—Acquisition of certain interest in Rapid Medical” for further details. Rapid Medical has been loss-making since we made investment in it. Upon the completion of our series D investment in Rapid Medical in 2021, we obtained significant influence over Rapid Medical and recognized our investment in Rapid Medical as interests in an associate under equity method. From the completion of our series D investment in Rapid Medical to December 31, 2021, Rapid Medical incurred a loss of RMB33.7 million, and we accordingly recorded share of losses of Rapid Medical of RMB7.5 million. Although Rapid Medical is loss-making, we believed that the investments in Rapid Medical would be of strategic value because it considered Rapid Medical a promising medtech company with (i) strong research and development capabilities and a product pipeline with a proven record of regulatory approvals that could potentially be complementary with ours; (ii) commercialization capabilities and sales networks that we could potentially leverage; and (iii) impressive revenue growth.

### **Asahi Intecc**

Asahi Intecc is a Japan-based medical device company dedicated to developing stainless steel wire products for catheter treatments. Asahi Intecc has a comprehensive product portfolio of guidewires and catheters for different treatments and purposes, such as PTCA guidewires, PTCA guiding catheters and PTCA balloon catheters. In November 2016, we entered into a distribution agreement with Asahi Intecc to be engaged as Asahi Intecc’s exclusive distributor to market, promote, distribute and sell its neurovascular guidewires in mainland China. We extended our distribution agreement with Asahi Intecc in July 2021. The distribution agreement has a fixed term of three years unless terminated earlier. For example, either party may terminate the agreement without cause upon written notice of three months to the other party. In addition, a party may terminate the agreement if, among other things, a breach committed by the other party remains uncured for a reasonable period of days after such other party has been asked to remedy the breach.

Asahi Intecc shall apply for NMPA approval for the products to be distributed in mainland China. We will order the products by means of purchase order and shall provide Asahi Intecc an order volume estimate beforehand. For each purchase order, we shall make the full payments to Asahi Intecc before the date of shipment. The purchase price is determined pursuant to terms specified in the agreement. We shall comply with the minimum purchase quantity requirements as specified in the agreement and if we fail to meet the specified minimum purchase quantity requirements, Asahi Intecc is entitled to terminate this agreement. We are permitted to use Asahi Intecc’s trademarks associated with products distributed in mainland China for purposes solely related to such distribution, which permission shall be terminated upon the termination of the agreement. All intellectual property associated with Asahi Intecc’s products are its sole and exclusive property.

### **RESEARCH AND DEVELOPMENT**

We are a domestic market leader in the neuro-interventional medical devices industry in China and our commercial success largely depends on our R&D capabilities. Leveraging our advanced technologies and engineering techniques, we have built our R&D platforms to support our product development, manufacturing and quality control.

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We are engaged in ongoing R&D activities to expand the application of our products and to deliver clinically advanced new products with enhanced features, such as improved efficacy, safety, reliability and ease of use. As of the Latest Practicable Date, we had a total of 12 approved self-developed products in China. In addition, our *NUMEN* and *NUMEN FR* have been approved in the United States, the European Union and South Korea. In line with the growth in the neuro-interventional medical devices market, we will continue to develop new product candidates to maintain and expand our product coverage. We incurred R&D expenditure (including the capitalized R&D expenses) of RMB76.0 million, RMB80.5 million and RMB102.9 million for the years ended December 31, 2019, 2020 and 2021, respectively.

While we believe that we are able to comply with the regulatory review process and therefore introduce new products in a timely manner, the time required from developing to commercializing a new product varies and may be affected by factors beyond our control, *e.g.*, clinical trial results and government approvals. See “Risk Factors—Risks Relating to the Development of Our Products and Product Candidates.”

### **Our In-house R&D Team**

As of the Latest Practicable Date, our in-house R&D team consisted of 137 members. Over 50% of our team members have a master’s degree or a doctoral degree and approximately 40% had previously worked at multinational pharmaceutical and medical device companies. Mr. Wang Yiqun Bruce, our executive vice president, is enrolled in the Shanghai Foreign Elite Talent Introduction Program (上海市高層次引進人才) and Mr. Xie Zhiyong, our president, has been recognized as a Zhangjiang Professional of Excellence (張江卓越人才). In addition, our R&D team has participated in drafting the industry standards for neurovascular intracranial stents and neurovascular intracranial coils.

Our R&D team is primarily responsible for the initiation and proposal of new R&D projects, specifically including design planning, prototyping and verification. Our R&D team also provides technical support for all subsequent steps in product development and commercialization, including clinical trials, product registration and quality management. Furthermore, our R&D team collaborates closely with leading experts and KOLs in the industry to gain their guidance and insights so that we can take first-hand clinical opinions into consideration throughout our R&D process.

We have entered into confidentiality and non-compete agreements with our key R&D team members. Pursuant to the employment agreements of our R&D personnel, any intellectual property conceived and developed during their employment belongs to our Company and they waive all relevant rights or claims to such intellectual property.

### **Our Technology Platforms**

We have various technology platforms to meet our R&D, manufacturing and quality control needs, including:

- *Braiding and coiling technology development and manufacturing platform.* With this platform, we apply multi-ratio and varied-density braiding technology to develop various multistrand medical devices such as our *Numen* and *Tubridge*.
- *Stent forming and processing platform.* With this platform, we developed our stent products such as *APOLLO*, *Bridge* and *Willis* using our high-precision laser cutting

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machines for microscopic device cutting. Our metal processing capabilities are further enhanced through our downstream electrochemical polishing and surface treatment technology.

- *Balloon technology development and manufacturing platform.* With complete balloon molding, laser welding, folding and final assembly production lines on this platform, we are able to develop our balloon catheter product candidates such as the intracranial drug-coated balloon catheter system and balloon dilatation catheters.
- *Catheter technology development and manufacturing platform.* With this platform, we applied coil winding, mesh-braiding, thermal-molding, marker-band placing and coating technologies to develop our catheter products such as the Fastrack Microcatheter and the U-track Intracranial Support Catheter.
- *Finite element analysis (FEA) platform.* With this platform developed by MicroPort Group, we use various finite element models to predict and optimize stent expansion process. This platform helps us optimize the stents in their design phase, which reduces the number of physical prototypes and experiments.
- *Fatigue testing platform.* With this platform, we carry out fatigue tests for our long-term implantable devices. Our platform is capable of carrying out such fatigue tests with fast turnaround in our product design and assembly.

With our technology platforms, our R&D team is able to carry out product design and development in accordance with the specific requirements for neuro-interventional medical devices, therefore overcoming technology bottlenecks in designing and developing our production concepts. With our technology platforms, we have also achieved synergy in R&D and manufacturing, which ensures a smooth transition from our product design to commercial manufacturing in accordance with our quality management system.

### **Product Design and Preclinical Development**

Our product design and development process includes the following steps:

- *Planning.* At this stage, we analyze market trends, regulatory requirements, existing products or product candidates as well as unmet clinical needs in the neuro-interventional medical devices industry and gather the information needed for designing a product candidate. Such information includes the product candidate’s function, performance, usability and safety requirements, selection of raw materials, applicable engineering techniques and other essential requirements.
- *Prototyping.* At this stage, we prepare the design production and testing process. We also evaluate the safety and efficacy of the sample product through an internal design assessment to ensure that the product design meets the applicable regulatory requirements and other essential requirements.
- *Verification.* At this stage, we conduct verification tests to ensure that the design outputs are suitable for manufacturing before becoming final production specifications. Our verification tests assess factors including a product candidate’s function, operability, reliability, safety and efficacy.

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After all the three steps have been completed, our product candidates generally undergo preclinical animal studies before reaching the clinical trial stage, which helps us identify potential risks and improve our product design. We have contracted with animal laboratories in China to conduct animal studies. Pursuant to the relevant agreements, we are primarily responsible for designing a specific protocol and monitoring the tests while the laboratories are primarily responsible for carrying out the animal test accordingly. Under the agreements, the laboratories adhere to strict confidentiality obligations and all the data, as well as any intellectual property rights developed from the animal tests belong to us.

### **Clinical Trials and Registration**

After the completion of the preclinical studies, our product candidates generally enter the clinical trial stage, which further helps us evaluate the safety and efficacy of such candidates. We typically collaborate with physicians in local hospitals to conduct clinical trials. We work with the physicians to formulate a clinical trial plan and select patients eligible for the clinical trials. We are responsible for the overall management of clinical trials, including designing clinical trial protocols, selecting trial sites and communicating with regulatory authorities. Physicians are mainly responsible for conducting the clinical trials and follow-up visits with the patients. We also engage CROs and SMOs, who are clinical trial service providers and assist us in the execution of clinical trials. Specifically, the CROs we engaged are primarily responsible for reviewing the clinical trial data, handling and managing transactional matters at the trial sites and operating the electronic data capture (EDC) system for the clinical trials. The SMOs we engaged assist researchers to complete certain supporting duties in relation to our ongoing clinical trials, including collecting source data and scheduling patient follow-up visits, among others. We are also responsible for overseeing the CROs' and SMOs' performance. In 2019, 2020 and 2021, we engaged six, seven and four CROs and four, four and five SMOs, respectively, to assist the R&D of our product candidates. During the same periods, we incurred service fees to CROs and SMOs of RMB4.1 million, RMB3.8 million and RMB2.9 million, respectively. The service fees we paid to our CROs and SMOs during the Track Record Period were determined on a case-by-case basis with regard to the scale of the relevant clinical trials (primarily depending on the number of patients, trial sites and follow-up visits) and the service scope. Payment schedules for CROs and SMOs are typically tied to clinical trial milestones, *e.g.*, the enrollment of a certain percentage of patients, the enrollment of all patients, the conclusion of the trial and the finalization of the clinical trial report. There is generally no fixed term on our agreement with CROs and SMOs, considering the uncertain nature of clinical trials. However, our CROs and SMOs are expected to complete their duties in a timely manner (*i.e.*, to complete specific milestone events in accordance with an agreed timeline). Furthermore, they are obligated to provide us with regular updates on the trial progress and data reports pursuant to the agreement. We invite qualified CROs and SMOs to submit bids and select the winning bid by considering a number of factors, such as experience in providing services for similar clinical trials, service quality and pricing. We own all intellectual property in relation to the clinical studies and the CROs and SMOs are obligated to maintain strict confidentiality in respect of all non-public information and data from the clinical studies. Typically, we may terminate an agreement with a CRO or SMO without cause if we provide the other party sufficient prior written notice and pay the outstanding service fees. In addition, an agreement may be terminated by either party, among other things, upon notice to the other party if a breach by the other party is not curable or remains uncured for a stipulated period of time (*e.g.*, 14 days) after notice of the breach is received by the other party.



