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Post Hearing Information Pack of



Cryofocus Medtech (Shanghai) Co., Ltd.

康豐生物科技(上海)股份有限公司

(the “Company”)

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

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Cryofocus Medtech (Shanghai) Co., Ltd.
康豐生物科技(上海)股份有限公司

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

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SUMMARY

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

OVERVIEW

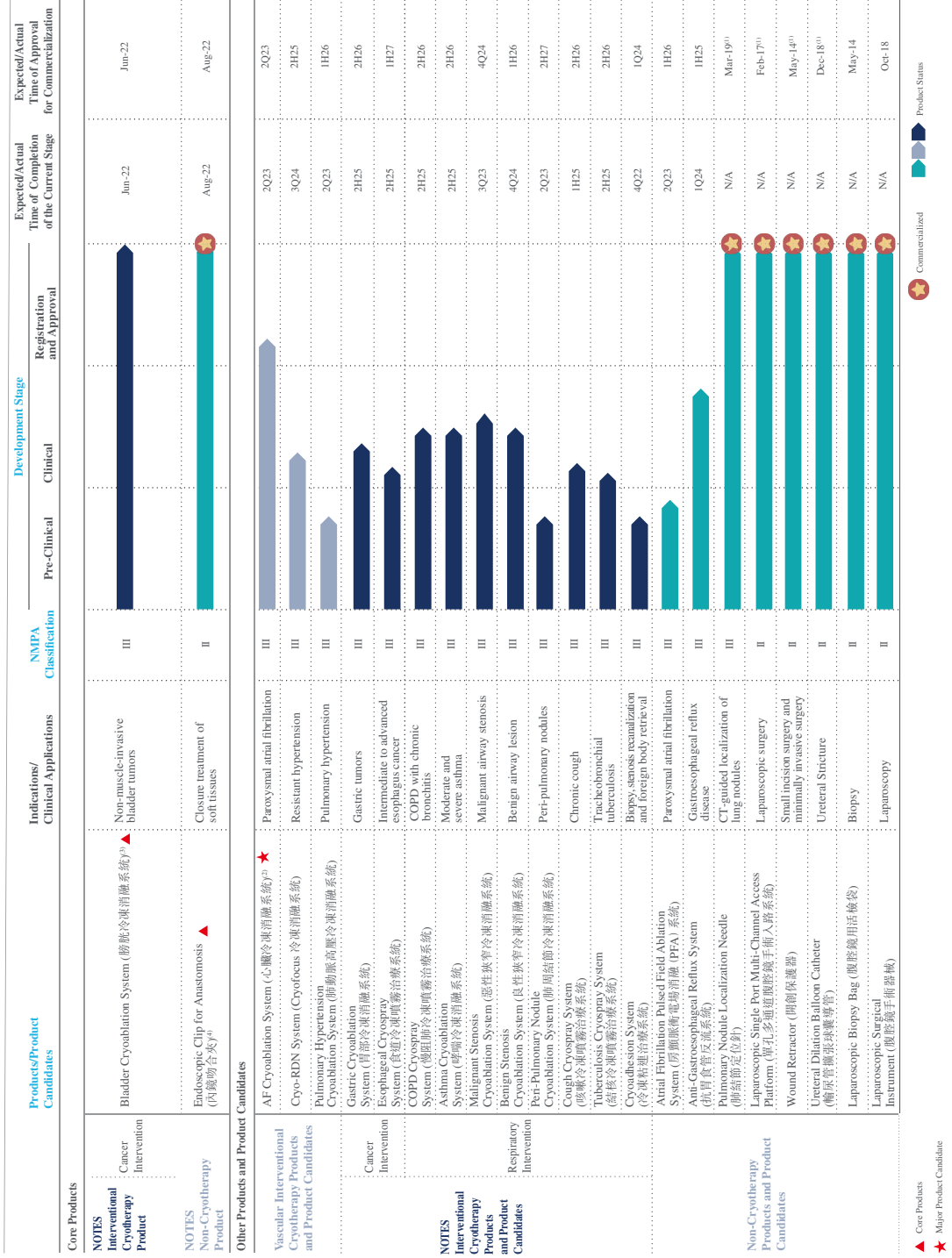
Founded in 2013, we are a medical device company in China with a main focus on the field of minimally-invasive interventional cryotherapy. We have two Core Products, the Bladder Cryoablation System (膀胱冷凍消融系統) and the Endoscopic Clip for Anastomosis (內鏡吻合夾). The Bladder Cryoablation System is a cryotherapy device designed for the treatment of bladder cancer approved for commercialization in China. The Endoscopic Clip for Anastomosis is an anastomotic device for closure of soft tissue in digestive tract, which is one of over-the-scope clips (“**OTS Clips**”) approved for commercialization in China. We have developed a comprehensive product portfolio mainly targeting the treatment of urinary, cardiovascular, respiratory and digestive diseases. Four of our pipeline products, including two Core Products, the Atrial Fibrillation Cryoablation System (心臟冷凍消融系統) (“**AF Cryoablation System**”) that is in the process of registration application and the Cryofocus Renal Denervation System (Cryofocus 冷凍消融系統) (“**Cryo-RDN System**”) that is still in the clinical trial stage, were recognized as “innovative medical devices” by the NMPA or its provincial counterparts. As of the Latest Practicable Date, we had three and eight material patents and patent applications directly related to the Bladder Cryoablation System and the Endoscopic Clip for Anastomosis, respectively. All of our products and product candidates are self-developed by us.

THERE IS NO ASSURANCE THAT WE WILL ULTIMATELY BE ABLE TO DEVELOP AND MARKET OUR CORE PRODUCTS SUCCESSFULLY.

SUMMARY

OUR PRODUCTS AND PRODUCT CANDIDATES

We have developed a comprehensive product portfolio including two Core Products, 15 other product candidates with a main focus on natural orifice transluminal endoscopic surgery, or NOTES, and vascular intervention, as well as six additional commercialized non-cryotherapy products. The following diagram summarizes the status of our products and product candidates as of the Latest Practicable Date:



█ Core Products
★ Major Product Candidate
█ Commercialized
★ Product Status

SUMMARY

Notes:

- (1) refers to the time of approval for commercialization in China. In addition to receiving approval in China, these four products obtained CE Marking in January 2019.
- (2) We plan to apply for CE Mark registration for the AF Cryoablation System in around 2027 and to expand its indication from paroxysmal atrial fibrillation to persistent atrial fibrillation. For further information, see “Business—Our Products and Product Candidates—Other Products and Product Candidates—Vascular Interventional Cryotherapy Products—1. AF Cryoablation System—Further Development Plan” in this document.
- (3) We plan to apply for CE Mark registration for the Bladder Cryoablation System in around 2027 and to expand its indication from non-muscle-invasive bladder cancer to muscle invasive bladder cancer. For further information, see “Business—Our Products and Product Candidates—Our Core Products—1. Bladder Cryoablation System—Further Development Plan” in this document.
- (4) We plan to apply for CE Mark registration for the Endoscopic Clip for Anastomosis in 2025. For further information, see “Business—Our Products and Product Candidates—Our Core Products—2. Endoscopic Clip for Anastomosis—Further Development Plan” in this document.

SUMMARY

Cryotherapy is a treatment method that freezes and destroys abnormal cells or diseased tissue through extreme cold. Interventional cryotherapy includes cryoablation that employs extremely low temperature to freeze tissue for destruction, as well as cryoadhesion that freezes tissue for adhesion. Many recent studies have demonstrated that interventional cryotherapy can destroy diseased tissues and stop the growth or spread of cancerous cells in a minimally invasive manner. As compared to traditional treatment solutions such as open surgeries, interventional cryotherapy is potentially cheaper, safer, associated with fewer side effects and lower chances of post-operative complications, and allows patients a quicker recovery with less scars, although additional risks of bleeding may be posed due to friction between the tissue and instruments used in interventional cryotherapy. The Bladder Cryoablation System is not the only cryoablation medical device that uses liquid nitrogen as its cryogen in China and in the world. For details of other cryoablation medical devices that use liquid nitrogen as cryogen for the treatment of solid tumors, see “Industry Overview—The Bladder Cancer Interventional Cryotherapy Market—Competitive Landscape of Interventional Cryotherapy Devices for Solid Tumor” in this document.

We use liquid nitrogen as the main cryogenic source for cryotherapy systems by leveraging our liquid nitrogen cryoablation technology and advanced flexible catheter technology. Compared to other cryogenic sources like nitrous oxide and carbon dioxide, liquid nitrogen is obtainable and affordable with rapid cooling rate. However, despite its advantages, the clinical application of liquid nitrogen had been limited, primarily because it tends to vaporize and undergo substantial volume expansion when delivering energy to the lesions, causing the catheter to become clogged with gas and unable to deliver liquid nitrogen continuously, and it also has a risk of destroying healthy cells surrounding the tumors. Our liquid nitrogen cryoablation technology platform can resolve the excessive volume change associated with vaporization to lower the device’s working pressure and increase operational safety, while keeping the advantages of ablation efficiency and controllability of liquid nitrogen. In addition, we continue to explore various underlying and supporting technologies based on our core technologies, such as precise temperature gradient control technology and real-time vacuum technology, to improve the efficacy and safety of our products and facilitate the clinical application of our cryotherapy systems.

We have a comprehensive product portfolio that includes two Core Products as well as other products and product candidates mainly targeting two markets, namely NOTES and vascular intervention:

- In the area of NOTES, we have developed a series of cryotherapy systems and surgical consumables. Our Core Products, the Bladder Cryoablation System and the Endoscopic Clips for Anastomosis, belong to this category. According to Frost & Sullivan, patients with bladder cancer generally have a high risk of recurrence after undergoing the transurethral resection of bladder tumor (“TURBT”) surgeries, and the overall recurrence rate of non-muscle-invasive bladder cancer (“NMIBC”) post TURBT can reach 60%. According to the *Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline (2020)*, among patients with NMIBC after TURBT, patients with low-grade Ta lesions generally demonstrate a recurrence rate of about 55%, while those with high-grade T1 lesions generally have a recurrence rate of about 45%. There is a growing demand for an effective treatment to lower the incidence of postoperative tumor residuals. Similar to BCG perfusion or chemotherapy, our self-developed Bladder Cryoablation System is indicated for use in conjunction with TURBT to reduce tumor residuals for patients suffering from NMIBC. The Endoscopic Clip for Anastomosis, is an anastomotic device for closure of soft tissues in digestive tract, treating bleeding, perforation, and tissue defects. This product is one of the OTS Clips approved for commercialization in China. Our other product candidates in this area focus on respiratory and digestive diseases, such as chronic obstructive pulmonary disease, asthma, airway stenosis, gastric cancer and esophageal cancer.

SUMMARY

- In the area of vascular intervention, we have developed product candidates for the treatment of atrial fibrillation, hypertension and other cardiovascular disease, although they are not our Core Products. Our AF Cryoablation System is a minimally-invasive interventional device that treats atrial fibrillation by freezing and damaging abnormal heart tissues that cause irregular heartbeats.

We have an in-house R&D team, which is led by industry experts with vast industry experience. We have also developed relationships with industry leaders, including scientists, physicians and industry practitioners, giving us a thorough understanding of the clinical needs and demands of patients and physicians. We held 110 registered patents and 44 pending patent applications in China and overseas.

Our two manufacturing facilities located in Shanghai and Ningbo can support the production and commercialization of our various cryotherapy devices and medical consumables. Our manufacturing facilities meet the applicable GMP requirements, and we follow rigorous manufacturing and quality control standards to ensure a high level of product quality and safety. As our pipeline products are gradually commercialized in the near future, we will continue to upgrade our production facilities.

During the Track Record Period, we have launched six minimally-invasive surgical consumables. We have established an extensive distributorship network, and had entered into distribution agreements with 57 distributors in China for the sales of our commercialized products as of August 31, 2022. In 2020, 2021 and the eight months ended August 31, 2022, our revenue amounted to RMB9.1 million, RMB22.4 million and RMB16.4 million, respectively. In October 2022, we also commercialized one of our Core Products, the Endoscopic Clip for Anastomosis. Given that we have only commercialized a small portion of our full product portfolio for now, our commercialization efforts are still at the early stages. However, we believe that our experience gained from commercializing our existing products, our established working relationships with physicians and hospitals, our reputation in the medical device industry in China, and our expanding sales and marketing team and distribution network will benefit our future commercialization of our cryoablation systems and other product candidates upon their approval.

Driven by the accelerated population aging and patient pool expansion, technological innovations and favorable policy support, as well as the advantages associated with the cryotherapy devices, the cryotherapy device market in China has experienced rapid growth. According to Frost & Sullivan, the market size of interventional cryotherapy devices in China has increased from RMB98.0 million in 2016 to RMB390.8 million in 2020 at a CAGR of 41.3%, and is expected to further climb to RMB11,233.9 million in 2030 at a CAGR of 39.9% from 2020 to 2030.

Bladder Cryoablation System—Our Core Product

Our Bladder Cryoablation System is a self-developed cryoablation system for the treatment of bladder tumors. This product candidate employs liquid nitrogen to perform cryoballoon ablation on target tissue, and similar to BCG perfusion or chemotherapy, this product candidate is indicated for use in conjunction with TURBT to reduce tumor residuals for patients suffering from NMIBC.

To evaluate the efficacy and safety of our Bladder Cryoablation System, we initiated a multi-center clinical trial in China for the Bladder Cryoablation System in November 2017. A total of 218 eligible subjects were enrolled in the clinical trial at six hospitals. Our Bladder Cryoablation System demonstrated good safety and efficacy results according to the final clinical trial report issued in May

SUMMARY

2021. We submitted the registration application for such product candidate with the NMPA in May 2021, and received the NMPA approval for it in June 2022. We plan to commercialize this product in China in December 2022.

We may not successfully commercialize the Bladder Cryoablation System as there are certain hurdles and risks of the Bladder Cryoablation System in gaining market shares. In particular, (i) there is currently no recommendation from national or international guidelines for the use of cryoablation therapy in the treatment of NMIBC. It may take time to educate the market, gain acceptance among physicians and patients and achieve sustainable business growth, if successful; (ii) the Bladder Cryoablation System currently is not covered by any government reimbursement program or private health insurance, and reimbursement is not available for treatment options that are not part of the standard of care in Europe, including the cryoablation of bladder cancer; and (iii) given the clinical trial for the Bladder Cryoablation System did not include long-term follow-up visits, there are currently no sufficient long-term clinical data to demonstrate whether this product significantly reduces tumor recurrence at a later stage or to support the use of this product as a standard of care post-TURBT. We plan to initiate post-launch clinical studies and conduct three- to five-year follow-ups for a sizable pool of patients to monitor the real-world clinical data and further evaluate the safety and efficacy profile of the Bladder Cryoablation System.

According to Frost & Sullivan, the incidence of bladder cancer in China increased from 77.1 thousand in 2016 to 85.7 thousand in 2020 at a CAGR of 2.5%, and is expected to further grow to 117.6 thousand in 2030. NMIBC accounts for approximately 75% of newly diagnosed bladder cancer, and patients with NMIBC may experience *in situ* tumor recurrence following TURBT, the first and standard treatment for NMIBC. Therefore, such patients are in need of treatment that effectively reduces postoperative tumor residuals.

Our Bladder Cryoablation System is a cryotherapy device designed for the treatment of bladder cancer approved for commercialization in China. It is not intended to replace Bacillus Calmette-Guerin (“BCG”) perfusion or chemotherapy. Instead, the Bladder Cryoablation System and BCG or chemotherapy can be synergistic to reduce tumor residuals in patients with bladder cancer following TURBT. In addition, based on publicly available information, there was no head-to-head clinical trial for comparing Bladder Cryoablation System with BCG or other immunotherapies as of the Latest Practicable Date.