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After successful completion of a registrational clinical trial, we apply for the approval from NMPA or other relevant authorities to register our candidates. For each product candidate, we are required to file the registration application in accordance with the relevant registration regulations. For example, as we prepare for further global expansion, our *NUMEN* obtained FDA approval in the United States, CE Marking in the European Union and MFDS approval in South Korea in 2021. The registration process is complex and time-consuming, requiring collaborations from multiple departments such as R&D, preclinical studies and clinical trials. We believe our extensive experience in managing the registration process is critical for us to obtain the regulatory approvals for our product candidates.

### MANUFACTURING

During the Track Record Period, we conducted manufacturing activities primarily at our manufacturing facility located in our leased properties in Zhoupu, Shanghai, with an aggregate GFA of approximately 2,300 sq.m. To expand our manufacturing capability as the market demand continues to grow, we constructed another manufacturing facility in our leased properties in Zhangjiang, Shanghai, with an aggregate GFA of approximately 7,000 sq.m. We obtained the production permit for this facility in May 2022. As of the Latest Practicable Date, we manufactured our commercialized stent, coil and catheter products at these facilities with an annual production capacity of approximately 110,000 units. We estimate that our designed production capacity will further increase to approximately 350,000 units per year in 2025.

As part of our global expansion strategy, we plan to lease a manufacturing facility with an aggregate GFA of approximately 1,000 sq.m. in Irvine, California, USA, which is expected to commence operations in 2023. After we obtain the relevant lease, we plan to seek FDA approval for this manufacturing facility. We plan to recruit talent locally and focus on the R&D, manufacturing and supply of our coil products at this facility. We believe such complete and localized production line of coil products could ensure prompt supply to local and global hospitals and help us penetrate the global neuro-interventional market. We may construct additional manufacturing facilities as necessary going forward. See “—Properties” in this section for more details of our properties.

Our manufacturing facilities and our manufacturing processes are and will continue to be subject to ongoing, periodic inspection by the NMPA, the European Medicines Agency (“EMA”) or other comparable regulatory agencies to ensure compliance with the quality standards, which is usually the prerequisite to obtain marketing approval in the respective jurisdictions.

### Manufacturing Process

The manufacturing process for our products primarily involves the following steps:

- (i) *Preparation*: We inspect and clean the raw materials or components of the manufactured products.
- (ii) *Laser cutting/braiding*: We laser cut or braid the metal materials to form the device frame based on designs developed by our engineers.
- (iii) *Surface treatment*: We treat the surface of key parts of the manufactured products.
- (iv) *Assembling*: We assemble parts of the manufactured products.

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- (v) *Work in progress quality inspection:* We inspect our work-in-progress after various stages, including preparation, cutting, surface treatment and assembling.
- (vi) *Packaging:* We package the manufactured products.
- (vii) *Sterilization:* We sterilize the packaged products.
- (viii) *Finished goods quality inspection:* We inspect the finished products before storing them in our warehouse.

We conduct substantially all of the steps above in-house, which increases our production efficiency and reduces our dependence on third-party suppliers. This vertical integration distinguishes us from our domestic competitors and enables us to be flexible with our production responding to changes in market demand for our products.

To stay compliant with the applicable quality standards, we have incorporated a series of quality control measures in our manufacturing process. We monitor and evaluate our product quality regularly and conduct internal audit on our quality management periodically. In 2019, 2020 and 2021, there were four, five and eight regulatory inspections on our manufacturing process, respectively, conducted by the Shanghai Drug Administration and other regulatory authorities. We passed all of these regulatory inspections without receiving any sanctions due to non-compliance. During the Track Record Period and up to the Latest Practicable Date, we had no product recalls for all products sold by us.

### Facilities

To support our diverse product portfolio, our key manufacturing equipment mainly includes laser cutting machines, digital display measuring microscopes and intelligent testing equipment. We develop specialized machinery in house as well as purchase from multiple domestic and overseas suppliers. Saved for some machinery with advanced features and quality from certain suppliers, we are able to purchase manufacturing machinery from alternative suppliers. During the Track Record Period, we had not experienced any material or prolonged interruptions of our machinery due to equipment or machinery failure.

We believe that our current manufacturing capacity is able to meet our short-term commercial needs. Our location also gives us an advantage in manufacturing over our international competitors given our geographic proximity to the China market. We have access to China’s vast labor pool, which makes it easier for us to hire people with the appropriate skills for our production. As of the Latest Practicable Date, we had a production team of over 130 employees. To enhance our production quality and efficiency, our production personnel is required to undergo rigorous training before they commence work on our production lines.

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### Production Capacity, Production Volume and Utilization Rates for Our Commercialized Products

The table below sets forth the production capacity, production volume and utilization rate for the products in our Zhoupu manufacturing facility for the periods indicated:

	<u>For the year ended December 31,</u>		
	<u>2019</u>	<u>2020</u>	<u>2021</u>
<b>Production capacity<sup>(1)</sup> (units)</b> .....	<b>40,000</b>	<b>50,000</b>	<b>112,500</b>
Hemorrhagic stroke products .....	10,500	19,500	60,700
Cerebral atherosclerotic stenosis products .....	24,000	24,000	38,800
Access products .....	4,000	5,000	10,500
AIS products .....	1,500	1,500	2,500
<b>Actual production volume (units)</b> .....	<b>30,845</b>	<b>36,231</b>	<b>96,798</b>
<b>Utilization rate</b> .....	<b>77.1%</b>	<b>72.5%</b>	<b>86.0%</b>
Hemorrhagic stroke products .....	60-70%	70-80%	80-90%
Cerebral atherosclerotic stenosis products .....	80-90%	70-80%	80-90%
Access products .....	70-80%	60-70%	80-90%
AIS products .....	70-80%	40-50%	80-90%

*Note:*

- (1) Our production capacity is calculated based on the assumptions of full annual attendance of our production employees and functional operations of our equipment.

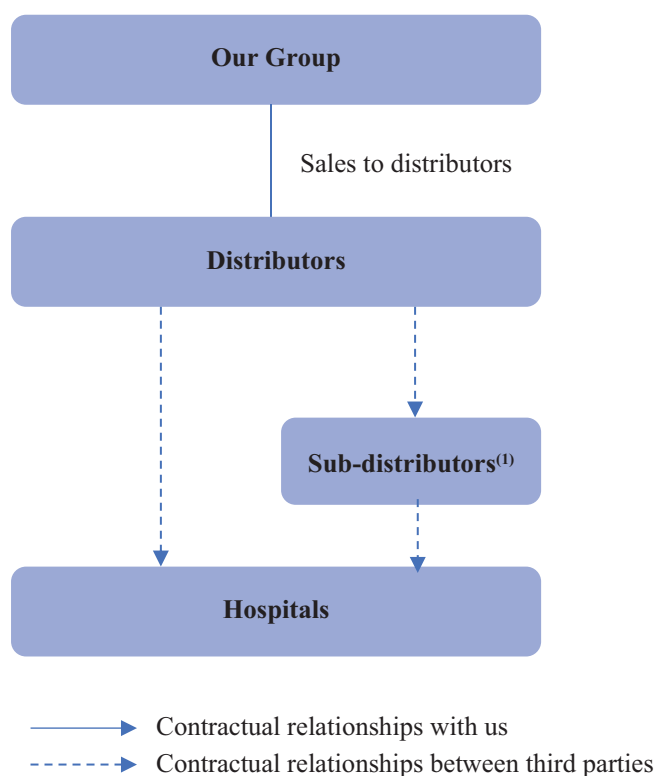
### SALES, DISTRIBUTION AND MARKETING

#### Our Sales and Distribution Model

In line with the medical device industry norm in China, we adopt a distributorship model, which we believe allows us to leverage the distributors’ customer bases and expertise in local markets. During the Track Record Period, all of our products were sold through distributors. We primarily operate a multi-layer distribution system, where a majority of our products are sold from distributors to sub-distributors, and such sub-distributors on-sell our products to hospitals through their own sales and distribution networks; and a relatively smaller proportion of our products are sold from our distributors directly to hospitals. We believe that the multi-layer distribution system allows us to reach a broader group of end-customers leveraging the sub-distributors’ local networks and expertise. In the meantime, under the multi-layer distribution system, the distributors manage their sub-distributors, which enhances our management efficiency.

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The following chart illustrates the structure of our sales and distribution model:



Notes:

- (1) We primarily operate a multi-layer distribution system.
- (2) In 2019 and 2020, all of our revenue was generated from domestic sales. Since July 2021, we began to enter into distribution agreements with overseas distributors. In 2021, our revenue from other countries amounted to RMB0.6 million, accounting for 0.2% of our total revenue in the same year. We expect that the China market will continue to be the predominant source of our revenue.