For a detailed description of the product structure and operation procedure, as well as clinical trial result, market opportunities and further development plan of our Bladder Cryoablation System, see “Business—Our Products and Product Candidates—Our Core Products—1. Bladder Cryoablation System” in this document. For a detailed description of market opportunities and competitive landscape of our Bladder Cryoablation System, including the basis for the estimated market growth, see “Industry Overview—The NOTES Interventional Cryotherapy Device Market—The Bladder Cancer Interventional Cryotherapy Device Market” in this document. For details of the relevant risks, see “Risk Factors—We may not be able to develop new products that are competitive in the market” in this document.

SUMMARY

Endoscopic Clip for Anastomosis—Our Core Product

Our Endoscopic Clip for Anastomosis is a self-developed anastomotic device for closure of soft tissue in digestive tract, treating bleeding, perforation, and tissue defects. It is suitable for treating perforation in gastrointestinal endoscopic surgery as well as endoscopic full-thickness closure following NOTES.

We initiated a multi-center clinical trial to evaluate the safety and efficacy of the Endoscopic Clip for Anastomosis in endoscopic soft tissue closure in October 2019. The trial was led by Zhongshan Hospital, Fudan University (復旦大學附屬中山醫院). A total of 99 subjects were enrolled, and received the closure with this product for their upper gastrointestinal perforation or bleeding. In this clinical trial, a relatively high rate of adverse events was observed, including a rate of treatment emergent adverse events of 54.4% and a rate of device- or procedure-related adverse events of 40%, although most of these adverse events were mild and unrelated to the device. After completing the clinical trial, we submitted the registration application with Zhejiang MPA in November 2021. We received the Zhejiang MPA approval for this product candidate in August 2022, and commercialized it in October 2022.

As of the Latest Practicable Date, there were 32 endoscopic clips commercialized in China, out of which, three products were OTS Clips and the other 29 products were all through-the-scope clips (“**TTS Clips**”), according to Frost & Sullivan. The OTSC[®] System Set of Ovesco and the Disposable Hemostatic Closure Clip of Micro-Tech and the Company’s Endoscopic Clip for Anastomosis were the commercialized OTS Clip products in China. In addition, based on public information, Ovesco’s registration certificate for the OTSC[®] System Set in China was expired, making Micro-Tech’s OTS Clip the only competitor of our Endoscopic Clip for Anastomosis in China. Key players in the international OTS Clip market are Ovesco and Aponos Medical, which in aggregate had six OTS Clip products approved by the FDA or CE Marked.

According to Frost & Sullivan, the market size of endoscopic clips in China increased rapidly from RMB98.7 million in 2016 to RMB292.5 million in 2020, representing a CAGR of 31.2%; the market size of endoscopic clips in China is predicted to increase to RMB571.1 million in 2025 at a CAGR of 14.3% from 2020 to 2025 and further reach RMB1,124.4 million in 2030 at a CAGR of 14.5% from 2025 to 2030, as endoscopic clips are anticipated to become common in gastrointestinal surgery due to their benefits such as allowing for faster recovery than traditional drug hemostasis, and OTS Clips, which are priced higher than TTS Clips, are expected to increase its market share. The endoscopic clip market in China is highly fragmented and competitive and is currently dominated with the TTS Clips.

As the OTS Clip market is still in an early stage of development, and due to the relatively high prices set by the market players, the current market share of the OTS Clips has been small within the overall endoscopic clip market. According to Frost & Sullivan, among the overall endoscopic clips market in China in 2020, the OTS Clip market occupied approximately 0.4% by value and 0.1% by volume. OTS Clips have advantages over TTS Clips, for example, OTS Clips are able to close larger wounds. In recent years, more guidelines and academic articles recommend OTS Clips. Thus, Frost & Sullivan anticipates that physicians will become increasingly willing to accept OTS Clips and the market share of OTS Clips will increase in the future if the price is reasonable and market promotion is strengthened.

SUMMARY

The Endoscopic Clip for Anastomosis has a separable structure that makes its clamp detachable and allows for easier clip removal. Such feature, though without head-to-head study, differentiates the Endoscopic Clip for Anastomosis from competing products. However, there is no assurance that the Endoscopic Clip for Anastomosis will ultimately outcompete other OTS Clips and TTS Clips in the market due to lack of more material competitive advantages.

For a detailed description of the product structure, operation procedure, clinical trial result and market opportunities of our Endoscopic Clip for Anastomosis, see “Business – Our Products and Product Candidates—Our Core Products—2. Endoscopic Clip for Anastomosis” in this document. For a detailed description of the addressable patient population, disease landscape and treatment paradigm, as well as market opportunities and competitive landscape of our Endoscopic Clip for Anastomosis, see “Industry Overview—The Endoscopic Clip Market” in this document.

AF Cryoablation System—Our Major Product

Our AF Cryoablation System is a self-developed cryoablation system indicated for the treatment of paroxysmal atrial fibrillation. The AF Cryoablation System treats atrial fibrillation by freezing and destroying abnormal heart tissues that create irregular heartbeats in a minimally-invasive procedure.

We initiated a multi-center clinical trial in October 2019 to evaluate the effectiveness and safety of the AF Cryoablation System in the treatment of paroxysmal atrial fibrillation. A total of 176 subjects were enrolled and we conducted follow-ups with the subjects up to 12 months after the procedures. The clinical trial involved ten hospitals, led by Zhongshan Hospital, Fudan University (復旦大學附屬中山醫院). The multi-center clinical trial for the AF Cryoablation System has been completed with the final clinical trial report issued in May 2022. We submitted the registration application for the AF Cryoablation System with the NMPA in July 2022, and currently expect to obtain the NMPA approval for this product candidate in China in or around the second quarter of 2023.

According to Frost & Sullivan, the number of atrial fibrillation patients in China has increased from 10.8 million in 2016 to 11.6 million in 2020, which is estimated to further climb to 16.6 million in 2030. The market size of atrial fibrillation cryotherapy catheters in China increased from RMB48.4 million in 2016 to RMB255.0 million in 2020 at a CAGR of 51.5%. Driven by the rising prevalence of atrial fibrillation and increasing penetration of cryoablation treatment, it is estimated that the market size of atrial fibrillation cryotherapy catheters in China is expected to continue to grow to RMB5,103.0 million in 2030.

As of the Latest Practicable Date, there was only one cryoablation device for the treatment of atrial fibrillation approved for commercialization in China, namely the Arctic Front Advance of Medtronic. Based on publicly available information, we were one of the four companies conducting clinical trials in China for cryoablation devices for the treatment of atrial fibrillation, and were the only one which uses low-pressure liquid nitrogen as cryogen.

For a detailed description of the product structure, operation procedure, clinical trial result and market opportunities of our AF Cryoablation System, see “Business—Our Products and Product Candidates—Other Products and Product Candidates—Vascular Interventional Cryotherapy Products—1. AF Cryoablation System” in this document. For a detailed description of market opportunities and competitive landscape of our AF Cryoablation System, see “Industry Overview—The Vascular Interventional Cryotherapy Device Market—Atrial Fibrillation and Treatment” in this document.

SUMMARY

OUR COMPETITIVE STRENGTHS

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

- A cryotherapy technology platform company with extensive presence in two fast-growing areas, namely NOTES and vascular intervention;
- Comprehensive surgical product portfolio catering to the natural orifice transluminal endoscopic surgery with a focus on cryotherapy;
- Product portfolio based on advanced cryotherapy technologies in the vascular interventional therapeutic area, with R&D progress in China;
- Strong R&D capabilities and strategically designed IP portfolio empowering rapid innovation of products;
- Growing commercialization capabilities and efficient manufacturing system that enable end-to-end integration; and
- Visionary management team with rich industry experience and profound expertise, backed by strong support from renowned shareholders.

OUR STRATEGIES

Our mission is to become a global medical device platform in the field of minimally-invasive interventional cryotherapy, bringing benefits to patients and physicians worldwide with our cryotherapy technology. We plan to implement the following strategies to achieve our goal:

- Rapidly advance the clinical development and commercialization of our product candidates;
- Further expand our product portfolio leveraging technology platforms and continue to focus on minimally-invasive interventional cryotherapy;
- Continue to research and develop various underlying and supporting technologies; and
- Selectively expand our worldwide footprint.

RESEARCH AND DEVELOPMENT

We have a dedicated product development team that comprises an in-house R&D team of 83 staff and a clinical operation team of 37 staff as of the Latest Practicable Date (including certain management members undertaking product development functions). Our product development team is jointly led by Mr. DIAO Yuepeng, Mr. LIU Yulong, Mr. Thach Buu DUONG, Dr. ZHAO Kuiwen and Mr. CHEN Zhimin, industry experts with an average of over ten years of experience in the medical device industry or in the field of engineering research and development.

SUMMARY

In 2020, 2021 and the eight months ended August 31, 2022, we incurred research and development expenses of RMB42.3 million, RMB89.8 million and RMB35.8 million, respectively. Furthermore, we have an intellectual property portfolio, consisting of 110 registered patents, 18 registered trademarks, as well as 44 pending patent applications and 13 pending trademark applications in China and overseas as of the Latest Practicable Date. During the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings in respect of intellectual property right infringement claims against us or initiated by us. For details, see “Business—Intellectual Property Rights” in this document.

Relationships with CROs and SMOs

We collaborate with CROs and SMOs for the support of our clinical trials. When selecting CROs and SMOs, we consider a number of factors, including their expertise, experience and reputation. Under the relevant legally-binding agreements, the CROs are generally responsible for preparing ethical committee application, assisting in selecting clinical trial institutions, managing and monitoring the implementation of clinical trials, collecting and keeping records of patients’ information and providing progress or summary reports. We provide the CROs with their required materials and information and make payments in accordance with the payment schedule agreed by parties. We also engaged SMO to assist researchers to complete certain supporting duties in relation to our clinical trials, including collecting source data and providing progress reports, among others. Under the agreements with CROs and SMOs, we own all intellectual property and trial results and the CROs and SMOs must maintain strict confidentiality with respect to the information they acquired from us during clinical trials.

For details, see “Business — Research and Development — Relationships with CROs and SMOs” in this document.

OUR CUSTOMERS

During the Track Record Period, we generated revenue from the sales of our self-developed medical consumables, which mainly include our Pulmonary Nodule Localization Needle and Laparoscopic Single Port Multi-Channel Access Platform. In line with industry norms, we adopt a distributorship model and we sell our commercialized products to hospitals primarily through distributors. As of August 31, 2022, we cooperated with 57 distributors who entered into distribution agreements with us for the sales of our commercialized products in China. Some of our distributors may engage sub-distributors to distribute our products within its respective sales region. As confirmed by our PRC Legal Adviser, during the Track Record Period and up to the Latest Practicable Date, we had not violated or circumvented any applicable PRC laws rules or regulations relevant to the “Two-Invoice System” in all material aspects. For further information, see “Business — Sales and Marketing — Our Sales and Distribution Arrangements” in this document. For sales of cryotherapy products after receiving registration approval, we will select suitable distributors from existing distributors and may engage new distributor after measuring market demands. For further information, see “Business — Sales and Marketing — Our Sales and Distribution Arrangements” in this document.

The aggregate sales to our five largest customers for 2020, 2021 and the eight months ended August 31, 2022 were RMB3.3 million, RMB8.2 million and RMB6.6 million, respectively, representing 37.0%, 36.5% and 40.3% of our revenue for the respective period. Sales to our largest customer for 2020, 2021 and the eight months ended August 31, 2022 were RMB0.8 million, RMB1.9 million and RMB1.8 million, respectively, representing 8.8%, 8.4% and 10.8% of our revenue for the respective period. Since we adopt a distributorship model, our five largest customers for 2020, 2021 and the eight months ended August 31, 2022 were our distributors.

SUMMARY

OUR SUPPLIERS AND RAW MATERIALS

Purchases from our five largest suppliers for 2020, 2021 and the eight months ended August 31, 2022 amounted to RMB9.2 million, RMB13.4 million and RMB3.7 million, respectively, representing 31.6%, 24.3% and 9.6% of our total purchases for the respective period. Purchases from our largest supplier for 2020, 2021 and the eight months ended August 31, 2022 amounted to RMB4.3 million, RMB5.8 million and RMB0.9 million, respectively, representing 14.8%, 10.6% and 2.3% of our total purchases for the respective period. In 2020 and the eight months ended August 31, 2022, our suppliers mainly included raw material suppliers and research service providers. In 2021, we (i) engaged a financial consulting service provider in connection with our Series B Financing, (ii) engaged several construction or decoration service providers when building our manufacturing facility in Shanghai, and (iii) engaged several professional service providers in connection with the [REDACTED]. We believe such purchases were primarily one-off purchases in nature, and expect that our major suppliers would change back to raw material suppliers and research service providers after such one-off purchases are fully settled.

For our cryotherapy products, we primarily use raw materials including outer tubes, balloons, microcomputer, vacuum pumps and solenoid valves. For our non-cryotherapy products, we primarily use raw materials including stainless steel tubes, braided tubes and handles. In 2020, 2021 and the eight months ended August 31, 2022, our costs of sales amounted to RMB4.4 million, RMB6.9 million and RMB5.2 million, respectively.

OUR PRODUCTION

We have established two production facilities, one in Ningbo and the other in Shanghai, and had a team of 117 production personnel as of the Latest Practicable Date. Our facility in Ningbo produces our commercialized products, mainly including the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform, and also produces, assembles and tests sample products related to NOTES. Our facility in Shanghai produces, assembles and tests sample products related to vascular intervention for product development.

We commenced commercialization of the Endoscopic Clip for Anastomosis in October 2022 and expect to commercialize the Bladder Cryoablation System in December 2022. Based on currently existing facilities and equipment, annual production capacity for our Core Products is estimated to be 10,000 units for the Endoscopic Clip for Anastomosis and 20 cryoablation equipment and 5,000 catheters for the Bladder Cryoablation System. We plan to increase physician acceptance and market penetration for our Core Products through physician training and other initiatives. In line with the expected growth in market acceptance and product sales, we will gradually enhance our production capacity for our Core Products by upgrading our manufacturing facilities, purchasing new machineries and equipment.

SUMMARY OF KEY FINANCIAL INFORMATION

This summary of key financial information set forth below has been derived from, and should be read in conjunction with, our consolidated audited financial statements, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix I to this document, as well as the information set forth in “Financial Information” in this document.

SUMMARY

Summary Consolidated Statements of Profit or Loss and Other Comprehensive Income

The following table summarizes our consolidated statements of profit or loss and other comprehensive income for the periods indicated:

	<u>Year Ended December 31,</u>		<u>Eight Months Ended</u>	
	<u>2020</u>	<u>2021</u>	<u>August 31,</u>	
	<i>RMB'000</i>	<i>RMB'000</i>	<u>2021</u>	<u>2022</u>
			<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Revenue	9,054	22,426	12,061	16,431
Cost of Sales	(4,414)	(6,881)	(4,146)	(5,225)
Gross profits	4,640	15,545	7,915	11,206
Research and development expenses	(42,307)	(89,827)	(71,647)	(35,751)
Administrative expenses	(124,049)	(50,753)	(28,343)	(40,547)
Loss before tax	(159,333)	(126,497)	(92,436)	(61,422)
Loss for the year/period	(159,333)	(126,497)	(92,436)	(61,422)
Attributable to:				
Owners of the parent	(137,085)	(101,873)	(68,930)	(57,944)
Non-controlling interests	(22,248)	(24,624)	(23,506)	(3,478)
	(159,333)	(126,497)	(92,436)	(61,422)

During the Track Record Period, all of our revenue was generated from the sales of our medical consumables, mainly including the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform. As of the Latest Practicable Date, we had not commercialized any cryotherapy systems. We have incurred net losses during the Track Record Period, which amounted to RMB159.3 million, RMB126.5 million and RMB61.4 million for 2020, 2021 and the eight months ended August 31, 2022, respectively. For more details, see “Financial Information—Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income” in this document.

SUMMARY

Our loss for the year/period decreased from RMB159.3 million for 2020 to RMB126.5 million for 2021, primarily due to (i) an increase in revenue of RMB13.4 million, mainly driven by the increase in the sales volume of the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform in PRC market; and (ii) a decrease of administrative expenses of RMB73.3 million mainly because we incurred significant share-based payment of RMB107.4 million in 2020, which was further due to transfers of shares to one of our Controlling Shareholders and an executive director, and an equity subscription by one of our ESOP Platforms in relatively low prices compared to the fair value of such shares as determined by the appraiser; partially offset by an increase in research and development expenses of RMB47.5 million mainly due to an increase in expenditures in proprietary technologies of RMB51.0 million resulting from Mr. Diao Yuepeng’s capital contributions to two of our subsidiaries in the form of proprietary technologies. Our loss for the year/period decreased from RMB92.4 million for the eight months ended August 31, 2021 to RMB61.4 million for the same period in 2022, primarily due to (i) a decrease in research and development expenses of RMB35.9 million mainly resulted from a decrease in expenditures in proprietary technologies of RMB51.0 million as such expenditures in proprietary technologies of RMB51.0 million were one off expenses in 2021, partially offset by an increase in staff cost of RMB9.2 million resulted from the increased number of R&D personnel in line with our recruitment plan for 2022; (ii) an increase in gross profit of RMB3.3 million in line with the increased sale of the Pulmonary Nodule Localization Needle; and (iii) an increase in other income and gains of RMB3.6 million mainly resulted from the increased government grants we received for the research and development activities from local government, partially offset by an increase in administrative expenses of RMB12.2 million as a result of an increase in average salaries and the number of administrative personnel. For details of the aforementioned transfers of shares and equity subscription, please see “Financial Information—Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income—Administrative Expenses” in this document.

Summary Consolidated Statements of Financial Position

The following table sets forth selected information from our consolidated statements of financial position as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31,
	<i>RMB'000</i>	<i>RMB'000</i>	2022 <i>RMB'000</i>
Total non-current assets	23,378	42,306	41,229
Total current assets	50,980	189,387	138,046

SUMMARY

	As of December 31,		As of
	2020	2021	August 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Total non-current liabilities	588	6,406	6,701
Total current liabilities	23,488	28,289	23,308
Net current assets	27,492	161,098	114,738
Net assets	50,282	196,998	149,266
Non-controlling interests	–	26,349	22,871

Our total assets increased from RMB74.4 million as of December 31, 2020 to RMB231.7 million as of December 31, 2021, mainly due to a significant increase in cash and cash equivalents from RMB7.5 million to RMB157.9 million resulting from the receipt of proceeds from our Series B financing. Our total assets decreased to RMB179.3 million as of August 31, 2022, primarily due to a decrease in cash and cash equivalents of RMB70.2 million mainly caused by our increased cash expenditures related to our operating activities, partially offset by an increase in prepayments, other receivables and other assets of RMB10.8 million mainly resulting from (i) the increased capitalized [REDACTED] of RMB[REDACTED] associated with the [REDACTED]; and (ii) an increase in prepayment to suppliers of RMB6.7 million mainly because of the increased procurement of raw materials and molds.

Our total liabilities increased from RMB24.1 million as of December 31, 2020 to RMB34.7 million as of December 31, 2021, which was primarily attributable to the increase of lease liabilities. Our total liabilities decreased to RMB30.0 million as of August 31, 2022 primarily due to a decrease in other payables and accruals of RMB7.0 million resulted from a decrease in accrued expenses of RMB5.6 million mainly because we accrued much less [REDACTED] for the eight months in 2022 as compared to 2021, and a decrease in payroll and welfare payable of RMB1.6 million resulted from settlement of huge amount of annual bonus payables in 2022, partially offset by an increase in trade payables of RMB1.4 million resulted from our increased procurement of raw materials.

SUMMARY

We recorded net current assets of RMB161.1 million as of December 31, 2021, compared to net current assets of RMB27.5 million as of December 31, 2020, mainly attributable to capital contribution by our shareholders of RMB204.4 million. Our net current assets decreased to RMB114.7 million as of August 31, 2022, primarily due to a decrease in cash and cash equivalents of RMB70.2 million mainly resulting from our increased cash expenditures related to our operating activities.

We recorded net assets of RMB197.0 million as of December 31, 2021, compared to net assets of RMB50.3 million as of December 31, 2020, mainly attributable to the net effect of: (i) the loss for the year of RMB126.5 million; (ii) capital contribution by our shareholders of RMB204.4 million; (iii) capital contribution from Mr. DIAO Yuepeng, a shareholder of two of our subsidiaries, of RMB51.0 million; and (iv) equity-settled share award expense of RMB17.8 million. Our net assets decreased to RMB149.3 million as of August 31, 2022, primarily attributable to the net effect of: (i) loss for the period of RMB61.4 million; and (ii) equity-settled share award expense of RMB13.5 million.

Summary Consolidated Statements of Cash Flows

The following table sets forth our cash flows for the periods indicated:

	Year Ended December 31,		Eight Months Ended	
	2020	2021	August 31,	
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Net cash flows used in operating activities	(34,199)	(62,491)	(33,880)	(59,969)
Net cash flows (used in)/generated from investing activities	27,009	15,653	(107,616)	(6,385)
Net cash flows (used in)/generated from financing activities	(608)	197,747	202,370	(5,839)
Net (decrease)/increase in cash and cash equivalents	(7,798)	150,909	60,874	(72,193)
Cash and cash equivalents at beginning of the year/period	15,381	7,486	7,486	157,867
Effect of foreign exchange rate changes	(97)	(528)	83	2,022
Cash and cash equivalents at end of the year/period	7,486	157,867	68,443	87,696

SUMMARY

For the eight months ended August 31, 2022, our net cash used in operating activities was RMB60.0 million, which was primarily attributable to our loss before tax of RMB61.4 million. Negative adjustments for non-cash and non-operating items primarily included equity-settled share award expense of RMB13.5 million and depreciation of property, plant and equipment of RMB2.9 million. The amount was then adjusted positively by changes in working capital, primarily including (i) an increase in prepayments, other receivables and other assets of RMB9.0 million; (ii) an increase in inventories of RMB3.9 million; and (iii) a decrease in other payables and accruals of RMB5.3 million.

In 2021, our net cash used in operating activities was RMB62.5 million, which was primarily attributable to our loss before tax of RMB126.5 million. Negative adjustments for non-cash and non-operating items primarily included equity-settled share award expense of RMB17.8 million and expenditures in proprietary technologies of RMB51.0 million. The amount was then adjusted positively by changes in working capital, primarily including (i) an increase in inventories of RMB3.6 million; (ii) an increase in prepayments, other receivables and other assets of RMB3.6 million; and (iii) a decrease in contract liabilities of RMB4.6 million.

In 2020, our net cash used in operating activities was RMB34.2 million, which was primarily attributable to our loss before tax of RMB159.3 million. Negative adjustments for non-cash and non-operating items primarily included equity-settled share award expense of RMB112.3 million. The amount was then adjusted negatively by changes in working capital, primarily included an increase in other payables and accruals of RMB8.8 million.

Our operating cash flow will continue to be affected by our research and development expenses. For more details, see “Financial Information—Liquidity and Capital Resources—Net Cash Flows Used in Operating Activities” in this document. During the Track Record Period, we mainly relied on capital contributions by our shareholders and equity financing as the major sources of liquidity. Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents, future operating cash flows in respective periods, and the estimated net [REDACTED] from the [REDACTED], we have sufficient working capital to cover at least 125% of our costs and expenses, including research and development expenses, administrative expenses, distribution costs, finance costs and other expenses (including any production costs), for at least the next 12 months from the date of this document.

Our cash burn rate refers to our average monthly (i) net cash used in operating activities; (ii) capital expenditures; and (iii) lease payments. Assuming that the average cash burn rate going forward will be approximately 2.5 times the level in 2021, we estimate that our cash and cash equivalents as of August 31, 2022, will be able to maintain our financial viability for approximately [REDACTED] or, if we also take into account the estimated net [REDACTED] (based on the [REDACTED] of HK\$[REDACTED] per [REDACTED]) from the [REDACTED], for at least [REDACTED].

SUMMARY

KEY FINANCIAL RATIOS

The following table sets forth the components of our key financial ratios as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31, 2022
Current ratio ⁽¹⁾	2.2	6.7	5.9
Quick ratio ⁽²⁾	1.8	6.3	5.2
	2.2	6.7	5.9
	1.8	6.3	5.2

Notes:

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories and divided by current liabilities as at the same date.

For more information on our key financial ratios, see “Financial Information—Key Financial Ratios” in this document.

SUMMARY OF MATERIAL RISK FACTORS

We believe that there are certain risks involved in our operations, many of which are beyond our control. These risks are set out in “Risk Factors” in this document. Some of the major risks we face include:

- We may not be able to commercialize new products that are competitive in the market. For instance, we may not successfully commercialize the Bladder Cryoablation System, as currently there is no existing product, and no recommendation from guidelines for using cryoablation in the treatment of NMIBC, and it may take time to educate the market and gain acceptance. Also, the Endoscopic Clip for Anastomosis may not be able to outcompete other OTS Clips and TTS Clips given that Endoscopic Clip for Anastomosis lacks material competitive advantages and the endoscopic clip market in China is highly fragmented and is currently dominated with the TTS Clips;
- Our future growth depends substantially on the successful development of our product candidates to commercialization;
- We have incurred significant operating losses since our inception, and may continue to incur operating losses for the foreseeable future. As a result, you may lose substantially all your [REDACTED] in us given the high risks involved in the medical device business;
- We have relatively limited experience in sales and marketing activities, and we may not be able to expand or integrate our in-house sales and marketing force successfully; and
- Our business, results of operations and financial position could be adversely affected by the ongoing COVID-19 pandemic.

You should read the entire section headed “Risk Factors” in this document before you decide to [REDACTED] in the [REDACTED].

SUMMARY

Given the high risks involved in our business and our industry in general, you may lose substantially all your [REDACTED] in us. You should read “Risk Factors” in this document before you decide to [REDACTED] in the [REDACTED].

PRE-[REDACTED] INVESTMENTS

The Pre-[REDACTED] Investments include: (i) Series A Financing; (ii) Ningbo SensCure Series Pre-A Financing; (iii) Ningbo SensCure Series A Financing; (iv) Series A+ Financing; (v) Ningbo SensCure Series A+ Financing; (vi) Series A++ Financing; (vii) Ningbo SensCure Series A++ Financing; and (viii) Series B Financing. Our Group raised a total of approximately RMB283.62 million through Series A Financing, Series A+ Financing, Series A++ Financing and Series B Financing in our Company and a total of RMB82 million through Ningbo SensCure Series A Financing, Ningbo SensCure Series A+ Financing and Ningbo SensCure Series A++ Financing in Ningbo SensCure. Our Pre-[REDACTED] Investors will be subject to lock-up arrangements for a period of 12 months from the [REDACTED] pursuant to the PRC Company Law. For details, see “History, Development and Corporate Structure — Pre-[REDACTED] Investments” in this document.

Our Pre-[REDACTED] Investors consist of private equity and venture capital funds and investment holding companies, among which some have a specific focus on the healthcare industry. Zhuhai Gao Ling, YuanBio Venture Capital and Proxima Ventures are sophisticated investors pursuant to the Guidance Letter HKEX-GL92-18 issued by the Stock Exchange. Upon completion of the [REDACTED], Zhuhai Gao Ling, YuanBio Venture Capital and Proxima Ventures, through their respective controlled entities, will hold approximately [REDACTED]%, [REDACTED]% and [REDACTED]% of the total issued share capital of our Company, respectively. For details, see “History, Development and Corporate Structure — Pre-[REDACTED] Investments — Information About Our Pre-[REDACTED] Investors” in this document.

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Ningbo Linfeng was able to exercise approximately 41.39% voting rights in our Company through (i) its direct interest as to 27.91%, (ii) Ningbo Maishang as to 5.62%, (iii) Ningbo Hongyingkang as to 5.45% and (iv) Ningbo Kangrui as to 2.42%. The executive partner of each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui, namely, Shidi Biotechnology, is wholly owned by Ningbo Linfeng. Shidi Biotechnology is entitled to exercise the voting power held by each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui in our Company pursuant to their respective partnership agreements.

As of the Latest Practicable Date, Shanghai Shidi was able to exercise approximately 47.66% voting rights in our Company through (i) its direct interest as to 6.27%; (ii) Ningbo Linfeng as to 27.91%, (iii) Ningbo Maishang as to 5.62%, (iv) Ningbo Hongyingkang as to 5.45% and (v) Ningbo Kangrui as to 2.42%. Ningbo Linfeng was owned as to 65% by Shanghai Shidi.

As of the Latest Practicable Date, Ms. Li was able to exercise approximately 47.66% voting rights in our Company through Shanghai Shidi which was wholly owned by Ms. Li. Mr. Lv was able to exercise approximately 9.59% voting rights in our Company through his personal capacity.

SUMMARY

Pursuant to a concert party agreement dated April 26, 2021, Ms. Li and Mr. Lv, the Concert Parties, confirmed that they have been acting in concert in exercising Shareholders’ rights pertaining to our Group (including our Company and Ningbo SensCure) since January 1, 2014, and they have agreed to continue to act in concert and reach consensus on proposals related to the daily management and operation of our Group presented to general meetings of the Shareholders of our Company for voting. As such, the Concert Parties will be entitled to exercise voting rights of approximately [REDACTED]% in our Company immediately upon completion of the [REDACTED]. Therefore, the Concert Parties, Shanghai Shidi, Ningbo Linfeng, Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui will constitute a group of Controlling Shareholders of our Company under the Listing Rules. See “History, Development and Corporate Structure — Concert Party Arrangement” in this document for further details on the concert party arrangement and “History, Development and Corporate Structure — Employee Incentive Platforms” in this document for further information on Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui.

CONTINUING CONNECTED TRANSACTIONS

We have entered into transactions which will constitute continuing connected transactions under Chapter 14A of the Listing Rules upon [REDACTED]. Further particulars about such transactions together with the application for a waiver from strict compliance with the relevant requirements under Rule 14A.105 of the Listing Rules are set out in “Continuing Connected Transactions” in this document.

DIVIDEND

No dividend have been declared or paid by the Company during the Track Record Period. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our board of directors and subject to our Articles of Association and the PRC Company Law, and will depend on a number of factors, including the successful commercialization of our products as well as our earnings, capital requirements, overall financial condition and contractual restrictions. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. As confirmed by our PRC Legal Adviser, any future net profit that we make will have to be applied to make up for our historically accumulated losses in accordance with the PRC laws, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above.