As of the Latest Practicable Date, we had established an extensive distribution network in China. The following table sets forth the changes in the number of our distributors (not including sub-distributors) during the Track Record Period:

	<b>For the year ended December 31,</b>		
	<b>2019</b>	<b>2020</b>	<b>2021</b>
As of the beginning of the period	89	79	60
Additions of new distributors <sup>(1)</sup>	28	17	8
Termination of existing distributors <sup>(2)</sup>	38	36	48
Termination due to regional distributors choosing to become sub-distributors of national distributors	35	16	32
Termination due to expiration of distribution agreements	3	20	16
As of the end of the period <sup>(3)</sup>	<u>79</u>	<u>60</u>	<u>20</u>

Notes:

- (1) The number of new distributors represents those distributors that were engaged in the year indicated but were not engaged in the year immediately preceding the year indicated.
- (2) The number of terminated distributors represents those distributors that were engaged in the year immediately preceding the year indicated but were not engaged in the year indicated.

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- (3) Based on information reported by our distributors, in the years ended December 31, 2019, 2020 and 2021, 4, 8 and 8 distributors engaged sub-distributors, respectively. We recorded revenue of RMB150.2 million, RMB209.1 million and RMB348.9 million attributable to such distributors in these periods, respectively, which represented a majority of our revenue.
- (4) The number of our distributors decreased significantly during the Track Record Period as we gradually established an extensive and extensible network centered on a smaller number of national distributors, which we have found suitable for the types of products we sell. Specifically, on the one hand, we terminated a number of distributors as they chose to become sub-distributors of other larger, national distributors or due to contract expiry. On the other hand, the number of new distributors that we engaged decreased during each period of the Track Record Period, as we strategically chose to center our distributor network on a smaller number of national distributors.

During the Track Record Period, as shown in the table above, we terminated certain distributors because (i) certain regional distributors chose to become sub-distributors of other larger, national distributors. Specifically, because neuro-interventional medical devices usually have many specifications with different diameters, lengths and softness levels (e.g., *NUMEN* has more than 170 specifications), distributors must maintain a sufficient level of inventory to accommodate needs from hospitals for various specifications. This requires distributors to have sufficient cash on hand and strong inventory management capabilities. As a result, certain regional distributors chose to become sub-distributors of larger national distributors to leverage such national distributors' stronger capital resources, storage and inventory management capabilities and logistic capacity; and (ii) our distribution agreements with certain distributors expired and we decided not to renew such distribution agreements due to commercial reasons, for example, the distributors' unsatisfactory sales performance or change of business focus. For distributors terminated during the years ended December 31, 2019, 2020 and 2021, the aggregated revenue attributable to such terminated distributors was RMB6.9 million, RMB11.6 million and RMB15.3 million in 2018, 2019 and 2020 (the previous period before termination), and the average revenue attributable to such terminated distributors was RMB0.2 million, RMB0.3 million and RMB0.3 million in the same periods, respectively. The average length of our business relationship with the distributors terminated in the years ended December 31, 2019, 2020 and 2021 was 2.6 years, 2.3 years and 3.4 years, respectively, and the average length of our business relationship with the remaining distributors in the same periods was 2.8 years, 3.4 years and 2.6 years, respectively. Our Directors confirm that there were no material disputes or litigation between us and the terminated distributors during the Track Record Period and up to the Latest Practicable Date.

During the Track Record Period, to the best of our Directors' knowledge, all of our distributors were Independent Third Parties, and none of our distributors were controlled by our current or former employees. During the Track Record Period, we did not provide any material advance or financial assistance to our distributors. To the best of our Directors' knowledge, during the Track Record Period, there were no other relationship or arrangement (family, business, financing, guarantee or otherwise) between our distributors and our Group, our Directors, shareholders and senior management and their respective associates. Our Directors confirm that there were no distributors or sub-distributors which (i), to our best knowledge, were the subject of any actual or threatened material non-compliant incidents, claims, litigation or legal proceedings in relation to sales of our products, or (ii) materially breached the distributorship agreements during the Track Record Period and up to the Latest Practicable Date.

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The tables below summarize the details of our five largest distributors for the periods indicated.

<u>Five Largest Distributors in 2019</u>	<u>Background</u>	<u>Revenue Derived from the Distributor</u> <i>(RMB'000)</i>	<u>Percentage of Total Revenue</u>
Distributor A	A distributor primarily engaged in the distribution of medical devices, cosmetics and household products	122,388	66.6%
Distributor B	A distributor primarily engaged in the distribution of medical devices and export and import of goods	13,443	7.3%
Distributor C	A distributor primarily engaged in the distribution of medical devices, medicine, cosmetics and household products	11,959	6.5%
Distributor D	A distributor primarily engaged in the distribution of medical devices, medicine and health products	4,745	2.6%
Distributor E	A distributor primarily engaged in the distribution of electronic devices, household goods and medical devices	2,699	1.5%
<b>Total</b>		<u>155,234</u>	<u>84.5%</u>
<u>Five Largest Distributors in 2020</u>	<u>Background</u>	<u>Revenue Derived from the Distributor</u> <i>(RMB'000)</i>	<u>Percentage of Total Revenue</u>
Distributor A	A distributor primarily engaged in the distribution of medical devices, cosmetics and household products	129,864	58.5%
Distributor D	A distributor primarily engaged in the distribution of medical devices, medicine and health products	57,950	26.1%
Distributor F	A distributor primarily engaged in the distribution of medical devices, cosmetics and construction materials	15,035	6.8%
Distributor G	A distributor primarily engaged in the distribution of medical devices, cosmetics, electronic products and textile	10,034	4.5%
Distributor H	A distributor primarily engaged in the distribution of medicine, medical devices, electronics and cosmetics	5,600	2.5%
<b>Total</b>		<u>218,483</u>	<u>98.4%</u>

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Five Largest Distributors in 2021	Background	Revenue Derived from the Distributor <i>(RMB'000)</i>	Percentage of Total Revenue
Distributor D	A distributor primarily engaged in the distribution of medical devices, medicine and health products	110,542	28.9%
Distributor A	A distributor primarily engaged in the distribution of medical devices, cosmetics and household products	101,120	26.4%
Distributor G	A distributor primarily engaged in the distribution of medical devices, cosmetics, electronic products and textile	86,769	22.7%
Distributor H	A distributor primarily engaged in the distribution of medicine, medical devices, electronics and cosmetics	41,049	10.7%
Distributor I	A distributor primarily engaged in the distribution of medical devices	18,257	4.8%
<b>Total</b>		<u>357,737</u>	<u>93.5%</u>

Our sales to the five largest distributors increased during the Track Record Period because certain regional distributors chose to become sub-distributors of these large, national distributors. Specifically, because neuro-interventional medical devices usually have many specifications with different diameters, lengths and softness levels, distributors must maintain a sufficient inventory level to accommodate needs from hospitals for various specifications. This requires distributors to have sufficient cash on hand and strong inventory management capability. As a result, certain regional distributors chose to become sub-distributors of larger national distributors to leverage such national distributors’ stronger capital resource, storage and inventory management and logistic capacity, thereby causing an increase in the sales concentration to the five largest distributors. Although our sales to the five largest distributors increased during the Track Record Period, such an increase in distributor concentration did not have a material impact on the gross profit margin, revenue or averaging selling price with respect to sales to such distributors during the Track Record Period. If we lose any major distributors, the distribution of our products may be interrupted. See “Risk Factors—Risks Relating to Commercialization and Distribution of our Products—If we lose our existing distributors and fail to secure new distributors, our business and sales of the relevant products could be adversely affected” and “—The number of our distributors decreased during the Track Record Period and our distribution network is centered on a small number of major distributors.” However, we do not foresee a significant risk of reliance on these largest distributors, because such national distributors are abundant in China. According to CIC, as of the Latest Practicable Date, there were over 100 national distributors in China who distribute neuro-interventional medical devices. We also host annual meetings with our existing distributors and potential distributors, through which we connect with many national distributors and have built up a rich candidate pool. Therefore, we will be able to find alternative national distributors in a timely manner if any of our current largest distributors terminates business relationship with us. Also, we primarily use distributors to streamline administration and logistics, and at the same time we already have regular and close contacts with the

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sub-distributors as we proactively monitor how our products are sold and used in hospitals. Therefore, should we need to replace a national distributor, we would only need to facilitate administrative arrangements between the new distributor and the sub-distributors (*e.g.*, establishing logistics arrangements). We believe that the switch cost would not have a material adverse effect on our business operations. We plan to increase the number of our distributors and reduce the concentration of our sales to major distributors. Specifically, our Eagle & Swallows team will continue to promote our products in lower-tier cities and counties to enhance our penetration in these markets. Through their market exploration initiatives, Eagle & Swallows team will connect with qualified distributors and sub-distributors who serve these lower-tier cities and counties. We will further evaluate such distributors and sub-distributors and engage suitable candidates to support our growing distribution needs in these under-penetrated markets. Also, we will continue to host our annual meetings with distributors, through which we have built up a rich distributor candidate pool and will continue to explore business opportunities with additional distributors.

### **Sales to Distributors**

#### *Selection and Management of Distributors*

We select our distributors based on a series of criteria regarding their credentials, capabilities and experience in the medical device industry. We also review the qualifications of our distributors to ensure that they possess the requisite business licenses and permits to sell medical devices in their designated territories. Our distributorship agreements typically have a term of one year, which are renewable upon our review of our distributors' performance. In addition, we typically have an early termination right in our distributorship agreements which enables us to terminate a distributorship relationship early if there is a material breach committed by the distributor as specified in the agreement.