THE [REDACTED]

This document is published in connection with the [REDACTED] as part of the [REDACTED]. The [REDACTED] comprises:

- (i) the [REDACTED] of initially [REDACTED] (subject to [REDACTED]) in Hong Kong as described in “Structure of the [REDACTED] — The [REDACTED]”; and
- (ii) the [REDACTED] of initially [REDACTED] (subject to [REDACTED]) (a) in the United States solely to QIBs in reliance on Rule 144A or another exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act, and (b) outside the United States in offshore transactions in reliance on Regulation S and the applicable laws of the jurisdiction where those [REDACTED] and [REDACTED] occur, as described in “Structure of the [REDACTED]”.

SUMMARY

APPLICATION FOR [REDACTED] ON THE [REDACTED]

We have applied to the [REDACTED] for the granting of the [REDACTED] of, and permission to [REDACTED], the H Shares to be [REDACTED] by us pursuant to the [REDACTED] and the H Shares to be converted from the Unlisted Shares.

[REDACTED] STATISTICS

	Based on the [REDACTED] of HK\$[REDACTED]
Market capitalization of our Shares ⁽¹⁾	<u>HK\$[REDACTED]</u>
Unaudited [REDACTED] adjusted consolidated net tangible assets per Share ⁽²⁾	<u>HK\$[REDACTED]</u>

Notes:

- (1) The calculation of market capitalization is based on [REDACTED] Shares expected to be in issue immediately after completion of the [REDACTED].
- (2) The unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company per Share is calculated after making the adjustments referred to in “Financial Information—Unaudited [REDACTED] Statement of Adjusted Consolidated Net Tangible Assets”.

SUMMARY

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED], after deducting [REDACTED] commissions, fees and estimated expenses payable by us in connection with the [REDACTED], at the [REDACTED] of HK\$[REDACTED] per [REDACTED]. We currently intend to apply these net [REDACTED] for the following purposes:

Amount of the estimated net

[REDACTED]

Intended use of net [REDACTED]

[73.9]%, or HK\$[REDACTED]

For research and development activities, commercial launch and manufacturing of our Core Products, of which:

[58.2]%, or HK\$[REDACTED] will be used to fund research and development activities, commercial launch (including sales and marketing) and manufacturing of the Bladder Cryoablation System

[15.7]%, or HK\$[REDACTED] will be used to fund research and development activities, commercial launch (including sales and marketing) and manufacturing of the Endoscopic Clip for Anastomosis

[6.1]%, or HK\$[REDACTED]

For research and development activities, planned commercial launch and manufacturing of our AF Cryoablation System

[20.0]%, or HK\$[REDACTED]

For research and development activities, registration filings, and planned commercial launch and manufacturing of the remaining 14 products and product candidates in our current product pipeline

For more details, see “Future Plans and Use of [REDACTED]” in this document.

[REDACTED]

SUMMARY

[REDACTED]

OUTBREAK OF COVID-19

Since the first quarter of 2020, the outbreak of COVID-19 has materially and adversely affected the global economy. In response, during the period from January 2020 to April 2020, China had imposed widespread lockdowns, closure of work places and restrictions on mobility and travel to contain the spread of the virus. The government lockdown and other restrictive measures had resulted in reduced mobility of our employees, such as reduced marketing activities, reduced business travels and working remotely during early phases of COVID-19 outbreak. During the COVID-19 outbreak, affected by containment measures put in place by local governments in reaction to COVID-19 pandemic across the nation, we experienced some delays in the patient enrollment and data entry for our clinical trials for AF Cryoablation System for approximately six months from January 2020 to June 2020. However, since April 2020, most of the Chinese cities had gradually eased or lifted domestic travel restrictions and resumed normal social activities, work and production. There has not been any material disruption of our ongoing clinical trials. We had resumed full and normal operations since April 2020. The COVID-19 pandemic has not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in the clinical trials.

However, since November 2021, new COVID-19 variants have been identified in many countries, including China, among which, Omicron and Delta are found to be aggressive, and highly transmissible. Certain areas across China, such as Xi'an, Chengdu and Shijiazhuang, had suffered from regional outbreaks of COVID-19 variants including Delta and Omicron. Such outbreak spread across the nation for the period from March 2022 to May 2022. In response, local governments in such affected areas imposed various restrictions on business and social activities, including city lockdowns, restrictions on travel and other emergency quarantines. We have one clinical trial center for AF Cryoablation System in Xi'an and one clinical trial center for feasibility clinical trials for COPD Cryospray System and Esophageal Cryospray System in Shanghai. Due to the enhanced containment measures in Xi'an from December 2021 to January 2022, we experienced delays in the issuance of final clinical trial report for the clinical trial of the AF Cryoablation System during such period. In May 2022, we obtained such final clinical trial report within the original timetable. In July 2022, we submitted the registration application for such product candidate with the NMPA, and currently expect to obtain the NMPA approval in or around the second quarter of 2023. Due to the enhanced containment measures in Shanghai from March 2022 to May 2022, we experienced delays in patient enrollment for feasibility clinical trials for COPD Cryospray System and Esophageal Cryospray System and for confirmatory clinical trial for Cryo-RDN System during such period. Such delays were temporary as we gradually resumed normal operations since June 2022 and the clinical trials of COPD Cryospray System, Esophageal Cryospray System and Cryo-RDN System can still be finished according to their respective original timetable.

SUMMARY

In addition, the manufacturing facility in Ningbo experienced certain difficulties in the procurement of raw materials from Shanghai from March 2022 to May 2022. However, such difficulties in procuring raw materials in Shanghai were moderate and have been further reduced since the reopening of Shanghai in June. In view of such difficulties, the Company has secured replacement for such raw materials in other cities. The production activities of our manufacturing facility in Shanghai was temporarily suspended due to the lockdown measures in Shanghai from March 2022 to May 2022, however, such influences of the suspension were limited since the manufacturing facility in Shanghai provides raw materials and prototype machines for the feature improvement activities of AF Cryoablation System (delayed due to the lockdown measures) and Cryo-RDN System (also suspended due to the lockdown measures), and it does not produce any commercialized products of the Company. It has resumed operation since the reopening of Shanghai in June. Although the logistics and distribution in some cities, such as Beijing and Shanghai, in China were affected by the pandemic from March 2022 to May 2022, delay in distribution of the Company’s products was rare, and there was no material impact of COVID-19 outbreak and its recurrence on the Company’s sales of commercialized products to hospitals or through distributors. As of the Latest Practicable Date, we did not see material impact of COVID-19 outbreak on our Company’s operations in its target markets. We cannot guarantee you that COVID-19 pandemic will not further escalate or have a material adverse effect on our results of operations, financial position or prospects. For more details, see “Risk Factors—Key Risks Relating to our Business, Business Operations, Intellectual Property Rights and Financial Prospects—Our business, results of operations and financial position could be adversely affected by the ongoing COVID-19 pandemic” in this document.

RECENT DEVELOPMENTS AND NO MATERIAL ADVERSE CHANGE

Since the end of the Track Record Period, we have continuously developed our business, and we expect to continue to incur significant expenses to fund the development and commercialization of our products and product candidates.

We obtained the NMPA approval for the Bladder Cryoablation System in June 2022, and expect to commercialize this product in December 2022. We also received the Zhejiang MPA approval for the Endoscopic Clip for Anastomosis in August 2022, and commercialized this product in October 2022. In addition, we completed a multi-center clinical trial for our major product, the AF Cryoablation System, and issued the final clinical trial report in May 2022. After completing the clinical trial, we submitted the registration application for the AF Cryoablation System with the NMPA in July 2022, and currently expect to receive the NMPA approval for this product candidate in or around the second quarter of 2023. For more details, see “Business—Our Products and Product Candidates—Other Products and Product Candidates—Vascular Interventional Cryotherapy Products—1. AF Cryoablation System” in this document.

The Company expects to incur increased net loss for the year ending December 31, 2022 due to the continuous research and development activities, increased staff costs for administrative activities, sales and marketing activities, and research and development activities due to the increased number of employees in 2022, and increased sales and marketing activities in 2022.

Our Directors confirm that, other than as stated above, there has been no material adverse change in our business, financial condition and results of operations since August 31, 2022, being the latest balance sheet date of our consolidated financial statements as set out in the Consolidated Financial Statements included in Appendix I to this document, and up to the date of this document.

DEFINITIONS

In this document, the following expressions shall have the meanings set out below unless the context otherwise requires.

“Accountants’ Report”	the accountants’ report from the reporting accountant of our Company, Ernst & Young, the text of which is set out in Appendix I to this document
“affiliate(s)”	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	the Accounting and Financial Reporting Council
	[REDACTED]
“Articles” or “Articles of Association”	our articles of association, as conditionally adopted on December 2, 2021 and will come into effect upon [REDACTED] (as amended, supplemented or otherwise modified from time to time), a summary of which is set out in Appendix V to this document
“associate(s)”	has the meaning ascribed thereto under the Listing Rules
“Board” or “Board of Directors”	our board of Directors
“Board of Supervisors”	our board of Supervisors
“Business Day”	a day that is not a Saturday, Sunday or public holiday in Hong Kong
“CCASS”	the Central Clearing and Settlement System established and operated by HKSCC
“CCASS Clearing Participant”	a person admitted to participate in CCASS as a direct clearing participant or a general clearing participant
“CCASS Custodian Participant”	a person admitted to participate in CCASS as a custodian participant
“CCASS Investor Participant”	a person admitted to participate in CCASS as an investor participant, which may be an individual, joint individuals or a corporation
“CCASS Operational Procedures”	the Operational Procedures of HKSCC in relation to CCASS, containing the practices, procedures and administrative requirements relating to operations and functions of CCASS, as from time to time in force

DEFINITIONS

“CCASS Participant”	a CCASS Clearing Participant, a CCASS Custodian Participant or a CCASS Investor Participant
“China” or “the PRC”	the People’s Republic of China excluding, for the purposes of this document, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“close associate(s)”	has the meaning ascribed thereto under the Listing Rules
“CNIPA”	China National Intellectual Property Administration (國家知識產權局)
“Companies Ordinance”	the Companies Ordinance, Chapter 622 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
“Companies (Winding Up and Miscellaneous Provisions) Ordinance”	the Companies (Winding Up and Miscellaneous Provisions) Ordinance, Chapter 32 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
“Company”, “our Company” or “Cryofocus”	Cryofocus Medtech (Shanghai) Co., Ltd. (康澧生物科技(上海)股份有限公司), a joint stock company incorporated in the PRC with limited liability on July 21, 2021, or, where the context requires (as the case may be), its predecessor, Cryofocus Medtech (Shanghai) Company Limited (康澧生物科技(上海)有限公司), a limited liability company established in the PRC on March 15, 2013
“Concert Parties”	Ms. Li and Mr. Lv and “Concert Party” means any one of them
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“Controlling Shareholders”	has the meaning ascribed to it under the Listing Rules and in this context, refers to the Concert Parties, Shanghai Shidi, Ningbo Linfeng, Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui and for further details, see “Relationship with our Controlling Shareholders” in this document
“core connected person(s)”	has the meaning ascribed thereto under the Listing Rules

DEFINITIONS

“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會)
“Director(s)”	the director(s) of our Company or any one of them
“EIT Law”	the PRC Enterprise Income Tax Law
“ESOP Platforms”	Ningbo Hongyingkang, Ningbo Kangrui and Ningbo Maishang
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong, or any extreme conditions or events, the occurrence of which causes serious interruption to the ordinary course of business operations in Hong Kong
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market research and consulting company
“Frost & Sullivan Report”	the industry report commissioned by us and independently prepared by Frost & Sullivan, a summary of which is set forth in “Industry Overview” in this document
“General Rules of CCASS”	General Rules of CCASS published by the Stock Exchange and as amended from time to time

[REDACTED]

“Group”, “our Group”, “our”, “we”, or “us”	the Company and its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
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[REDACTED]

DEFINITIONS

“H Share(s)”	overseas [REDACTED] foreign invested ordinary share(s) in the ordinary share capital of our Company, with a nominal value of RMB1.00 each, which are to be [REDACTED] for and [REDACTED] in Hong Kong dollars and for which an application has been made for the granting of [REDACTED] and permission to [REDACTED] on the [REDACTED]
“HKFRS”	Hong Kong Financial Reporting Standards
“HKSCC”	the Hong Kong Securities Clearing Company Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
“HKSCC Nominees”	HKSCC Nominees Limited, a wholly owned subsidiary of the HKSCC
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong dollars” or “HK dollars” or “HKD” or “HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong

[REDACTED]

“Hong Kong Stock Exchange” or “Stock Exchange”	The Stock Exchange of Hong Kong Limited, a wholly-owned subsidiary of Hong Kong Exchanges and Clearing Limited
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[REDACTED]

DEFINITIONS

[REDACTED]

“Independent Third Party” or
“Independent Third Parties”

a person or entity which, to the best of our Directors’ knowledge, information and belief, having made all reasonable enquiries, is not a connected person of our Company within the meaning of the Listing Rules

[REDACTED]

DEFINITIONS

[REDACTED]

“Joint Sponsors” or
“[REDACTED]”

Citigroup Global Markets Asia Limited and Huatai Financial Holdings (Hong Kong) Limited

“Latest Practicable Date”

December 1, 2022, being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication

[REDACTED]

“Listing Committee”

the listing committee of the Stock Exchange

[REDACTED]

“Listing Rules”

the Rules Governing the Listing of Securities on the Stock Exchange (as amended, supplemented or otherwise modified from time to time)

“Main Board”

the stock market (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with the GEM of the Stock Exchange

“Mandatory Provisions”

the “Mandatory Provisions for Articles of Association of Companies to be Listed Overseas” (到境外上市公司章程必備條款), as amended, supplemented or otherwise modified from time to time, for inclusion in the articles of association of companies incorporated in the PRC to be listed overseas (including Hong Kong), which were promulgated by the former Securities Commission of the State Council (國務院證券委員會) and the former State Commission for Restructuring the Economic Systems (國家經濟體制改革委員會) on August 27, 1994

“MOF”

Ministry of Finance of the PRC (中華人民共和國財政部)

“MOFCOM”

Ministry of Commerce of the PRC (中華人民共和國商務部)

DEFINITIONS

"Mr. Lv"	Mr. LV Shiwen (呂世文), a non-executive Director and one of our Controlling Shareholders upon [REDACTED]
"Ms. Li"	Ms. LI Hui (李輝), one of our Controlling Shareholders upon [REDACTED]
"NDRC"	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
"Ningbo Hongyingkang"	Ningbo Hongyingkang Enterprise Management Partnership (Limited Partnership) (寧波弘盈康企業管理合夥企業(有限合夥)), one of our ESOP Platforms and one of our Controlling Shareholders upon [REDACTED]
"Ningbo Kangrui"	Ningbo Kangrui Investment Management Partnership (Limited Partnership) (寧波康銳投資管理合夥企業(有限合夥)), one of our ESOP Platforms and one of our Controlling Shareholders upon [REDACTED]
"Ningbo Linfeng"	Ningbo Linfeng Biotechnology Co., Ltd. (寧波麟豐生物科技有限公司), a limited company established in the PRC which is a non-wholly owned subsidiary of Shanghai Shidi and one of our Controlling Shareholders upon [REDACTED]
"Ningbo Maishang"	Ningbo Maishang Investment L.P. (Limited Partnership) (寧波脈尚投資合夥企業(有限合夥)), one of our ESOP Platforms and one of our Controlling Shareholders upon [REDACTED]
"Ningbo SensCure"	Ningbo SensCure Biotechnology Co., Ltd. (寧波勝杰康生物科技有限公司), a limited company established in the PRC and our wholly-owned subsidiary
"NMPA"	the National Medical Products Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
"NPC"	the National People's Congress of the PRC (中華人民共和國全國人民代表大會)

DEFINITIONS

[REDACTED]

“PBOC”	People’s Bank of China (中國人民銀行), the central bank of the PRC
“PRC Company Law”	the Company Law of the PRC (中華人民共和國公司法), as amended and adopted by the Standing Committee of the Eighth National People’s Congress on December 29, 1993 and effective on July 1, 1994, which was last amended and became effective on October 26, 2018, as amended, supplemented or otherwise modified from time to time;
“PRC Government”	the central government of the PRC and all governmental subdivisions (including provincial, municipal and other regional or local government entities) and instrumentalities thereof or, where the context requires, any of them
“PRC Intellectual Property Legal Adviser”	JunHe LLP Shanghai Office
“PRC Legal Adviser”	AllBright Law Offices

DEFINITIONS

“Pre-[REDACTED] Investments”	the pre-[REDACTED] investments in our Group undertaken by the Pre-[REDACTED] Investor(s), details of which are set out in “History, Development and Corporate Structure” in this document
“Pre-[REDACTED] Investor(s)”	Zhuhai Gao Ling Junheng Equity Investment L.P. (Limited Partnership) (珠海高瓴鈞恒股權投資合夥企業(有限合夥)), Suzhou Industrial Park New Phase 2 Venture Capital Enterprise (Limited Partnership) (蘇州工業園區新建元二期創業投資企業(有限合夥)), Hangzhou Proxima Innovative Investment L.P. (Limited Partnership) (杭州比鄰星創新投資合夥企業(有限合夥)), Suzhou Proxima Venture Investment L.P. (Limited Partnership) (蘇州比鄰星創業投資合夥企業(有限合夥)), FutureX Investment I Company Limited, Mr. LIU Ya (劉亞), Galaxy Yuanhui Investment Co., Ltd (銀河源匯投資有限公司), Suzhou Jingtian Medical Investment Partnership (Limited Partnership) (蘇州景天醫療投資合夥企業(有限合夥)), Shanghai Shengshan Xingqian Venture Capital Center (Limited Partnership) (上海盛山興錢創業投資中心(有限合夥)), Suzhou Shengshan Huiying Venture Capital Enterprise (Limited Partnership) (蘇州盛山惠贏創業投資企業(有限合夥)), Ningbo Fuchuang Innovation and Venture Capital Center (Limited Partnership) (寧波複創創新創業投資中心(有限合夥)) Qingdao Marine Innovation Industry Investment Fund Co., Ltd. (青島海洋創新產業投資基金有限公司), Ningbo Tongshang Linfeng Equity Investment Partnership (Limited Partnership) (寧波通商麟澧股權投資合夥企業(有限合夥)), Ningbo Tongshang Venture Capital Partnership (Limited Partnership) (寧波通商創業投資合夥企業(有限合夥)) and Shenzhen Furong No.1 Venture Capital Partnership (Limited Partnership) (深圳富鎔一號創業投資合夥企業(有限合夥))
“Promoters”	the promoters of our Company, being Shareholders of our Company as of June 15, 2021

DEFINITIONS

“Qualified Institutional Buyers” or “QIBs”	qualified institutional buyers within the meaning of Rule 144A under the U.S. Securities Act
“Regulation S”	Regulation S under the U.S. Securities Act
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國外匯管理局)
“SAMR”	the State Administration for Market Regulation of the PRC (中華人民共和國市場監督管理總局), formerly known as the State Administration for Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局)
“SAT”	the State Administration of Taxation of the PRC (中華人民共和國國家稅務總局)
“Securities and Futures Commission” or “SFC”	the Securities and Futures Commission of Hong Kong
“Securities Law”	the Securities Law of the PRC (中華人民共和國證券法), as amended, supplemented or otherwise modified from time to time
“SFO”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
“Shanghai Shidi”	Shanghai Shidi Industrial Development Co., Ltd. (上海仕地實業發展有限公司) (formerly known as Shanghai Shidi Investment Management Co., Ltd. (上海仕地投資管理有限公司)), a limited company established in the PRC and wholly owned by Ms. Li and one of our Controlling Shareholders upon [REDACTED]
“Share(s)”	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each, comprising Unlisted Shares and H Shares
“Shareholder(s)”	holder(s) of the Share(s)
“sophisticated investor(s)”	has the meaning given to it under the Guidance Letter HKEX-GL92-18 issued by the Stock Exchange

DEFINITIONS

“Special Regulations”	the Special Regulations of the State Council on the Overseas Offering and Listing of Shares by Joint Stock Limited Companies (國務院關於股份有限公司境外募集股份及上市的特別規定), promulgated by the State Council on August 4, 1994, as amended from time to time
“State Council”	the State Council of the PRC (中華人民共和國國務院)
“subsidiary(ies)”	has the meaning ascribed thereto under the Listing Rules
“substantial shareholder(s)”	has the meaning ascribed thereto under the Listing Rules
“Supervisor(s)”	member(s) of our Board of Supervisors
“Track Record Period”	the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022

[REDACTED]

“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“Unlisted Share(s)”	ordinary share(s) issued by our Company with a nominal value of RMB1.00 each and are not listed on any stock exchange
“U.S. dollars”, “US\$” or “USD”	United States dollars, the lawful currency of the United States
“U.S. Securities Act”	the U.S. Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder
“VAT”	value-added tax

[REDACTED]

“Zhejiang MPA”	Zhejiang Medical Products Administration
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DEFINITIONS

For ease of reference, the names of the PRC established companies or entities, laws or regulations have been included in this document in both the Chinese and English languages; in the event of any inconsistency, the Chinese versions shall prevail.

For the purpose of this document, references to “provinces” of China include provinces, municipalities under direct administration of the central government and provincial-level autonomous regions.

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

GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain technical terms used in this document in connection with us and our business. These may not correspond to standard industry definitions, and may not be comparable to similarly terms adopted by other companies.

“ablation therapy”	a minimally-invasive treatment option that uses extremely high or low temperatures to destroy abnormal tissue or tumors, or to treat other conditions
“active device”	a device that requires an artificial power source, such as a battery or other electrical supply, for its operation
“all-cause mortality”	all of the deaths that occur in a population, regardless of the cause, which is measured in clinical trials and used as an indicator of the safety or hazard of an intervention
“airway stenosis”	narrowing of airways caused by neoplastic or nonneoplastic processes, which may develop with several diseases
“asthma”	a long-term inflammatory disease of the airways of the lungs characterized by variable and recurring symptoms, reversible airflow obstruction, and easily triggered bronchospasms
“atrial fibrillation” or “AF”	a quivering or irregular heartbeat, namely arrhythmia, which can lead to blood clots and stroke
“benign stenosis” or “benign airway stenosis”	airway stenosis caused by nonneoplastic diseases
“biopsy”	a pathological examination of lesion tissues removed from the patient body to discover the presence, cause, or extent of a disease
“bladder cancer”	a type of cancer arising from the tissues of the bladder, in which cells may grow abnormally and acquire the potential to metastasize
“CAGR”	compound annual growth rate
“CE Marking” or “CE”	Conformite Europeenne, an administrative marking that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)

GLOSSARY OF TECHNICAL TERMS

“Class III hospital”	a top-level hospital in China. Among the hospital classes, Class III hospitals are the highest level, typically having more than 500 beds, providing high-level specialist medical and healthcare services to several regions and performing advanced teaching and research tasks
“Class III-A hospital”	a Class III hospital that scores over 900 (with a total score of 1,000), in the evaluation of its comprehensive capabilities in terms of its technology, management and research capability
“CO ₂ ”	carbon dioxide
“complication”	an unfavorable evolution of a disease, health condition or medical treatment
“confirmatory clinical trial”	a controlled clinical trial of a medical device product designed to demonstrate statistically significant clinical efficacy and safety of such product as used in human patients for regulatory approval of such product
“chronic bronchitis”	inflammation, swelling and irritation of the bronchial tubes
“COPD”	chronic obstructive pulmonary disease, a chronic inflammatory lung disease that causes obstructed airflow from the lungs
“COVID-19”	coronavirus disease 2019, a disease caused by a novel virus designated as severe acute respiratory syndrome coronavirus 2
“CRO”	contract research organization, an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“cryoablation”	a type of ablation that uses extreme cold produced by cryogen such as liquid nitrogen and carbon dioxide to freeze and destroy abnormal cells or diseased tissues
“cryoablation device” or “cryoablation system”	a minimally-invasive device for cryoablation treatment, which typically includes an active device and catheters or cryoprobes to deliver cold temperatures generated by cryogen to the therapeutic tissue
“CT”	computed tomography

GLOSSARY OF TECHNICAL TERMS

“95% CI”	95% confidence interval of the mean, a range with an upper and lower number calculated from a sample. Because the true population mean is unknown, this range describes possible values that the mean could be. If multiple samples are drawn from the same population and a 95% confidence interval calculate for each sample, the population mean would be expected to be found within 95% of these confidence intervals.
“DBP”	diastolic blood pressure, an indicator of how much pressure the blood is exerting against the artery walls when the heart is relaxed between beats
“endoscopic clip” or “Endoscopic Clip for Anastomosis”	an anastomosis device for closure treatment of soft tissues of digestive tract, including bleeding, perforation, and tissue defects
“esophagus cancer”	a type of cancer arising from the lining cells of esophagus
“Ex-factory Prices”	the prices at which our products are sold to our distributors
“FAS”	full analysis set, a set of subjects randomly assigned to a treatment group that had at least one efficacy assessment after randomisation and are used for the primary analysis
“FDA”	the United States Food and Drug Administration, a federal agency of the Department of Health and Human Services
“feasibility clinical trial”	a clinical trial of a medical device product designed to preliminarily demonstrate the safety of such product as used in human patients
“FEV1”	forced expiratory volume in 1 second
“FEV1/FVC ratio”	a calculated ratio in diagnosing COPD, which represents the proportion of a person’s vital capacity that they are able to expire in the first second of forced expiration (FEV1) to the full, forced vital capacity (FVC)
“FVC”	forced vital capacity
“GCP”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans

GLOSSARY OF TECHNICAL TERMS

“GERD”	gastroesophageal reflux disease, a disease where acid-containing contents in your stomach persistently leak back up and reflux into the esophagus
“GMP”	good manufacturing practices, the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification
“GOLD”	The Global Initiative for Chronic Obstructive Lung Disease
“Hospital Procurement Prices”	the prices at which our products are resold to hospitals by distributors
“hypertension”	also known as high blood pressure, is a long-term medical condition in which the blood pressure in the arteries is persistently elevated; as defined by the Chinese Center for Disease Control and Prevention, hypertension patients refers to patients having an average SBP of over 140 mmHg or an average DBP of over 90 mmHg, or currently using antihypertensive medication
“ICH-GCP”	good clinical practice guidelines formulated by the International Council for Harmonisation that intend to protect the rights and safety of trial participants in line with the principles set out in the Declaration of Helsinki
“implanted pacemaker”	an electronic device that prevents one’s heart from beating too slowly inserted just under the skin in the chest with wires attached to the heart
“incidence”	the number of new cases occurring in a specified population per year
“keyhole surgery” or “laparoscopy”	a type of surgical procedure that allows a surgeon to access the inside of the abdomen (tummy) and pelvis without having to make large incisions in the skin
“LES”	lower esophageal sphincter, a bundle of muscles at the low end of the esophagus, where it meets the stomach
“LN ₂ ”	liquid nitrogen

GLOSSARY OF TECHNICAL TERMS

“malignant stenosis” or “malignant airway stenosis”	airway stenosis caused by malignant diseases, including lung cancer and extratracheal lesions, such as intestinal tumors, liver tumors, kidney tumors that metastasize to the lungs
“MIS” or “minimally invasive surgery”	a surgical procedure that is performed through tiny incisions instead of a large opening
“mmHg”	millimeter of mercury, a unit of measure for pressure
“N ₂ ”	nitrogen
“N ₂ O”	nitrous oxide
“natural orifice interventional cryoablation”	a type of cryoablation, in which the cryoablation catheter enters a patient’s body guided by an endoscope via natural cavity such as respiratory, digestive or urinary tracts in a NOTES procedure to freeze and destroy abnormal or diseased cells
“NMIBC”	non-muscle invasive bladder cancer, cancer found in the tissue that lines the inner surface of the bladder
“NOTES”	natural orifice transluminal endoscopic surgery, a form of scarless surgery performed through cavities that connect to the outside of the body (such as the stomach wall or vagina) to access the abdominal cavity
“OTS Clip”	an over-the-scope clip that consists of an applicator cap, a mounted clip, a hand wheel, thread, and thread retriever
“paroxysmal atrial fibrillation”	episodes of atrial fibrillation that occur occasionally and usually stop spontaneously
“PET-CT”	a procedure that combines the pictures from a positron emission tomography (PET) scan and a computed tomography (CT) scan
“PFA”	pulsed field ablation, a type of ablation that destabilizes cell membranes by forming irreversible nanoscale pores, which leads to cell death and achieve therapeutic effect
“PH”	pulmonary hypertension, high blood pressure in the blood vessels that supplies the lungs
“PI”	principal investigator, the individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project

GLOSSARY OF TECHNICAL TERMS

“PPS”	per protocol set, a comparison of treatment groups that includes only those patients who completed the treatment originally allocated and are used for testing the treatment effect under optimal conditions
“prevalence”	the number of disease cases present in a particular population at a given time
“RDN” or “renal sympathetic denervation”	a minimally-invasive procedure for the treatment of hypertension in which energy released through the ablation catheter acts on the sympathetic nerve fibers in the perivascular wall of the renal artery, reducing the hyperactivity of the renal artery sympathetic nerve and, as a result, lowering the blood pressure
“Re-TURBT”	re-transurethral resection of bladder tumor, repeated surgical removal of bladder tumours that targets residual disease in case of incomplete first resection
“RH” or “resistant hypertension”	blood pressure cannot be maintained below 140/90 mmHg despite optimal use of at least three antihypertensive medications of different types, including a diuretic
“R&D”	research and development
“SBP”	systolic blood pressure, an indicator of how much pressure the blood is exerting against the artery walls when the heart beats pumping blood out
“SMO”	site management organization, an organization that provides clinical trial related services to medical device companies having adequate infrastructure and staff to meet the requirements of the clinical trial protocol
“SPL”	single-port laparoscopy, a minimally invasive surgical procedure in which the surgeon operates almost exclusively through a single-entry point, typically the patient’s navel
“sq.m.”	square meter, a unit of area
“survival rate”	the percentage of people in a study or treatment group still alive for a given period of time after diagnosis

GLOSSARY OF TECHNICAL TERMS

“target value”	criteria widely accepted by professionals for evaluating the efficacy or safety of a type of medical devices, including objective performance criteria and performance goals
“TLD”	targeted lung denervation, a bronchoscopic procedure intended to disrupt pulmonary parasympathetic inputs and is an experimental treatment for COPD and asthma
“TTS Clip”	a through-the-scope clip that is an endoscopic surgical instrument with a metal clip for the anastomosis of tissues in the gastrointestinal tract
“TURBT”	the transurethral resection of bladder tumor, a minimally-invasive surgery for removal of bladder tumors through the urethra
“UC”	urothelial carcinoma, the most common cancer of the renal pelvis or ureter that starts in the urothelial cells that line the inside of the renal pelvis and ureter
“UH” or “uncontrolled hypertension”	hypertension cases which are more severe than controlled hypertension, but less severe than resistant hypertension
“vascular interventional cryoablation”	a type of cryoablation, in which the cryoablation catheter enters a patient’s body through blood vessel to freeze and destroy abnormal or target cells
“VATS”	video-assisted thoracoscopic surgery, a minimally invasive surgical technique used to diagnose and treat problems in chest

FORWARD-LOOKING STATEMENTS

This document contains certain forward-looking statements relating to our plans, objectives, beliefs, expectations, predictions and intentions, which are not historical facts and may not represent our overall performance for the periods of time to which such statements relate. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks, uncertainties and other factors facing the Company which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- our business strategies and plans to achieve these strategies;
- our ability to complete the development and obtain the relevant requisite regulatory approvals of our product candidates;
- our ability to commercialize our approved products in a timely manner;
- our future debt levels and capital needs;
- changes to the political and regulatory environment in the industry and markets in which we operate;
- our expectations with respect to our ability to acquire and maintain regulatory licenses or permits;
- changes in competitive conditions and our ability to compete under these conditions;
- future developments, trends and conditions in the industry and markets in which we operate;
- general economic, political and business conditions in the markets in which we operate;
- effects of the global financial markets and economic crisis;
- our financial conditions and performance;
- our dividend policy; and
- change or volatility in interest rates, foreign exchange rates, equity prices, volumes, operations, margins, risk management and overall market trends.