We conduct regular reviews of our distributors, based on their financial performance, business performance and regulatory compliance. Financial performance is primarily evaluated by credit records and business performance is primarily evaluated by sales performance, especially whether they meet the target order amount, and the designated hospitals' feedback. We also review their compliance with applicable laws and regulations. We retain the discretion to adjust their credit terms, renegotiate order price and certain other commercial terms with them based on the review results. Our sales and marketing personnel monitors, manages and supports the activities of our distributors to help ensure that they comply with our guidelines, policies and procedures. We have adopted the following measures and policies to better manage the network of our distributors: (i) we either require our distributors to make full payment when making the purchase orders, or grant credit terms on a case-by-case basis to distributors who have passed our credit assessment; (ii) we currently do not require a minimum purchase amount by any distributors so that we can focus on market expansion; (iii) we require our distributors to report their product flow, sales data and inventory level regularly and submit sales invoices and delivery records; (iv) our distributorship agreements provide a strict return and exchange policy, wherein we accept product exchange due to packaging defects and expiry. Near-expiry products can only be returned or exchanged under situations specified in the agreement; and (v) we require our distributors to comply with all relevant anti-corruption and anti-bribery laws and regulations and any breach of such laws and regulations would allow us to unilaterally terminate the underlying distribution agreements pursuant to the early termination right.



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Our distributors and sub-distributors are only authorized to sell to their designated hospitals in designated geographic regions, and cannot sell, directly or indirectly, to end customers outside their designated geographic regions. We do not appoint more than one distributor or sub-distributor for the same type of product for a hospital in the PRC.

### *Management of Sub-distributors*

During the Track Record Period, certain of our distributors engaged sub-distributors from time to time, which then on-sold our products to hospitals. We only enter into bipartite distribution agreements with distributors, and do not enter into tripartite distribution agreements with distributors and their sub-distributors. We require our distributors to verify the sub-distributors’ qualifications, financial conditions and compliance history before engaging any sub-distributors, and to submit such documentation to us for review before engaging a sub-distributor. Any sub-distributors engaged by our distributors must seek our consent prior to using our trademarks. After the engagement of a sub-distributor, we require our distributors to regularly monitor and report to us the sub-distributor’s compliance status, sales performance, inventory level and any breach of the sub-distributorship agreement.

### *Distribution Agreements*

The table below summarizes the salient terms of the standard agreement with our distributors:

<b>Term</b>	Generally one year, with automatic renewal for another year in the absence of disagreement.
<b>Relationship with distributors</b>	We form a seller-buyer relationship rather than a principal-agent relationship with our distributors. Our distributors are Independent Third Parties.
<b>Designated geographical regions</b>	Distributors are authorized to distribute our products in designated regions as specified in the agreement.
<b>Minimum purchase amount, minimum sales target</b>	We do not mandate minimum purchase amount. We sometimes mandate a minimum sales target, and whether the target is met will be considered as a factor whether the agreement will be renewed next year.
<b>Selling price to sub-distributors or end-customers</b>	We do not mandate the selling price of products sold from distributors to sub-distributors, and we provide guiding price to distributors for reference. We require distributors to report the actual selling price to us after they determine the selling price with sub-distributors or end-customers.
<b>Payment and credit terms</b>	We either require our distributors to make full payment when making the purchase orders, or grant credit terms on a case-by-case basis to distributors who have passed our credit assessment.
<b>Product return/exchange</b>	We accept product exchange due to packaging defects, quality issues and expiry. Near-expiry products can only be exchanged under situations specified in the agreement. Such return/exchange policy is in line with industry practice.
<b>Transportation and delivery</b>	Distributors are responsible for transporting the products and bearing the costs and risk of loss during the course of transportation.

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<b>Warranty</b>	We warrant that our products meet the quality standards as specified in the product manual.
<b>Regulatory compliance</b>	We require our distributors to comply with all laws, regulations and mandatory industry standards and not to adversely affect our compliance with such laws, regulations and industry standards.
<b>Restriction on sub-distributors</b>	We require our distributors to conduct due diligence on any potential sub-distributors before engaging them. Any sub-distributors engaged by our distributors must provide us with relevant certificates and qualifications and seek our written consent prior to distribution of our products.
<b>Reporting obligations</b>	We require our distributors to report to their inventory level, the product flow and sales data periodically as agreed.
<b>Intellectual property and confidentiality</b>	All intellectual properties related to our products belong to us. Our distributors are required to maintain confidentiality as agreed.
<b>Termination</b>	The agreement may be terminated by us when, among other things, the distributor fails to comply with relevant laws and regulations, or breaches material undertaking specified in the agreement.

### *Product Return*

Under our standard distribution agreement with distributors, we accept product exchange due to packaging defects and quality issues. We also allow returns of near-expiry products, limited to a low single-digit percentage of the total purchase amount. Such return policy is in line with industry practice. We allow return of a small percentage of near-expiry products because neuro-interventional medical devices usually have many specifications with different diameters, lengths and softness levels, which means distributors must maintain a high inventory level to accommodate needs from hospitals for various specifications. By allowing return of a small percentage of near-expiry products, we intend to encourage our distributors to maintain sufficient level of inventory to better address hospitals and patients’ needs. See “—Distribution Agreement” above.

During the Track Record Period, among all of our commercialized products, only certain units of *Apollo*, *Willis*, *Tubridge* and *T-track/Fastrack* were returned. Specifically, the number of *Apollo*, *Willis*, *Tubridge* and *T-track/Fastrack* returned during the Track Record Period was 1,256, 167, 141 and 61, respectively, representing a return rate of 2.4%, 12.3%, 2.1% and 2.5%, respectively. The return rate of *Willis* was relatively high because we terminated certain distributors in 2019 and 2020, and we agreed to repurchase *Willis* sold to such distributors on a one-off basis. We terminated these distributors for *Willis* because we decided to switch to other distributors with more warehouses across China and greater logistics capacity, who could distribute our products more efficiently. According to CIC, our rate of return is in line with industry norm.

### *Pricing*

We take into account a number of factors in determining the prices of our products sold to distributors, such as prices of competing products, our manufacturing costs, patient affordability and the differences in features between our products and competing products. We from time to time consider adjusting the prices sold to distributors according to the market conditions and competition. For the impact of diagnosis related groups (DRG) mechanism and centralized procurement on the pricing of our products, see “—Recent Evolvments in Our Regulatory Environment” for details.

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As of the Latest Practicable Date, there was no price guidance set by the PRC government on neuro-interventional medical devices. If the PRC government sets such a price guidance, the prices of our products may be negatively affected. See “Risk Factors—Risks Relating to Commercialization and Distribution of Our Products—Downward change in pricing of our products caused by changes in market competition may have a material adverse effect on our business and results of operations.”

### **Our Marketing Model**

Our in-house sales and marketing team consists of highly experienced sales personnel. As of the Latest Practicable Date, we had a sales and marketing team of approximately 100 personnel in China. We are also planning and building localized sales and marketing teams in our overseas markets. We expect to continue expanding our international team to cover Asian Pacific, Latin America, the European Union, United Kingdom, the Middle East and Africa.

We have adopted customized sales and marketing approaches tailored for different markets to maximize the penetration of our products. For markets where we have established a solid brand name, which are mainly first-tier cities, our sales and marketing personnel continue providing well-rounded supporting services to maintain our market position. For markets where we are yet to establish our market recognition, which are mainly lower-tier cities and counties, our Eagle & Swallows (神雕飛燕) team carry out various marketing activities to enhance the awareness for neurovascular surgeries and our products. For example, we provide training on neuro-interventional surgery and routine guidance to local physicians. We believe lower-tier cities represent markets with great growth potential, given that the treatment for stroke is highly time-sensitive whereas the hospitals eligible for such surgeries are currently insufficient to meet such medical demands.

We are committed to making neuro-interventional surgeries more accessible. Therefore, we devote significant efforts in providing training to physicians. Our training programs, such as Twins Program and Spark Training Camp (星火訓練營), help young physicians improve their technical skills and broaden their understanding of neuro-interventional surgery. During the Track Record Period, we also supported the training programs held by top-tier hospitals across China by providing technical support.

We interact with leading principal investigators, KOLs and physicians. In addition, we actively participate in academic or industry conferences in neurovascular surgery, including the annual Oriental Conference of Interventional Neurovasculology (東方腦血管大會), the Annual Conference of Chinese Interventional Neuroradiology Society of Chinese Stroke Association (中國卒中協會神經介入分會學術年會) and the Western Stroke Interventional Conference (西部卒中介入會議). As part of our globalization initiative, we also regularly attend international conferences, such as the annual meetings of the Society of NeuroInterventional Surgery held in the United States, to establish our market recognition overseas. We believe such conferences provide us with opportunities to have a better understand of the recent progress in this area and showcase our innovations.

### **RECENT EVOLVEMENTS IN OUR REGULATORY ENVIRONMENT**

As a medical device developer and manufacturer based in the PRC, we operate in a heavily regulated environment that keeps evolving. We summarize below recent developments in certain regulatory movements that are material to our business and prospects.

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### Two-Invoice System

#### *Implementation Status and Impact on our Group*

The “two-invoice system” is a pilot regulatory mechanism initially proposed by the PRC government in 2016 to restrain high pricing of medicine and high-value medical devices due to multiple layers of distribution. As designed, a maximum of two invoices (one invoice from the manufacturer to the distributor and another invoice from the distributor to the hospital) would be allowed to be issued in the chain of distribution.

As of the Latest Practicable Date, the two-invoice system for medical devices was not mandatorily implemented nationwide; it was only mandatorily implemented in three provinces, namely, Anhui, Shaanxi and Fujian. Whether and when the two-invoice system will be mandatorily implemented in other provinces for medical devices remains uncertain, as advised by our PRC Legal Advisers. Specifically, pursuant to the Reply of the National Healthcare Security Administration to Recommendation No. 1209 of the Second Session of the Thirteenth National People’s Congress issued in July 2019, the implementation of two-invoice system for high-value medical devices should be further discussed given the huge differences between high-value medical devices and drugs and the complexity of clinical use and after-sales service. As advised by our PRC legal advisers, pursuant to relevant PRC regulations, for imported medical devices, the invoice for any initial sale from the overseas manufacturer to its general distributor in China will not count as one invoice under the two-invoice system, because the general distributor in China is considered equivalent to the manufacturer for this purpose. See “Regulatory Overview—Laws and Regulations on Medical Device—Two-Invoice System for Medical Devices” for details.