Additional factors that could cause actual performance or achievement to differ materially include but are not limited to those discussed in "Risk Factors" and elsewhere in this document. In some cases, we use the words "aim," "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "going forward," "intend," "ought to," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "will," "would" and similar expressions to identify forward-looking statements. In particular, we use these forward-looking statements in the "Business" and "Financial Information" sections of this document in relation to future events, our future financial, business or other performance and development, the future development of our industry and the future development of the general economy of our key markets.

FORWARD-LOOKING STATEMENTS

We caution you not to place undue reliance on these forward-looking statements which are based on current plans and estimates, and speak only as of the date they were made. We undertake no obligation to update or revise any forward-looking statements in light of new information, future events or otherwise. Forward-looking statements involve inherent risks and uncertainties and are subject to assumptions, some of which are beyond our control. We caution you that a number of important factors could cause actual outcomes to differ, or to differ materially, from those expressed in any forward-looking statements.

Our Directors confirm that the forward-looking statements are made after reasonable care and due consideration. Nonetheless, due to the risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect, or at all. Statements of or references to our intentions or those of any of our Directors are made as of the date of this document. Any such intention may change in light of future developments.

Accordingly, you should not place undue reliance on any forward-looking statements in this document. All forward-looking statements contained in this document are qualified by reference to this cautionary statement.

RISK FACTORS

An [REDACTED] in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before deciding to [REDACTED] in our Shares. Particularly, we are a biotechnology company seeking to [REDACTED] on the [REDACTED] of the [REDACTED] under Chapter 18A of the Listing Rules. Our operations and the biotech industry involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your [REDACTED] in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any such an event, the [REDACTED] of our Shares could decline, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-Looking Statements” in this document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) key risks relating to our business, business operations, intellectual property rights and financial prospects; (ii) risks relating to our products and product candidates, comprising (a) risks relating to the development of our product candidates, (b) risks relating to the commercialization of our product candidates, (c) risks relating to extensive government regulations, (d) risks relating to manufacture and supply of our products and product candidates, and (e) risks relating to our intellectual property rights; (iii) risks relating to our financial position and need for additional capital; (iv) risks relating to our operations; (v) risks relating to doing business in China; and (vi) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also harm our business, financial condition and operating results. You should consider our business and prospects in light of the challenges we face, including those discussed in this section.

KEY RISKS RELATING TO OUR BUSINESS, BUSINESS OPERATIONS, INTELLECTUAL PROPERTY RIGHTS AND FINANCIAL PROSPECTS

Our future growth depends substantially on the successful development of our product candidates to commercialization.

Our business substantially depends on our ability to complete the development and obtain the requisite regulatory approvals of our product candidates and successfully commercialize our approved products in a timely manner. We have devoted significant efforts and financial resources in the development of our product candidates. As of the Latest Practicable Date, we had developed two Core Products, 15 other product candidates in various development stages and six additional commercialized products. Our commercialized products mainly include the Pulmonary Nodule Localization Needle and Laparoscopic Single Port Multi-Channel Access Platform, which are covered by governmental health

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insurance in certain cities, such as Shanghai, in China. The successful development and commercialization of our product candidates will depend on several factors, including but not limited to:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals for our product candidates;
- enhancing commercial manufacturing capabilities, either by enlarging our existing facilities or building new facilities ourselves or making arrangements with third-party manufacturers;
- the ability of our CROs and SMOs to conduct or assist in conducting our clinical trials safely and efficiently and in accordance with our specified trial protocols;
- the performance by any other third parties we may retain in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- obtaining required marketing authorizations and launching commercial sales in China and other targeted markets, if and when approved;
- obtaining favorable governmental and private health insurance for our products, if and when approved;
- appropriately pricing our product candidates and timely collecting payments;
- efficiently and cost-effectively enhancing our marketing and distribution capabilities;
- competition with other comparable medical devices; and
- continued acceptable safety profile of our product candidates following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to obtain approval for our product candidates, and/or to successfully commercialize our approved products, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations. Even if we successfully commercialize our approved products, it is uncertain if the market share of such products will grow as we expect since such growth is based on various assumptions, which may be aggressive.

RISK FACTORS

We may not be able to commercialize new products that are competitive in the market.

The market for cryotherapy devices is characterized by technological changes, frequent new product introductions, and evolving industry standards. Our products and product candidates could become technologically obsolete or more susceptible to competition without timely introduction of new and improved technologies. We expect the cryotherapy device market to evolve towards newer and more advanced products, some of which we do not currently produce. Our success therefore depends on our ability to accurately anticipate industry trends and continuously identify, develop and market new and advanced products in a timely manner that meet our customers’ demand. Because product designs can change with market conditions and hospitals’ and physicians’ preferences, identifying and developing new products in a timely manner can be difficult. Our research and development efforts may not lead to new products that will be commercially successful. Even if we develop new products, we may encounter delays in obtaining regulatory clearance, restrictions imposed on approved indications, entrenched patterns of clinical practice, uncertainty over third-party reimbursement, or other factors.

In addition, it takes much time and efforts for the new products to gain acceptance after we launch them in the market. We may not be able to successfully market our new products or our end customers may not be receptive to our new products. For example, we may not successfully commercialize Bladder Cryoablation System, one of our Core Products, as currently there is no existing products, and no recommendation from national or international guidelines for the use of cryoablation therapy in the treatment of NMIBC. Since the clinical trial for the Bladder Cryoablation System did not include long-term follow-up visits, there are currently no sufficient long-term clinical data to support the use of this product as a standard of care after TURBT. It may take time to educate the market and gain acceptance among physicians and patients. For further information, see “Industry Overview—The Bladder Cancer Interventional Cryotherapy Device Market—Market Size of Bladder Cancer Interventional Cryotherapy Catheters” in this document. On the other hand, it may not obtain adequate coverage, favorable medical reimbursement, or optimal pricing by third-party payors and government authorities.

The success of our new product offerings will depend on several factors, including our ability to (i) properly identify and predict industry trends and market demand; (ii) complete product development process successfully in a timely manner; (iii) minimize the time and costs required to obtain regulatory approvals; (iv) optimize our procurement and manufacturing processes to predict and control costs; (v) manufacture and deliver new products in a timely manner; (vi) efficiently and cost-effectively enhance our marketing platform and distribution channels; (vii) price our products at both competitive and commercially justifiable levels; (viii) increase end-customer awareness and acceptance of our new products; and (ix) compete effectively with other medical device developers, manufacturers and marketers. For example, despite its innovative separable structure, the Endoscopic Clip for Anastomosis may not be able to outcompete other OTS Clips and TTS Clips in the market given this product candidate lacks material competitive advantages and the endoscopic clip market in China is highly fragmented and is currently dominated with the TTS Clips.

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

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We have incurred significant operating losses since our inception, and may continue to incur operating losses for the foreseeable future. As a result, you may lose substantially all your [REDACTED] in us given the high risks involved in the medical device business.

We are a development-stage biotechnology company. Investment in medical device development is highly speculative because it entails substantial upfront capital expenditures and significant risks that a product candidate may fail to complete clinical trials, gain regulatory approval or become commercially viable. As a result, you may lose substantially all of your [REDACTED] in our Company given the nature of the biotechnology industry. We have incurred significant expenses related to the research and development of our products and product candidates in the past. In 2020, 2021 and the eight months ended August 31, 2022, our research and development expenses amounted to RMB42.3 million, RMB89.8 million and RMB35.8 million, respectively. In addition, we also incurred costs in connection with the commercialization of our approved products as well as selling and distribution expenses, and administrative expenses associated with our operations. As a result, we have incurred net losses amounted to RMB159.3 million, RMB126.5 million and RMB61.4 million in 2020, 2021 and the eight months ended August 31, 2022, respectively.

We expect to continue to incur operating losses in the foreseeable future, and such operating losses may even increase as we continue to conduct preclinical and clinical trials for our product candidates, seek regulatory approvals for our product candidates, manufacture our product candidates for clinical trials and our products for commercial sale, commercialize our approved products, attract and retain qualified personnel, maintain, protect and expand our intellectual property portfolio, and comply with laws, regulations and rules applicable to our business and our status as a public company in Hong Kong, among others. Our future financial performance will depend, in part, on the number, scope and complexity of our product development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive with arrangements with third parties.

We are unable to predict when, or whether, we will be able to achieve or maintain profitability. To become and remain profitable, we must be successful in a range of challenging activities, including completing the clinical trials for our product candidates, obtaining regulatory approval from the NMPA and other competent regulatory bodies, and commercializing our approved products to achieve market acceptance. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown facts, and may never succeed in any or all of these activities. For example, if our products are not widely accepted by physicians and hospitals, we may be unable to increase or sustain our sales and we may fail to achieve and sustain growth or profitability. Even if we do succeed in all of the above activities, we may not be able to generate revenues that are significant or sufficient enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable may impact investors’ perception of the potential value of our Group and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. Any decline in the value of our Group could also cause you to lose all or part of your [REDACTED].

RISK FACTORS

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

During the clinical trial process, failure can occur at any time. The results of preclinical studies and feasibility clinical trials of our product candidates may not be predictive of the results of confirmatory clinical trials. Product candidates in confirmatory clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and/or feasibility clinical trials. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the physical conditions of the patient populations and the rate of dropout among clinical trial participants. Clinical trials of our product candidates may produce negative or inconclusive results. Even if our future clinical trial results show favorable efficacy, not all patients may benefit. Our product candidates may not suit the conditions of certain patients, and severe adverse events and complications may occur for some patients after the treatment procedure. If we decide or are required by regulators to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate or abandon our product development programs, or if we are unable to successfully complete clinical trials of our product candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be subject to substantial liabilities, (ii) be delayed in or even prevented from obtaining regulatory approval for our product candidates, (iii) obtain approval for indications that are not as broad as intended, (iv) have the product removed from the market after obtaining regulatory approval, (v) be subject to additional post-marketing testing requirements, (vi) be subject to restrictions on how the product is distributed or used; or (vii) be unable to obtain reimbursement for use of the product. Any of such events could materially and adversely affect our ability to commercialize the subject products and generate revenue.

We have relatively limited experience in sales and marketing activities, and we may not be able to expand or integrate our in-house sales and marketing force successfully.

Our ability to successfully market our products may involve more inherent risks, take longer time and cost more resources than it would if we were a company with sufficient experience launching such products. As of the Latest Practicable Date, we only commercialized several products mainly including our Pulmonary Nodule Localization Needle, Laparoscopic Single Port Multi-Channel Access Platform and Endoscopic Clip for Anastomosis and have limited experience in commercializing cryotherapy devices.

The success of our sales and marketing efforts depends on our ability to attract, motivate and retain qualified and professional employees in our sales and marketing team who have, among other things, the sufficient expertise in cryotherapy devices and are able to communicate effectively with medical professionals. Furthermore, we expect to hire more employees with relevant medical device experience and knowledge to strengthen our marketing and sales workforce. However, due to the intense competition for experienced personnel, we may be unable to attract, motivate and retain a sufficient number of qualified sales and marketing employees to support our business development and expansion, and our sales revenue and results of operations may be negatively affected.

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We may be unable to develop and commercialize our product candidates as anticipated if the third parties with which we contract for clinical trials do not perform in an acceptable manner or if these third parties do not successfully carry out their contractual duties or meet expected deadlines.

We rely on third parties, including clinical trial institutions, public hospitals, CROs and SMOs, to assist us in designing, implementing and monitoring our clinical trials. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. If any of these parties terminates its agreements with us, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all, and the development of the product candidates covered by those agreements could be substantially delayed. In addition, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocols, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. However, these third parties may not successfully carry out their contractual obligations, meet expected deadlines or follow regulatory requirements, including clinical and manufacturing guidelines and protocols. Moreover, if any of these parties fail to perform their obligations under our agreements with them in the manner specified in those agreements, the NMPA and/or other comparable regulatory authorities may not accept the data generated by those studies or relevant regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, which would increase the cost of and the development time for the relevant product candidate. If any of the preclinical studies or clinical trials of our product candidates is affected by any of the above-mentioned reasons, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business and prospects.

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

Our success depends in a large part on our ability to protect our proprietary technology, products and product candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technology, products and product candidates that we consider commercially important by filing patent applications in the PRC and other regions, relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories. In particular, we may not be able to use our patents to restrict competitors from developing and commercializing products identical or similar to the Bladder Cryoablation System in Europe, which could affect our commercialization of this product in Europe.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior deficiencies in the patent applications or the lack of novelty of the underlying invention or technology. We may also fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with our employees, contractors and other third parties who have access to confidential or patentable aspects of our research and development output, any of these parties may breach such agreements and disclose such output before a patent application is filed, jeopardizing our

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ability to seek patent protection. In addition, publications of discoveries in the scientific or patent literature often lag behind the actual discoveries. For instance, in China and other jurisdictions, patent applications for inventions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions.

Furthermore, the PRC has adopted the "first-to-file" system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, even after reasonable investigation we may be unable to determine with certainty whether any of our products, product candidates, processes, technologies, inventions, improvement and other related matters have infringed upon the intellectual property rights of others, because such third party may have filed a patent application without our knowledge while we are still developing that product, and the term of patent protection starts from the date the patent was filed, instead of the date it was issued. Therefore, the validity of issued patents, patentability of pending patent applications and applicability of any of them to our products or product candidates may be lower in priority than third-party patents issued on a later date if the application for such patents was filed prior to ours and the technologies underlying such patents are the same or substantially similar to ours. We may also be involved in claims and disputes of intellectual property infringement in other jurisdictions. In addition, under PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the CNIPA, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future are to be issued as patents, they may not be issued in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the PRC or other countries. We may be subject to a third-party pre-issuance submission of prior art to the CNIPA, or other related intellectual property offices, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or product candidates and compete directly with us without payment to us. Moreover, we may have to participate in invalidation proceedings before the CNIPA, or courts in China to determine patentability of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or the patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. Consequently, we do

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not know whether any of our technologies, products or product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

In addition, although various extensions may be available, the life of a patent and the protection it affords is limited. We may face competition for any approved product candidates even if we successfully obtain patent protection once the patent life has expired for the product. The issued patents and pending patent applications, if issued, for our product candidates are expected to expire on various dates as described in the paragraphs headed "Business—Intellectual Property Rights" in this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Third parties may initiate legal, administrative or other proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, and the outcome of such legal proceedings would be uncertain. Such proceedings could be costly and time consuming to defend, and could prevent us from developing or commercializing our product candidates, or delay the development or commercialization process.

We may be involved in allegations regarding infringements of intellectual property rights (including the use of computer software, trademarks, copyright and patents), and some of which may be raised by other market players as a way of malicious competition. These allegations, with or without merits, may lead to potential litigations, administrative proceedings, and other disputes. In addition, we may be subject to allegations, litigations or administrative proceedings because of intellectual property infringement committed by our employees or third-party collaborators (for instance, distributors or manufacturers where we purchased our computers or software).

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves an analysis of complex legal and factual issues, the determination of which is often uncertain. We may be unaware of third-party patents or patent applications, and given the dynamic area in which we operate, additional patents are likely to be issued that relate to aspects of our business.

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We face the risk of claims that we have infringed on third parties’ intellectual property rights in the countries where we operate, principally China. In addition, there can be no assurance that our employees have not used, or will not use in the future, proprietary know-how or trade secrets of their previous employers, if any, in their work for us, which could result in litigation against us. Prior to developing major new products, we evaluate existing intellectual property rights. However, our competitors may also have filed for patent protection which is not as yet a matter of public knowledge or claim trademark rights that have not been revealed through our searches of relevant public records. Our efforts to identify and avoid infringing on third parties’ intellectual property rights may not always be successful. Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Any claims of patent or other intellectual property infringement, even those without merit, could:

- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;
- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products or product candidates, if feasible;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party’s intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management;
- result in hospitals and physicians terminating, deferring or limiting their purchase of the affected products until resolution of the litigation;
- reduce the resources available for our development activities or any future sales, marketing or distribution activities; or
- result in securities analysts or investors perceive these results to be negative, which could have a substantial adverse effect on the [REDACTED] of our Shares.

In addition, new patents obtained by our competitors could threaten a product’s continued life in the market even after it has already been introduced.

Our business, results of operations and financial position could be adversely affected by the ongoing COVID-19 pandemic.

Our business operation has been, and may continue to be, negatively affected by the COVID-19 outbreak. For example, we experienced some delays in the patient enrollment for our feasibility clinical trials for COPD Cryospray System and Esophageal Cryospray System and for confirmatory clinical trial for Cryo RDN System in Shanghai from March 2022 to May 2022. Please refer to the paragraphs headed “Summary—Outbreak of COVID-19” and “Financial Information—Impact of the COVID-19 Outbreak” in this document for a detailed discussion of the relevant impact on us.

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While many of the restrictions on movements within China have been relaxed, there is great uncertainty around the future of the COVID-19 outbreak and how it will impact our operations. In particular, we cannot accurately forecast the potential impact of additional outbreaks as government restrictions are relaxed, further shelter-in-place or other government restrictions implemented in response to such outbreaks, or the impact on the ability of our suppliers and other business partners to remain in business as a result of the ongoing pandemic or such additional outbreaks. With the uncertainties surrounding the COVID-19 outbreak until a cure and vaccine has been discovered, the threat to our business disruption and the related financial impact remains.

RISKS RELATING TO OUR PRODUCTS AND PRODUCT CANDIDATES

Risks Relating to the Development of Our Product Candidates

Clinical product development involves a lengthy and expensive process with an uncertain outcome.

According to a catalogue issued by the NMPA, medical devices are classified into three different categories, Class I, Class II and Class III, depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Most of our product candidates are classified as Class III medical devices. To obtain product registrations for medical devices of Class III in China, we need to conduct, at our own expense, adequate and well-controlled clinical trials to demonstrate the safety and efficacy of our product candidates (except for those exempted from clinical trial requirements in accordance with applicable laws and regulations).

Clinical testing is expensive and can take multiple years to complete, and its outcome is inherently uncertain. There can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication. We may experience numerous unexpected events before and during the clinical trials that could delay or prevent us from obtaining regulatory approval or commercializing our product candidates, including but not limited to:

- regulators or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our inability to reach agreements on acceptable terms with prospective CROs, SMOs and hospitals as trial centers, the terms of which can be subject to extensive negotiation and may vary significantly among different trial centers;
- manufacturing issues, including problems with supply quality, or obtaining sufficient quantities of a product candidate for use in a clinical trial in a timely manner;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

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- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of unexpected characteristics or a finding that participants are being exposed to unacceptable health risks (including deaths in the worst case scenario);
- regulators or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate and we are unable to obtain additional funding in a timely manner, or at all; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commercialize our approved products and generate related revenues. Any of these occurrences may adversely affect our business, financial condition and prospects to a significant extent.

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

The timely completion of clinical trials in line with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties or delays in patient enrollment in our clinical trials for a variety of reasons, including but not limited to:

- the size and nature of the patient population;
- the size of the study population required for the analysis of the trial's primary endpoints;
- our ability to obtain and maintain patients' consents;
- the patient eligibility criteria defined in the protocol;
- the accessibility of trial sites for the patients;
- our ability to recruit clinical trial site investigators with sufficient competence and relevant experience; and
- the patients' perceptions as to the potential advantages and side effects of the product candidates being studied in relation to other available products, product candidates or therapies.

Our clinical trials will likely compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead

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opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the projected clinical trials. If we experience delays in the completion of, or even termination of, any clinical trial of our product candidates, our ability to obtain requisite regulatory approvals, commercialize our products, commence product sales and generate revenues will be jeopardized. Any of these occurrences may have a material adverse effect our business, financial condition and prospects.

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

In order to maintain our competitiveness, we must keep pace with new technologies and methodologies. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. Although technical innovations often require substantial time and investment before we can determine their commercial viability, we intend to continuously enhance our technical capabilities in research and development. We cannot assure you that we will be capable to identify new technological opportunities, enhance or adapt to new technologies and methodologies, develop and bring new or enhanced products to market, obtain sufficient intellectual property protection for such new or enhanced products, obtain the necessary regulatory approvals in a timely and cost-effective manner, or achieve market acceptance if such products are launched. Any failure to do so could harm our business and prospects.

Our employees, collaborators, service providers, independent contractors, principal investigators, vendors, CROs and SMOs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in delay or failure to develop our product candidates.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, vendors, CROs and SMOs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these individuals and institutions could include intentional, reckless or negligent conduct or unauthorized activity that violates the regulations of the NMPA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information and data to such regulatory authorities, or data privacy, security, fraud and abuse and other healthcare laws and regulations in the PRC and other relevant jurisdictions.

Misconduct by these parties could involve the creation of fraudulent data in our preclinical studies or clinical trials. Their improper activities could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of medical devices.

We may not be able to identify and deter employees' and third parties' misconduct, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those

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actions could severely delay our research and development programs, or result in failure to obtain regulatory approval for our product candidates. The regulatory authorities may also impose civil, criminal and administrative penalties, damages and monetary fines on us, which could materially and adversely affect our reputation and business operation.

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

Risks Relating to the Commercialization of Our Product Candidates

If physicians and hospitals are not receptive to our product candidates, our results of operations may be negatively affected.

Physicians and hospitals play important roles in recommending and deciding what products to be used. They not only provide professional advice but also offer help throughout the entire therapeutic procedures from candidate screening, operation assistance to post operation follow-up visit. Our strategic marketing model provides that our in-house marketing force actively works with physicians and hospitals. We will endeavor to convince them as to the distinctive characteristics, advantages, safety and cost effectiveness of our products as compared to our competitors' products, and train physicians and hospitals in the proper application of our products. If our products and product candidates (upon commercialization) are not widely accepted by physicians and hospitals, our sales of our currently commercialized products may decline, and we may not be able to effectively market our product candidates upon commercialization.

In addition, many of our products or product candidates represent innovative therapies in China or even globally. Physicians face a learning process to become proficient in the use of some of our products and product candidates, which may take a longer time than we expected. Encouraging physicians to dedicate their time and energy necessary for adequate training remains challenging, and we may not be successful in these efforts. If physicians are not properly trained, they may misuse or ineffectively use our products and product candidates, which may also result in unsatisfactory patient treatment outcomes, patient injury, negative publicity or lawsuits against us, any of which could have a significant adverse effect on our reputation, business, financial condition, results of operations and prospects. Following completion of training, we also rely on trained physicians to advocate the benefits of our products in the marketplace. If we are not able to enhance our product awareness and receive recognition from these physicians, other physicians and hospitals may not be inclined to use our products, and our results of operations may be adversely affected.

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

The commercial success of our products depends upon the degree of market acceptance they can achieve, particularly among hospitals and physicians. For example, as a novel treatment modality, liquid nitrogen-based cryoablation may fail to receive broad acceptance from patients or physicians as

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anticipated. We may need to make significant efforts to educate the market, to convince patients of the benefits of our cryotherapy, and to train the physicians to properly use the cryotherapy devices. We cannot guarantee that our efforts in this regard would be successful. If any of our future approved products fail to gain sufficient market acceptance by physicians, patients, third-party payors or others in the industry, the sales of our future approved products will be adversely affected, and we may fail to effectively market our product candidates upon commercialization. Physicians, patients and third-party payors may prefer other novel products to ours. If our products do not achieve an adequate level of acceptance, we may not be able to generate significant product sales revenues and to achieve profitability. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

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

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

In the medical device industry, it is customary to rely on distributors for sale of medical devices to hospitals. During the Track Record Period and up to the Latest Practicable Date, we sold all of our commercialized products to third-party distributors, which then sell these medical devices to hospitals and/or sub-distributors. We intend to continue engaging distributors to sell our products in the foreseeable future. However, we may not be able to identify or engage a sufficient number of distributors with an extensive sales network. Furthermore, all products we now commercialize are non-cryotherapy products. However, we aim to commercialize more products, including NOTES interventional cryotherapy products and vascular interventional cryotherapy products in the future, and we cannot assure you that the existing distributors that we now engage have adequate sales network for our future products. We may either educate our existing distributors for our new products, or engage new distributors with different sales network, which attempts may fail or take a lot of time. For further information, see "Business — Sales and Marketing — Our Sales and Distribution Arrangements" in this document. If our distributors fail to expand their sales network, or otherwise encounter any difficulties in selling our products, our business, results of operations and prospects may be materially and adversely affected.

In addition to ensuring our reputation through high quality products and responsive services, our well-trained sales team works with our distributors to help them become more sophisticated. We also provide our distributors with technical support, including training in the basic technologies of our products, participating in presentations to physicians and hospitals, and assisting in preparing documents for contracts awarded through competitive biddings and tenders. Our distributors face a learning process with respect to our products, particularly for those newly introduced to the market. We cannot assure you that our distributors will be able to gain the required knowledge in order to market our products effectively in a timely manner or at all.

In addition, we have limited control to manage the activities of our distributors, who are independent from us. We cannot assure that our distributors will not violate our distribution agreements with them. Such violations may include, among other things, (i) failing to meet target sales amounts; (ii) selling our products outside their designated distribution territories or to hospitals without further authorization; (iii) selling our products at prices below our designated lowest price; (iv) failing to comply with applicable laws or regulatory requirements when marketing, promoting or selling our products; (v) failing to provide proper training and other services to our end customers; or (vi) selling products that compete with ours. Failure to adequately manage our network of distributors, or non-compliance by distributors with our distribution agreements, violations of applicable laws and other illegal or inadequate practices by distributors could harm our corporate reputation and disrupt our sales, and our financial condition and results of operations could be materially and adversely affected.

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

Our future growth and success significantly depend on our ability to successfully market our products to hospitals and other medical institutions through our distributors. Hospitals and other medical institutions may organize public tenders either by themselves or through local governments. The procedures of such public tenders vary from hospital to hospital and from region to region, and there could be uncertainties with respect to the timing of such procedures. As a result, we are primarily

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dependent on experienced local distributors to assist us during such procedures. However, we may not always be able to locate a sufficient number of experienced local distributors to sell our products to hospitals and other medical institutions.

Furthermore, even if we could locate a sufficient number of experienced distributors, our bids during the public tender process may not be successful and our products may not be chosen for a number of reasons, including where: (i) our prices are not competitive; (ii) our products fail to meet the technical or quality requirements imposed by the hospitals or are less clinically effective than competing products; (iii) our reputation is adversely affected by unforeseeable events; or (iv) our service quality or any other aspect of our operation fails to meet the relevant requirements. If we fail in the tender process, we may face difficulties in maintaining the existing level of sales of our products, and we may find it difficult to sell our product candidates (upon commercialization) and our revenue may decline, materially adversely affecting our results of operations and financial condition.

The policies of centralized procurement of high-value medical consumables set by the PRC government may cover our products in the future, and the prices of our products may experience downward changes, which in turn may have a material adverse impact on our revenue, financial condition and results of operation.

Since 2007, China started to adopt a centralized procurement regime in an effort to regulate prices of medical devices through group procurement at the provincial level. In particular, in order to improve the pricing mechanism and reduce the falsely high prices of high-value medical consumables, the General Office of the State Council issued the Reform Plan for Governance of High-value Medical Consumables (《治理高值医用耗材改革方案》) (the “**Reform Plan**”) on July 19, 2019, exploring the classified and centralized procurement of high-value medical consumables. For details, see “Regulatory Overview—Laws and Regulations Relating to Administration of Medical Devices—Tender Management for Medical Device Procurement” in this document. On November 5, 2020, Tianjin Medical Purchasing Center implemented the first national-level centralized procurement of high-value medical devices in China.

As of the Latest Practicable Date, our products and product candidates were not included in the centralized procurement regime and there was generally no special tender or bidding process or price guidance set on such products for enterprises by the PRC government. For details about our pricing strategies, please see “Business—Sales and Marketing—Pricing” in this document. Nevertheless, there are uncertainties whether the centralized procurement scope would be expanded in the future, resulting in the inclusions of our products or product candidates (upon commercialization). Moreover, if any products comparable or similar to our products were included in the centralized procurement, patients’ willingness to use our products might be materially and adversely affected and we might be forced to change our pricing strategy. If any or all of the foregoing were to occur, our sales revenue may decrease, which in turn will have a material adverse impact on our financial condition and results of operation.

Downward changes in the pricing of our products may have a material adverse effect on our business and results of operations.

In line with market practice, we expect to price our product candidates (upon commercialization) by taking into consideration a variety of factors, including pricing guidance and centralized procurement policies set by the government authorities, bargaining power and preferences of hospitals, prices of similar products offered by our competitors, our operating costs and the continuous upgrades of existing products, among others, and some of which are beyond our control:

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If the PRC government issues pricing guidance for our product candidates (upon commercialization), it may negatively affect the price at which we can sell our products and therefore have a material adverse effect on our business and results of operations. We may also face downward pricing pressure if our products are included in the medical insurance reimbursement list, even if such inclusion in the medical insurance reimbursement list is expected to increase the sales volume of our products.

Hospitals may gain more bargaining power depending on the availability of alternative products, demands of patients and the preferences of physicians. If certain hospitals seek to lower retail prices of our product candidates (upon commercialization), our future profitability may be adversely affected.

Furthermore, along with our increasing efforts to promote our product candidates, as well as our competitors’ continuous development of similar product candidates, awareness of these products is expected to increase. More competing products may become available, which will offer alternatives for hospitals and patients to choose.

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

Even if we are able to commercialize any of our product candidates, our sales may be affected by the level of medical insurance reimbursement patients receive for using our products.