We primarily operate a multi-layer distribution system (where our distributors engage sub-distributors to on-sell products to hospitals), but we only do so in provinces where the two-invoice system is not mandatorily implemented. Our sales in the provinces where the two-invoice system has been mandatorily implemented for medical devices (*i.e.*, Anhui, Shaanxi and Fujian) represented an insignificant proportion of our revenue during the Track Record Period. Specifically, our sales from these three provinces amounted to RMB4.6 million, RMB3.3 million and RMB4.3 million in the years ended December 31, 2019, 2020 and 2021, respectively, representing 2.5%, 1.5% and 1.1% of our revenue in the respective periods.

#### *Our Compliance Status and Measures to Ensure Ongoing Compliance*

As advised by our PRC Legal Advisers, we had complied with the two-invoice system in all material aspects for all of our commercialized products (including our self-developed products and products developed by Rapid Medical and Asahi for which we served as their exclusive distributor in China) during the Track Record Period and up to the Latest Practicable Date. During the Track Record Period and up to the Latest Practicable Date, in Anhui, Shaanxi and Fujian, we only engaged distributors but not sub-distributors after the relevant local regulations of two-invoice system were implemented. In these provinces where the two-invoice system is implemented, hospitals are required to verify the number of invoices that have been issued in the chain of distribution before they pay the distributors, which ensures that the distributors have complied with the two-invoice requirement.

We have put in place a system to actively monitor policy changes. If the two-invoice system is implemented in other provinces in the future, we will take prompt action to ensure strict compliance,

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including, for example, distributing directly through the hitherto sub-distributors. For example, we have established a designated team which constantly monitors the regulatory changes, especially regulations on the two-invoice system and centralized procurement, in each province. Once a regulatory change is announced in a province, this team will also be responsible for formulating and executing corresponding business strategies and compliance measures with the support of the local team in the respective province. Also, if the two-invoice system is implemented in other provinces, we believe we will be able to leverage the rich experience that we have gained from the three provinces where the two-invoice system was implemented earlier in handling the transition from distributing through distributors to distributing through hitherto sub-distributors. Further, we are confident that we will be able to do so without material impact on our operations and financial conditions, because in our current distributor network we use national distributors primarily to streamline administration and logistics, leveraging such national distributors’ capital resources and logistics and inventory management capabilities, and at the same time we already have regular and close contacts with the sub-distributors as we proactively monitor how our products are sold and used in hospitals. Given that we have achieved wide acceptance of our products in hospitals nationwide, we believe we can rearrange distribution of our products to reach hospitals if needed, and such rearrangement will only cause immaterial administrative costs and will not materially adversely affect our business operations and financial performance.

### Centralized Procurement

In 2019, China initiated pilot programs to regulate prices of medical devices through government-mandated centralized procurement at the provincial level. See “Regulatory Overview—Overview—Laws and Regulations on Medical Device—The Reform Plan of High-Value Medical Consumables” for details.

As of the Latest Practicable Date, the only category of neuro-interventional medical devices that had become subject to centralized procurement and had an impact on us was coil embolization products, and in Hebei, Jiangsu and Fujian provinces only, pursuant to regulations recently promulgated there. In Zhejiang province, microcatheters *for general use* are subject to centralized procurement, whereas our *Fastrack* microcatheter is designed to work specifically with *Tubridge* and is therefore not subject to centralized procurement.

Our *NUMEN* successfully won the bid to be enrolled in Hebei’s centralized procurement program in December 2021 for a period of one year. We believe the Hebei program is positive for us because it will help us gain market access to the province as we had not sold *NUMEN* in Hebei before. *NUMEN*’s sales in Hebei commenced in February 2022. *NUMEN*’s enrollment in Hebei’s centralized procurement program allows us to generate sales volume in Hebei, expand our business with relatively low marketing expenses and enhance our brand awareness. *NUMEN*’s enrollment in Hebei’s centralized procurement program has very limited impact on our gross profit margin. The program regulates the price that the products are sold to hospitals in the province, not the ex-factory price that we sell the products to our distributors. According to CIC, there was on average an over 40% price decline in Hebei for coil embolization products generally before and after the program took effect. Nevertheless, since the commencement of sales of *NUMEN* in Hebei in February 2022 and up to the Latest Practicable Date, our ex-factory price for *NUMEN* destined for Hebei had been the same as that for *NUMEN* destined for other provinces. From our perspective, we expect that revenue from *NUMEN*

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in Hebei will account for less than 1% of our revenue in 2022. From an industry perspective, Hebei is a relatively small market for coil embolization products as well, where the number of coil embolization products sold in 2021 only accounted for approximately 2% of coil embolization products sold in China, according to CIC.

In March and May 2022, Jiangsu and Fujian announced their centralized procurement programs for coil embolization products, respectively. As of the Latest Practicable Date, the commencement dates of the bidding process in these two provinces had not been determined. We similarly expect the impact of the Jiangsu and Fujian programs on our gross profit margin to be limited. Our revenue from *NUMEN* in Jiangsu or Fujian represented less than 1% of our revenue in 2021. We expect that revenue from *NUMEN* in Jiangsu or Fujian will account for less than 1% of our revenue in 2022. From an industry perspective, Jiangsu and Fujian are also relatively small markets for coil embolization products. The number of coil embolization products sold in Jiangsu and Fujian accounted for approximately 4% and 2% of coil embolization products sold in China in 2021, respectively, according to CIC. Because of the limited scope and inchoate nature of these programs as relevant to our products, they had had limited impact on our selling prices or profitability as of the Latest Practicable Date, and we will closely monitor the implementation of centralized procurement programs in other provinces or for other products going forward.

As advised by our PRC Legal Advisers, we had complied with centralized procurement regulations in all material aspects during the Track Record Period and up to the Latest Practicable Date. Whether and when centralized procurement will be implemented for other products or in other provinces that are relevant to us remains uncertain, as advised by our PRC Legal Advisers. Pursuant to a series of official documents and communications (such as the National Medical Insurance Plan under the 14th Five-Year Plan promulgated in September 2021), the implementation of centralized procurement may be expected to be further expanded. In particular, the National Medical Insurance Plan under the 14th Five-Year Plan provides a non-binding guidance suggesting that provinces shall target to enroll at least five types of high-value medical consumables (not limited to any particular therapeutic area) to centralized procurement programs by 2025, but there had not been any specific binding requirement or non-binding guidance with regard to any particular product category, including neuro-interventional medical devices, as of the Latest Practicable Date. If our products become subject to centralized procurement in any province, we will formulate a strategic plan to decide our approach to participating in the bidding process and, if we prevail, leveraging the limited market access to achieve significant sales volume.

### **Diagnosis Related Groups (DRG) Mechanism**

In June 2020, the Office of the National Health Security Administration initiated the diagnosis-related groups (DRG) mechanism to control the prices of medical devices and treatments by dividing patients into different diagnosis-related groups and making medical reimbursement payments according to a standard set for each group instead of actual expenses incurred by patients. The DRG mechanism encourages hospitals to treat patients efficiently, thereby reducing unnecessary costs to be reimbursed by the national medical insurance program. As a result, hospitals tend to prioritize the purchase of medical devices with a higher performance-price ratio. See “Regulatory Overview—Laws and Regulations on Medical Devices—National Medical Insurance System” for details.

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As of the Latest Practicable Date, the pilot DRG program had been implemented in certain cities in about 30 provinces in China. According to the National Medical Insurance Plan under the 14th Five-Year Plan (“十四五”全民醫療保障規劃) promulgated in September 2021, the hospitalization expenses reimbursed under the DRG mechanism is planned to reach 70% of the total hospitalization expenses reimbursed by the national medical insurance program. Therefore, we expect the DRG mechanism to be implemented more comprehensively nationwide. As a result, hospitals will tend to choose medical devices with greater cost efficiency, which we believe will bring us competitive advantages against international medical device developers. For example, clinical studies demonstrated *Tubridge*'s non-inferiority in respect of efficacy as compared to a competing product developed by an international company, but the end user price of *Tubridge* is cheaper by approximately 20% than that of the competing product, according to CIC, suggesting greater cost efficiency, or a higher performance-price ratio, of *Tubridge*. We will continue to finetune our products to improve their cost efficiency, thereby improving their competitiveness under the DRG mechanism.

### PRC National Reimbursement Drug List (NRDL)

As of the Latest Practicable Date, neuro-interventional medical devices had not been covered by the PRC NRDL. As of the same date, our commercialized products, including *APOLLO*, *Willis*, *Tubridge*, *NUMEN*, *Bridge*, *U-track* and *Asahi* guidewires, had obtained the medical insurance registration code, a prerequisite for these products to be eligible for being covered by the NRDL and the provincial reimbursement drug lists. As of the same date, these products had been covered by multiple provincial medical insurance reimbursement lists, *i.e.*, eligible for partial reimbursement in such provinces. For risks related to the PRC national medical insurance reimbursement list, see “Risk Factors—Risks Relating to Commercialization and Distribution of Our Products—Our sales may be affected by the level of medical insurance reimbursement available to patients using our products.”

### OUR CUSTOMERS

Our direct customers include distributors in China and overseas. For details about our distributors, see “—Sales, Distribution and Marketing—Sales to Distributors” in this section. In 2019, 2020 and 2021, the aggregate sales to our five largest customers were RMB155.2 million, RMB218.5 million and RMB357.7 million, representing 84.5%, 98.4% and 93.5% of our revenue, respectively. Sales to our largest customer for the same periods were RMB122.4 million, RMB129.9 million and RMB110.5 million, representing 66.6%, 58.5% and 28.9% of our revenue, respectively. Our largest customer in 2019 and 2020 is an Independent Third Party and a distributor of our various products, such as *APOLLO*, *Tubridge*, *NUMEN*, *NUMEN FR*, *Bridge* and *Fastrack*. Our largest customer in 2021 is an Independent Third Party and is another distributor of our various products. The decrease in sales to our largest customer during the Track Record Period was primarily a result of our efforts in diversifying our distribution channels. None of our Directors or their associates, and none of our existing Shareholders who (to the knowledge of our Directors) own more than five percent of our issued share capital, have any interest in any of our five largest customers.

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### RAW MATERIALS AND OUR SUPPLIERS

#### Raw Materials

Our principal raw materials are alloy metal wires, metal tubes and polymer plastic tubings, which we use to make our stent, coil and catheter products. We also purchase various chemicals which we use to prepare subassemblies and products.

#### Suppliers

To ensure the quality of our raw materials, we only procure them from selected suppliers that can satisfy our stringent raw material requirements and quality standards. We have set up a series of criteria for evaluating and selecting our supplier candidates, which covers factors such as industry qualifications, services and quality assessments. We also conduct an overall evaluation combining all aforementioned factors before we consider a supplier candidate qualified and formulate any purchase schedules. Our current suppliers include both overseas and domestic suppliers. Our overseas suppliers include companies in Japan and the United States. In the long term, we expect to select more qualified suppliers in line with our business expansion. We also have established stringent rules for subsequent maintenance and management of suppliers. We conduct quality inspections of our suppliers by evaluating and inspecting their manufacturing process and purchased materials. Upon receiving the raw materials, we retain the right to reject or return based on our inspection results. In addition, we conduct regular review and annual audit for qualified suppliers to maintain the continual high quality of our purchased materials. During the Track Record Period, we did not encounter any material dispute with our suppliers or any material breach of our purchase agreements.

In 2019, 2020 and 2021, purchases from our five largest suppliers amounted to RMB45.8 million, RMB57.0 million and RMB88.7 million, respectively, accounting for 61.0%, 54.7% and 48.4%, respectively, of our total purchases for the same periods. Purchases from our largest supplier for the same periods totaled RMB24.1 million, RMB38.2 million and RMB43.0 million, representing 32.1%, 36.7% and 23.5% of our total purchases, respectively. Our largest supplier during the Track Record Period was Asahi Intecc, which has engaged us as its exclusive distributor for its neurovascular guidewires in mainland China since November 2016. Except for MicroPort Group, all of our five largest suppliers during the Track Record Period were Independent Third Parties. Save as disclosed above, none of our Directors or their associates, and none of our existing Shareholders who (to the knowledge of our Directors) own more than five percent of our issued share capital, have any interest in any of our five largest suppliers.



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The tables below summarize the sales to our five largest suppliers for the periods indicated:

<u>Five Largest Suppliers in 2019</u>	<u>Purchases</u>	<u>Purchase Amount</u> <i>RMB'000</i>	<u>Percentage of Total Purchases</u> %
Asahi Intecc .....	Guidewires	24,125	32.1
MicroPort Group .....	Manufacturing materials and technical services	11,300	15.0
Supplier A .....	Raw materials	6,547	8.7
Supplier B .....	Raw materials	2,092	2.8
Supplier C .....	Manufacturing facilities construction	1,743	2.4
<b>Total</b> .....		<b>45,807</b>	<b>61.0</b>

<u>Five Largest Suppliers in 2020</u>	<u>Purchases</u>	<u>Purchase Amount</u> <i>RMB'000</i>	<u>Percentage of Total Purchases</u> %
Asahi Intecc .....	Guidewires	38,195	36.7
MicroPort Group .....	Manufacturing materials and technical services	8,787	8.4
Supplier D .....	Raw materials	4,110	3.9
Supplier A .....	Raw materials	3,311	3.2
Supplier E .....	Property rental services	2,551	2.5
<b>Total</b> .....		<b>56,954</b>	<b>54.7</b>

<u>Five Largest Suppliers in 2021</u>	<u>Purchases</u>	<u>Purchase Amount</u> <i>RMB'000</i>	<u>Percentage of Total Purchases</u> %
Asahi Intecc .....	Guidewires	43,020	23.5
Supplier F .....	Manufacturing facilities construction	17,367	9.5
MicroPort Group .....	Manufacturing materials and technical services	11,109	6.1
Supplier D .....	Raw materials	11,033	6.0
Supplier G .....	Raw materials	6,134	3.3
<b>Total</b> .....		<b>88,663</b>	<b>48.4</b>

## INVENTORY MANAGEMENT

Our inventories consist of raw materials, work in progress and finished goods. Depending on our procurement plans and expenses, demand of our distributors and economic order quantities, our inventory level varies. We currently store all our inventories in warehouses in our production facilities in Shanghai.

Our products generally have a shelf life of approximately two to three years. As we sell our products on a first-in-first-out basis, we regularly monitor our inventories to reduce the risk of expiration and overstocking. Our internal policies require a physical count of all our raw materials, work in progress and finished goods from time to time to identify products that are damaged, expired or soon-to-be expired, which are disposed of or for which provisions are made. Our inventory control policies have been effective and we did not experience any material shortage in supply or overstocking of inventories during the Track Record Period and up to the Latest Practicable Date.

## QUALITY CONTROL

Quality control and assurance are crucial to us, and we endeavor to ensure the quality of our operations through a comprehensive quality management system in accordance with NMPA regulations, ISO13485:2016 standards as well as other applicable regulations and standards on the quality management system of medical devices, covering essentially every aspect of our operations, including, among other things, product design, procurement and manufacturing. Our management team is actively involved in setting quality control policies and managing our internal and external quality performance.

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We have established a comprehensive set of quality control and assurance procedures to monitor our operations to ensure compliance with relevant regulatory requirements and our internal quality requirements. We implement quality control measures throughout our production process, primarily including raw material control and inspection, production process control, product inspection as well as product life cycle risk management.

- **Raw material control and inspection:** we conduct due diligence on our suppliers and only purchase our raw materials from suppliers selected based on a strict set of criteria. We also regularly conduct audits on suppliers’ operations, including documentation inspection and/or on-site inspection on such qualified suppliers to ensure their compliance with our requirements and that there are no quality or other issues. See “—Our Raw Materials and Suppliers” for details;
- **Production process control:** we plan the production process based on the technologies adopted by each product type and monitor the entire production process, particularly certain key steps of the production process;
- **Product inspection:** we compile our product inspection manual based on our product specifications, and inspect our products in accordance with our product inspection manual, including testing the capability and measurement of our products, verifying the product labels and manuals as well as confirming that the products are properly packaged and sterilized; and
- **Product life cycle risk management:** we establish a comprehensive risk management system covering the entire life cycle of our products and product candidates, and monitor the implementation of such system to ensure that there are no material risks or other concerns about these products and product candidates.

We complied with all of our quality qualification requirements in all material respects and have passed all of the inspections during the Track Record Period and up to the Latest Practicable Date. See “—Manufacturing—Manufacturing Process” for details.

## COMPETITION

The neuro-interventional medical device industry in China is fast growing and highly competitive. We face competition with both internationally renowned companies and emerging domestic neuro-interventional medical device companies that have entered the market with affordable alternatives. We believe we are well positioned to compete in this market with our strengths in product performance, R&D capabilities, distribution and marketing networks, proprietary manufacturing processes and brand recognition.

For information about competition in the relevant markets, please refer to “Industry Overview” in this document.

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### AWARDS AND RECOGNITIONS

We and our products have received various awards and recognitions, including the following:

Awardee	Award	Year of Award	Awarding Organization
APOLLO	National Key New Product (國家重點新產品)	2011	PRC Ministry of Science and Technology (中國科學技術部)
	Second Place, Shanghai Science and Technology Award (上海市科技進步二等獎)	2009	Shanghai Municipality (上海市政府)
Willis	Second Place, National Science and Technology Award (國家科學技術進步獎二等獎)	2014	PRC State Council (中國國務院)
	First Place, Science and Technology Award (科學技術進步獎一等獎)	2012	PRC Ministry of Education (中國教育部)
	First Place, Shanghai Science and Technology Award (上海市科技進步一等獎)	2009	Shanghai Municipality (上海市政府)
	Innovative Stent Device for Intracranial Aneurysm	2007	<i>Stroke</i> (a journal published by American Heart Association and American Stroke Association)
Our Company	Shanghai Patent Model Enterprise (上海市專利示範企業)	2021	Shanghai Intellectual Property Administration (上海市知識產權局)
	Specialized & Innovative “Little Giant” Enterprise (專精特新小巨人企業)	2020	PRC Ministry of Industry and Information Technology (中國工業和信息化部) and PRC Small and Medium Enterprise Bureau (中小企業局)
	Shanghai Brand Cultivation Demonstration Enterprise (上海市品牌培育示範企業)	2020	Shanghai Municipal Commission of Economy and Informatization (上海市經濟和信息化委員會)
	High and New Technology Expertise (高新技術企業)	2020	Science and Technology Commission of Shanghai Municipality (上海市科學技術委員會), Ministry of Financial Affairs of Shanghai Municipality (上海市財政局), Taxation Administration of Shanghai Municipality (上海市稅務局) and State Taxation Administration (國家稅務總局)

### INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we had 102 patents and 113 trademarks in China. As of the same date, we had also obtained 30 patents and 47 trademarks overseas. In addition, we had 200 patent and 23 trademark applications pending in and outside China as of the Latest Practicable Date. We believe there is no material legal impediment for us to obtain the approvals for these pending applications. All of the patents that we owned or applied for are related to self-developed technologies by our R&D teams. We may seek additional patents and/or other forms of intellectual property to protect our innovations in the future.

We also follow procedures to ensure that we do not infringe on the intellectual property rights of others, including monitoring and conducting clearance searches on all relevant intellectual property

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for our products and product candidates on an on-going basis. During the Track Record Period and up to the Latest Practicable Date, we were not involved in and we were not aware of any intellectual property disputes that may materially and adversely affect our operations.

The table below summarizes the portfolio of our key patents as of the Latest Practicable Date:

<u>Related Product</u>	<u>Name of Patent</u>	<u>Patent Type</u>	<u>Application / Registration No.</u>	<u>Validity Term</u>	<u>Jurisdiction</u>
<i>APOLLO</i>	Net-like intraluminal stent	Invention	CN200810037610.3	May 15, 2008 to May 15, 2028	China
<i>Tubridge</i>	Micro Catheter	Invention	CN200910054209.5	June 30, 2009 to June 30, 2029	China
<i>Tubridge</i>	Aneurismal surgical device	Invention	CN201010116448.1	March 2, 2010 to March 2, 2030	China
<i>Willis</i>	Membrane laminating device	Invention	CN201110129984.X	May 18, 2011 to May 18, 2031	China
<i>Tubridge</i>	Micro Catheter	Invention	EP10793559.5	June 17, 2010 to June 17, 2030	Germany
<i>Neurohawk</i>	Intracranial vascular thrombectomy apparatus	Invention	CN201210148870.4	May 14, 2012 to May 14, 2032	China
<i>Tubridge</i>	Surgical Apparatus for Aneurysms	Invention	JP2012555290	March 2, 2011 to March 2, 2031	Japan
<i>Tubridge</i>	Surgical Apparatus for Aneurysms	Invention	KR1020127022741	March 2, 2011 to March 2, 2031	South Korea
<i>Tubridge</i>	Surgical Apparatus for Aneurysms	Invention	EP11750177.5	March 2, 2011 to March 2, 2031	Germany
<i>Tubridge</i>	Surgical Apparatus for Aneurysms	Invention	EP11750177.5	March 2, 2011 to March 2, 2031	France
<i>Tubridge</i>	Surgical Apparatus for Aneurysms	Invention	EP11750177.5	March 2, 2011 to March 2, 2031	UK
<i>Willis</i>	Membrane laminating system with thickness control, including membrane laminating device and thickness control method	Invention	CN201210458368.3	November 14, 2012 to November 14, 2032	China
<i>Numen</i>	Embolization device and coils	Invention	CN201811170237.9	October 9, 2018 to October 9, 2038	China
<i>Numen</i>	Embolization device and coils thereof	Invention	US16639456	— <sup>(1)</sup>	United States

*Note:*

(1) Validity term is not stipulated for pending patent applications.

## HEALTH, SAFETY, SOCIAL AND ENVIRONMENTAL MATTERS

We are subject to various health, safety, social and environmental laws and regulations and our operations are regularly inspected by local government authorities. We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees, patients, and communities. We have implemented company-wide environmental, health and safety (EHS) manuals,

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policies, and standard operating procedures in relation to air pollution, wastewater treatment, noise treatment, solid waste management and incident response planning.

We have an EHS manager, who is primarily responsible for the development of our EHS policies and overseeing the implementation of measures and procedures to ensure compliance with all applicable environmental protection and health and safety laws, regulations and standards and to safeguard the health and safety of our employees and the neighboring communities. We have also established and strictly implemented a comprehensive EHS management system, such as promulgating safety operation procedures and rules relating to every aspect of our operation and providing EHS training tailored to the demand of our R&D and production activities to all relevant personnel.

### **Occupational Health and Safety**

Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous wastes. To further ensure our compliance with applicable environmental protection and health and safety laws and regulations, we (i) have established various guidelines governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes to ensure such guidelines are strictly enforced for the disposal of laboratory materials and wastes; (ii) inspect our equipment and facilities regularly to identify and eliminate safety hazards; (iii) provide regular safety awareness training to our employees; (iv) keep health records for all employees and conduct health examinations before, during and after their time at the company, especially for employees engaged in work involving occupational hazards; and (v) conduct regular fire safety inspections, maintenance of fire-fighting equipment and regular emergency drills.

### **Environmental, Social and Governance**

Corporate social responsibility is our obligatory responsibility as a corporate citizen and a key driving factor to promote the long-term development of our Group. Therefore, we have integrated environmental, social and governance (“ESG”) matters into corporate management and operations and we are committed to comply with the ESG reporting requirements upon the [REDACTED]. Our Board of Directors has the overall responsibility for establishing, adopting and reviewing the ESG vision, policy and target of our Group, and evaluating, determining and addressing our ESG-related risks periodically. Our Board of Directors will also periodically review our compliance status with ESG policies after the [REDACTED].

We are in the process of establishing ESG policies in accordance with Appendix 27 of the Listing Rules, which would cover, among others, (i) ESG policies and performance; (ii) ESG management strategy; and (iii) ESG risk management and monitoring. We focus on areas such as economic responsibility, employee responsibility, customer responsibility, environment responsibility and public responsibility. We also intend to establish communication channels with stakeholders, so that we could review the issues material to stakeholders, and monitor how our environmental, social and climate-related performance has impacted different stakeholders.

### ***Social Matters***

In respect of social responsibilities, we are committed to offering a fair and caring working environment to our employees. We have transparent policies on compensation and dismissal, equal

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opportunities and anti-discrimination. We hire employees based on their merits and it is our corporate policy to offer equal opportunities and fair compensations to our employees. We encourage our employees who encounter any discrimination to seek immediate assistance, which also allows us to conduct timely investigation and follow up as needed. In addition, we provide training programs on industry and regulatory developments to our employees.

In light of the COVID-19 pandemic, we have endeavored to provide a safe work environment by implementing company-wide self-protection policies for employees, including providing protective masks and sanitization to our employees.

### *Environmental Matters*

We are dedicated to taking environmental responsibility in all aspects of our business, from procurement of raw materials to treatment of wastes. The major pollutants generated from our manufacturing processes include wastewater, gas emission, noise and solid waste. During the Track Record Period, we engaged professional and qualified third-party waste treatment service provider to collect and treat dangerous chemicals involved and hazardous waste produced in our operations. During the Track Record Period, we also engaged third-party environmental testing institutions to evaluate our pollutants emission and other impact on the environment, including gas emission and noise pollution level of our production bases, on a regular basis. The following chart summarizes our actual emission volume and target emission volume specified in regulatory requirements or industry standards (where applicable) for each type of pollutants during the Track Record Period.

<u>Pollutant content</u>	<b>For the year ended December 31,</b>			<b>Target emission volume</b>
	<b>2019</b>	<b>2020</b>	<b>2021</b>	
	<b>Actual emission volume</b>			
Noise (dB (A))	53.25	50.55	60.00	65
Gas - NMHC (mg/m <sup>3</sup> )	4.55	2.57	1.74	70
Hazard wastewater - waste pickle liquor (ton)	3.053	4.17	10.20	N/A
Hazard solid waste (ton)	0.22	0.84	2.75	N/A

During the Track Record Period, we actively monitored our resource consumption for our manufacturing function. For the years ended December 31, 2019, 2020 and 2021, our annual consumption of water amounted to 4,440 tons, 7,935 tons and 8,171 tons, respectively. For the same periods, our annual consumption of electricity amounted to approximately 1.1 million kiloWatt-hours, 1.5 million kiloWatt-hours and 1.3 million kiloWatt-hours, respectively. Our current environmental footprint is relatively small and our operations do not have a significant impact on the environment. Nonetheless, we adhere to the concept of green management and actively seek low-carbon sustainable development in our operations. We plan to further improve our resource consumption management system to promote efficient energy management and reduce the carbon footprint in our operations. We will closely monitor relevant industry developments and make management improvements in accordance with changes in market condition or industry standards when appropriate.

### *Identification and assessment of environmental, social and governance risks and issues*

In respect of physical risk, we focus on acute physical risk, such as extreme weather events. Our production plan and product delivery are impacted by extreme weather events through workplace, production facilities, personnel commuting and transportation, as well as supply chain. To this end, we

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have formulated an emergency response plan with clear division of labor and specific implementation measures to ensure the full implementation of safety and health management guidelines. We also regularly organize employees to conduct relevant training and drills.

In respect of transition risks, we are not in an industry highly sensitive to climate-related risks and we are mainly concerned with policy and legal risks. We pay close attention to the global trend and China’s national strategy of addressing climate change and ecological environment protection, and will actively enhance our ability to address climate change and cope with China’s initiatives and action plans regarding future carbon dioxide emission.

We have taken certain measures to reduce ESG-related risks in the process of operation. We have established system procedures for hazard identification, risk assessment and accident investigation within the scope of production workshops, office areas, and parts warehouses to reduce occupational health and safety risks. We will continue to develop ESG guidelines, clarify departmental responsibilities and monitor our operations. In addition, we will make constant improvement of the ESG management regulation and operation rules. Necessary improvement will then be implemented to mitigate the risks and/or the issues identified. We may engage independent professional third parties to help us make necessary improvements on ESG issues, when necessary.

We believe we have maintained good relationships with the communities surrounding our production facilities. During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations in all material aspects, and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or impact on the operations of our business during the period. For the years ended December 31, 2019, 2020 and 2021, our total cost of compliance with environmental protection, health and safety laws and regulations amounted to approximately RMB140,000, RMB264,000 and RMB658,000, respectively. We do not expect our costs of complying with current and future environmental protection, health and safety laws to increase significantly going forward. However, because the requirements imposed by these laws and regulations may change, we may be unable to accurately predict the cost of complying with these laws and regulations. See “Risk Factors—Risks relating to Our Operations—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.”

## EMPLOYEES

As of the Latest Practicable Date, we had 460 employees in total. The following table sets forth the number of our employees by function as of the Latest Practicable Date.

<u>Function</u>	<u>Number of employees</u>
R&D .....	137
Production and supply chain .....	133
Sales and marketing .....	97
Quality control and regulatory registration .....	54
Finance, HR, legal and administration .....	39
<b>Total</b> .....	<b>460</b>

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As of the Latest Practicable Date, a small percentage of our workforce was employed through master service agreements we entered into with the third-party dispatched labor agencies in China.

To stay compliant with PRC labor laws, we enter into standard confidentiality and employment agreements with all employees. For a majority of our employees, including management, R&D, sales and marketing, manufacturing and quality control personnel, we also enter into a standard non-compete agreement with these employees to prevent direct or indirect competition during and for one to two years after the employment. We have representative employees participating in the labor union established within the MicroPort Group. As required by PRC labor laws, we make contributions to social insurance and housing provident funds for all of our employees based in China. During the Track Record Period and as of the Latest Practicable Date, we had not experienced any labor disputes or strikes that would materially and adversely affect our business, financial condition or results of operations.

We recruit our employees through recruitment websites, recruiters, internal referrals and job fairs. We offer remuneration packages based on individuals' qualifications and experiences and generally match the market rate for salary and bonus to stay competitive in the labor market. We also provide extensive training programs to our employees and award incentives to encourage inventions by our R&D team. We believe that we maintain a good working relationship with our employees and we did not experience any difficulty in recruiting staff for our operations during the Track Record Period.

## **PROPERTIES**

We are headquartered in Shanghai. As of the Latest Practicable Date, we had obtained property ownership certificates of two properties with an aggregate GFA of approximately 2,455 sq.m. in Shanghai. Our current manufacturing facilities in Zhangjiang and Zhoupu, Shanghai, are leased with a GFA of approximately 7,000 sq.m. and 2,300 sq.m., respectively. As of the Latest Practicable Date, we leased eight properties with an aggregate GFA of approximately 18,497 sq.m. in China for our daily business operations, R&D and manufacturing.

As of the Latest Practicable Date, six lease agreements relating to our leased properties in China that are immaterial to our operations had not been filed with the relevant PRC housing administration authorities. As advised by our PRC Legal Advisers, such non-compliance does not affect the validity of the property lease agreement according to PRC Civil Code and will not have a material adverse effect on our business operations and financial performance. See “Risk Factors—Risks Relating to Our Operations—We may be subject to penalties for the non-registration of lease agreements in the PRC.”

## **INSURANCE**

As of the Latest Practicable Date, we had maintained certain insurance policies for our properties, manufacturing facilities, plant and machinery, equipment and inventories against damage caused by accidents. We also maintain clinical trial liability insurance policies against losses arising from severe adverse events that may occur during clinical trials. During the Track Record Period, we did not maintain product liability insurance against claims or liabilities that may arise from products sold by us, which is in line with the industry norm, according to CIC. We consider our current



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insurance coverage adequate for our operations and in line with the industry norm. During the Track Record Period, we had not made, or been the subject of, any material insurance claims.

### LICENSES AND PERMITS

As a PRC-based medical device company, we are required to obtain various licenses and permits from government authorities for our operations. Our PRC Legal Advisers are of the view that, during the Track Record Period and up to the Latest Practicable Date, we had obtained from the relevant government authorities all necessary licenses, approvals and permits that are material for our business operations in China. We plan to renew all material licenses and permits upon expiration, and there is no material legal impediment to renew such material licenses and permits.

The following table summarizes material licenses and permits we held as of the Latest Practicable Date:

<u>Product</u>	<u>License/Permit</u>	<u>Validity Period</u>	<u>Authority</u>
<i>X-track</i>	PRC Medical Device Registration Certificate (國械註准20223030494)	April 2022 to April 2027	NMPA
<i>Neurohawk</i>	PRC Medical Device Registration Certificate (國械註准20223030183)	February 2022 to February 2027	NMPA
<i>Numen</i>	Shanghai Medical Device Production Permit (滬食藥 監械生產許20141986號) PRC Certificate for Exportation of Medical Products (滬食藥監械 出20200339號) PRC Medical Device Registration Certificate (國械註准20203130761)	February 2021 to August 2023 December 2020 to December 2022 September 2020 to September 2025	Shanghai Drug Administration Shanghai Drug Administration NMPA
<i>Willis</i>	PRC Certificate for Exportation of Medical Products (滬藥監械 出20210276號) Shanghai Medical Device Production Permit (滬食藥 監械生產許20141986號) PRC Medical Device Registration Certificate (國械註准20143131916)	December 2021 to September 2022 February 2021 to August 2023 August 2019 to August 2024	Shanghai Drug Administration Shanghai Drug Administration NMPA

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<u>Product</u>	<u>License/Permit</u>	<u>Validity Period</u>	<u>Authority</u>
<i>Tubridge</i>	PRC Certificate for	December 2021 to	Shanghai Drug
	Exportation of Medical	September 2022	Administration
	Products (滬藥監械	February 2021 to	Shanghai Drug
	出20210276號)	August 2023	Administration
	Shanghai Medical Device	March 2018 to	NMPA
<i>APOLLO</i>	Production Permit (滬食藥	March 2023	
	監械生產許20141986號)		
	PRC Medical Device		
	Registration Certificate		
	(國械註准20183770102)		
<i>Bridge</i>	PRC Certificate for	December 2021 to	Shanghai Drug
	Exportation of Medical	September 2022	Administration
	Products (滬藥監械	February 2021 to	Shanghai Drug
	出20210276號)	August 2023	Administration
	Shanghai Medical Device	September 2017 to	NMPA
<i>Bridge</i>	Production Permit (滬食藥	September 2022	
	監械生產許20141986號)		
	PRC Medical Device		
	Registration Certificate		
	(國械註准20173464386)		
<i>Bridge</i>	Shanghai Medical Device	February 2021 to	Shanghai Drug
	Production Permit (滬食藥	August 2023	Administration
	監械生產許20141986號)	December 2020 to	NMPA
	PRC Medical Device	December 2025	
	Registration Certificate		
(國械註准20203130971)			

## LEGAL PROCEEDINGS AND REGULATORY COMPLIANCE

We may from time to time become involved in legal, arbitral or administrative proceedings arising in the ordinary course of our business. Our Directors are of the view that, as of the Latest Practicable Date, we were not a party to any legal, arbitral or administrative proceeding that would have a material and adverse effect on our business, financial condition or results of operations. Our Directors are not aware of any threatened legal, arbitral or administrative proceedings to which we would be named as a party. Our Directors further confirm that as of the Latest Practicable Date, none of our Directors or senior management personnel was personally involved in any material legal, arbitral or administrative proceedings.

Our Directors are of the view that, during the Track Record Period, and up to the Latest Practicable Date, we did not have any material non-compliance incidents. Our PRC Legal Advisers have advised that, during the Track Record Period and up to the Latest Practicable Date, we had complied with the applicable laws and regulations in all material respects.

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### RISK MANAGEMENT AND INTERNAL CONTROL

Risk management is vital to our business as we are exposed to various risks during our operations. In addition, we are exposed to financial risks that may arise in the ordinary course of our business. Our Board is responsible for establishing our internal control system and reviewing its effectiveness, which is key to reliable financial reporting and compliance with applicable laws and regulations. We have adopted risk management policies and internal control measures to continuously monitor and assess the potentials risks that could harm our business.

#### Operational Risk Management

Our operations are highly regulated and thus compliance with PRC laws and regulations is essential in our operational risk management. We continue monitoring the development of PRC laws and regulations to ensure the ongoing compliance of our operations. We also consult with legal counsel to ensure that we have all the necessary permits and licenses required for our operations. We impose the same requirement on our distributors and suppliers.

We typically follow MicroPort Group’s measures against corruption and bribery to maintain policy consistency among group members. We maintain strict anti-corruption policies for our sales and marketing activities, and provide routine anti-corruption training programs to our employees and distributors. Our internal anti-corruption regulations define specific areas and key steps of our anti-corruption function, as well as the responsibilities and authorities of relevant departments in carrying out our anti-corruption function. We also set up comprehensive internal protocols detailing our reporting, investigation and remedy procedures with respect to anti-corruption matters. We have provided and will continue to provide periodic training to our Directors and senior management regarding the relevant requirements of the Listing Rules. To ensure compliance with the Listing Rules, such as aspects related to risk management, connected transactions and information disclosure, we have adopted various measures and policies in our operations, which are regularly monitored and assessed.

#### Financial Reporting Risk Management

For our financial reporting risk management, we have adopted comprehensive accounting policies and continue to train our finance team so that they understand and implement the policies during daily operations.

We [have established] an audit committee, consisted of three qualified members, that reviews, supervises and advises on our financial reporting process, risk management and internal control system. For the qualifications and experience of these committee members, see “Directors and Senior Management.” Along with our senior management, our audit committee monitors and assesses our risk management policies across the Company on an ongoing basis to ensure its effectiveness.

We have engaged an internal control consultant to review the effectiveness of our internal controls associated with our major business processes, identify deficiencies and improvement opportunities, provide recommendations on remedial actions and review the implementation status of these remedial actions. During the review process of our internal control consultant, certain internal control matters were identified and we have adopted corresponding internal control measures, including the recommendations made by our internal control consultant, to improve on these matters.

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Our internal control consultant has completed the follow-up procedures on our internal control system with regard to those actions taken by us and have not identified any material deficiencies in our internal control system.