The availability of governmental and private health insurance in China for treatments using our products will influence our ability to sell our products. China has a complex medical insurance system that is currently undergoing reform. The governmental insurance coverage or reimbursement level in China for new procedures and the medical devices used in such procedures is subject to significant uncertainty and varies from region to region, as local government approvals for such coverage must be obtained in each geographic region. In addition, the PRC government may change, reduce or eliminate the governmental insurance coverage then available for treatments using our products. Please refer to the paragraphs headed “Regulatory Overview—Other Laws and Regulations—Laws and Regulations on Employment and Social Security” in this document for more details. We cannot assure you that our product candidates (upon commercialization) will be included in the medical insurance reimbursement list at all times, if at all. To the extent that our products are not included in the medical insurance reimbursement list or if any such insurance schemes are changed or canceled which result in any removal of our products from medical insurance catalogue, patients may choose, and hospitals may recommend alternative treatment methods, which would reduce demand for our products, and our sales may be adversely impacted or not able to achieve our expected levels, which may lead to a material and adverse effect on our business, results of operations and financial condition.

In addition, insurance companies in China tend to reimburse patients for a higher percentage of the product cost if they use a medical device manufactured by a Chinese domestic company as opposed to an imported device. We cannot guarantee that insurance companies will continue to adopt this favorable policy in the future.

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Moreover, we may need to lower the prices of our products in order to have them included in the medical insurance reimbursement list, while such price cut and reimbursement may not necessarily cause our sales to increase and our results of operations may be adversely affected.

Risks Relating to Extensive Government Regulations

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

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

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

The regulatory approval processes are lengthy, expensive and inherently unpredictable.

We currently intend to market a substantial portion of our product candidates in China in the foreseeable future. We are required to obtain the NMPA's or its local counterpart's approval before we can market our product candidates in China. As the PRC government has been tightening the regulatory control over the medical device industry in recent years, the regulatory approval process tends to take longer to complete than before. Significant effort, expense and time are required to bring our product candidates to market in compliance with the regulatory process, and we cannot assure you that any of our product candidates will be approved for sale.

Before obtaining regulatory approvals for the commercial sale of any product candidates for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. We are also required to report any serious or potentially serious incidents involving our product candidates to the NMPA or the local counterparts. When we submit a filing application to the NMPA, the NMPA will decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the NMPA. The NMPA may also slow down, suspend or cease review of our applications and any of these could prolong the registration process of our product candidates. Even if regulatory approval or clearance of our product candidates is granted, the approval or clearance could limit the uses for which our product candidates may be labeled and promoted, which may in turn limit the market for our product candidates.

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Furthermore, results of the regulatory approval process are unpredictable. We could fail to receive regulatory approval for product candidates for many reasons, including: (i) failure to begin or complete clinical trials; (ii) failure to demonstrate that a product candidate is safe and effective; (iii) failure to deliver clinical trial results to meet the level of statistical significance required for approval; (iv) data integrity issues related to our clinical trials; (v) government authority's disagreement with our interpretation of data from preclinical studies or clinical trials; (vi) changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols; (vii) regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our product candidates or other products; (viii) failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; (ix) clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial; and/or (x) rejection by the relevant authorities to approve pending applications or supplements to approved applications filed by us or suspension, revocation or withdrawal of approvals.

We are also required to obtain various governmental approvals in the relevant jurisdictions if we determine to sell our product candidates in international markets. Regulatory authorities outside of China also have requirements for approval of medical devices for commercial sale with which we must comply prior to marketing in those areas. Foreign regulations may vary from jurisdiction to jurisdiction and may be different from PRC regulations and NMPA requirements, and therefore could delay or prevent the introduction of our product candidates in those areas. Approval processes vary among jurisdictions and can involve additional product testing and validation and additional administrative review periods, and obtaining regulatory approval in one jurisdiction does not mean that regulatory approval will be obtained in any other jurisdiction. Additional time, efforts and expenses may be required to bring our product candidates to international markets in compliance with different regulatory processes.

The process to obtain regulatory approval for medical device product candidates is long, complex and costly both inside and outside China. Even if our product candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following an approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA and/or comparable regulatory authorities. Regulatory approvals for any of our product candidates may also be withdrawn.

Undesirable adverse events related to our products and product candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved production label, limit market acceptance or result in significant negative consequences following any regulatory approval such as regulatory disciplines and other liabilities.

Some of our product candidates are still considered as emerging and relatively novel therapeutics in China. Undesirable side effects caused by our product candidates could (i) cause us or regulatory authorities to interrupt, delay or halt clinical trials; (ii) affect patient recruitment or the ability of enrolled patients to complete the trial; (iii) adversely impact our ability to obtain regulatory approval in China and other jurisdictions including result in a more restrictive label on our product candidates, and/or (iv) subject us to substantial damages and liabilities. By their nature, clinical trials only assess a sample of the

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potential patient population. Side effects may only be uncovered when a significantly larger number of patients is exposed to the products. If undesirable side effects caused by our product candidates are identified after we receive regulatory approval for such product candidates, a number of potentially significant negative consequences could follow, including, among others:

- the relevant products may be recalled, withdrawn or seized;
- regulatory authorities may withdraw or limit their approval of our product candidates;
- we may be required to change the way our products are distributed or administered, conduct additional clinical trials, change the labeling or add additional warnings on the labeling of such products;
- we may be required to develop risk evaluation and mitigation measures for the products, or if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;
- we may be subject to regulatory investigations and government enforcement actions;
- we may be required to suspend marketing or remove relevant products from the marketplace;
- a severe decrease in the demand for, and sales of, the relevant products;
- we could be sued and held liable for injury caused to individuals using our products; and
- our reputation, business and prospects may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular products, and could harm our reputation, business, financial condition and prospects significantly. For instance, in the clinical trial for the Endoscopic Clip for Anastomosis, there was a comparatively high rate of adverse events, even though most of them were minor and unrelated to the device. The use of OTS Clips in China could be limited mainly by adverse events, which may prevent us from gaining or maintaining market acceptance for the Endoscopic Clip for Anastomosis.

We or parties on whom we rely on may fail to maintain or renew the necessary permits, licenses and certificates required for the development and production of our product candidates.

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products, including but not limited to the Registration Certificate for Medical Device (醫療器械註冊證) and the Medical Device Production License (醫療器械生產許可證). For details, please refer to the paragraphs headed “Regulatory Overview—Laws and Regulations Relating to Administration of Medical Devices” in this document. Furthermore, third parties, such as research institutions, distributors and suppliers on whom we may rely to develop, produce, promote, sell and distribute our products, may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the third parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits,

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licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates in a timely manner or at all.

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

Our products will be subject to ongoing or additional regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China and other jurisdictions where we market or sell our products. As such, we will be subject to continual review and inspections by the regulators in order to assess our compliance with applicable laws and requirements and adherence to commitments we made in any application materials with the NMPA or other authorities.

Any approvals that we receive for our product candidates may be subject to other conditions which may require potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of our product candidates. Such limitations and conditions could adversely affect the commercial potential of our future approved products.

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

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines or warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our products and pipeline products; and/or
- injunction or the imposition of civil or criminal penalties.

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We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or abroad, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

Changes in regulatory requirements may adversely affect our business.

In China and some other jurisdictions, a number of legislative and regulatory changes and proposed changes regarding healthcare could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our products and any product candidates for which we obtain regulatory approval. In recent years, there have been and will likely continue to be efforts to enact administrative or legislative changes to healthcare laws and policies, including measures which may result in more rigorous coverage criteria and downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to commercialize our products and generate revenue.

We cannot be sure whether additional legislative changes will be enacted, or whether NMPA regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be. For example, on February 9, 2021, the amended Regulation for Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) (the “**Amended Medical Device Regulations**”) was released by the State Council of the People’s Republic of China, which went into effect on June 1, 2021. As a medical device company, after the effectiveness of the Amended Medical Device Regulations, the requirements of clinical trial, sales and regulation would be changed. To be specific, the Amended Medical Device Regulations adopts a nationwide marketing authorization holder (“**MAH**”) system for medical devices and makes clear that the medical device MAH is responsible for the safety and efficacy of the device throughout its whole life cycle.

The implementation status of the “Two-Invoice System” for medical consumables may have material impact on our business.

In July 2019, the General Office of the State Council issued the *Circular on High-value Medical Consumables* (《治理高值醫用耗材改革方案》), which encouraged local governments to adopt the “Two-Invoice System” for high-value medical consumables. The “Two-Invoice System” refers to a mechanism where only up to two invoices are issued along the chain of distribution process, with one invoice issued by the manufacturer to the distributor, and the other issued by the distributor to the hospitals and other medical service providers. The “Two-Invoices System” aims to eliminate the multiple layers of distributors involved in the process, to streamline the procurement and distribution process, and to ensure more transparent prices for pharmaceuticals and medical consumables. For details, see “Regulatory Overview—Laws and Regulations Relating to Administration of Medical Devices—‘Two Invoice System’ (兩票制) for Medical Devices” in this document.

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According to our PRC Legal Adviser, as of the Latest Practicable Date, the progress of implementation of the “Two-Invoice System” for medical consumables varies in different provinces, autonomous regions and municipalities (collectively, “**provinces**”) in China, and in some provinces, the implementation of the “Two-Invoice System” for medical consumables was not mandatory. To date, no local competent authorities of the provinces in which our products were sold has taken the position that the “Two-Invoice System” applies to our products. For details, see “Business—Sales and Marketing—Our Sales and Distribution Arrangements—Management of our Distribution Network—Implication of and Compliance with the ‘Two-Invoice System’” in this document.

As the implementation of the “Two-Invoice System” is still at an early stage, and the interpretation and enforcement of such system in the medical device industry are evolving and subject to uncertainty, we cannot predict how the implementation and enforcement will evolve in different provinces in China, or whether and how that will affect our business and results of operations in the future. In addition, although we could enter into supplemental agreements with our distributors, in order to ensure that the distributors will resell our products directly to hospitals, we cannot assure you that all our distributors are willing to enter into such supplemental agreements with us; even if they are, we cannot assure you that they will not breach such contractual obligations. If any of our distributors, without our permission, sell our products to sub-distributors in violation of the relevant laws and regulations related to the “Two-Invoice System”, we might be exposed to certain legal consequences.

Risks Relating to Manufacture and Supply of Our Products and Product Candidates

The manufacture of our products and product candidates is highly complex and subject to strict quality controls. Our business could suffer if our products or product candidates are not produced in compliance with all the applicable quality standards.

The manufacture of many of our products and product candidates is highly complex and subject to strict quality controls. We have established a quality control and assurance system and adopted standardized operating procedures in order to prevent quality issues with respect to our products and product candidates and operation processes. For further details of our quality control and assurance system, please refer to the paragraphs headed “Business—Quality Control” in this document.

Despite our quality control and assurance system and procedures, we cannot eliminate the risk of product defects or failure. Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, defects or other issues in raw material, or human error. Furthermore, if contaminants are discovered in our product candidates or in our manufacturing facilities, we may need to close our manufacturing facilities for an extended period of time to investigate and remedy the contamination. In addition, stability failures and other issues relating to the manufacture of our product candidates could occur in the future. Although closely managed, disruptions can also occur during the implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions.

Failure of our products and product candidates to meet the requirements of the NMPA or other applicable regulatory authorities or our internal quality standard could result in patient injury or death, product recalls, safety alerts or withdrawals, license revocation or regulatory fines, product liabilities claims or other negative effects that could seriously harm our reputation, business and results of operations.

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We mainly rely on our two production facilities in Shanghai and Ningbo for the manufacturing of our products and product candidates; any disruptions to the operation of our production facilities could materially adversely affect our business, financial condition and results of operations.

We manufacture, assemble and test our products at our two production facilities in Shanghai and Ningbo. For details, see “Business—Our Production Facilities and Processes—Production Facilities” in this document. The operation of our production facilities may be substantially interrupted due to a number of factors, many of which are outside of our control, including but not limited to fires, floods, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars, loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities, and regulatory changes.

If the operation of any of our production facilities is substantially disrupted, we may not be able to replace the equipment at such facilities, or use a different facility to continue production in a timely and cost-effective manner. As a result, we may fail to fulfill contract obligations or meet market demand for our products, and our business, revenue and profitability could be materially adversely affected.

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

Most of our current product candidates are classified as Class III medical devices. Such classifications represent a high risk to the human body and requires a high level of supervision to ensure safety and effectiveness. We may be subject to product liability claims if our products have quality issues. For example, we may be sued if our product candidates are perceived to cause injury or are found to be otherwise unsuitable during clinical testing and manufacturing. Any such product liability claims may include allegations of defects in design, component failure, manufacturing error, a failure to warn of dangers inherent in the medical device product, negligence or strict liability.

Further, we cannot ensure that physicians will strictly and accurately follow our instructions on the proper usage of our products and product candidates. If our product or product candidates are used incorrectly by physicians, injury may result, which could require review and corrective action by the manufacturer or even give rise to product liability claims against us.

Should there occur any misdiagnosis or faulty management of patients involving the use of our products including the Core Products, we may be held liable under certain circumstances, either during or after clinical development stage. According to our PRC Legal Adviser, there are mainly three circumstances in which we may be liable:

- if a patient gets injured due to the fault or operating error of the medical personnel during the process of diagnosis and treatment, the medical institute is liable for all damages and compensation arising therefrom;
- if a patient’s injury is due to the inherent product defect of our products, we may be held liable for the patient’s damages; and

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- if a patient's injury is caused by both the operating errors of the medical personnel and the inherent product defects, the medical institution and us may be jointly and severally liable. If the percentage of fault can be determined between the infringing parties, each of them will be ultimately liable for an amount equivalent to their corresponding fault. If the percentage of fault can not be determined, then each of the infringing parties bears the liability equally.

Any serious failures or defects could cause us to withdraw or recall products, and subject us to product liabilities, which may damage our brand name and may have a material adverse effect on our business, financial condition, results of operations and prospects. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material customer complaint or product return from customers.

We have purchased insurance for our clinical trials as required by applicable laws and regulations. However, the coverage of such insurance policies may not be broad enough or the indemnifiable amount may not be sufficient to cover all of our losses incurred by the relevant product liabilities. Pursuant to the applicable PRC laws and regulations, in the event a trial subject suffers from personal injuries or death in relation to a clinical trial conducted for a medical device, the sponsor for the clinical trial could be found liable for the relevant damages regardless of whether the relevant medical device was defective or not. We may incur significant liabilities for any such event occurred in the clinical trials for our product candidates. In this regard, if we cannot successfully defend ourselves against, obtain indemnification from our collaborators for product liability claims, or acquire sufficient product liability insurance at an acceptable cost, we may incur substantial liabilities or be required to limit commercialization of our product candidates, and our business, financial condition, results of operations and prospects may be materially and adversely affected.

If we fail to increase our production capacity as planned, our business prospects could be materially and adversely affected.

To increase our production capacity in anticipation of our commercialization of a few product candidates (after obtaining the approval), we plan to expand our manufacturing capacity in our production facilities. Changes in the manufacturing process or procedure, require prior review by regulatory authorities and/or approval of the manufacturing process and procedures in accordance with applicable requirements. Companies manufacturing medical devices in China are required to obtain permits and licenses issued by various government authorities, including but not limited to the medical device production permit (醫療器械生產許可證) and the medical device operation permit (醫療器械經營許可證) if such manufacturing companies store and sell medical devices in places other than their domiciles and the places of production of medical devices. Such permits, licenses and certificates are subject to periodic reviews and renewals by the relevant government authorities, and the standards of such reviews and renewals may change from time to time. There can be no assurance that the relevant authorities will approve our applications in the future. Any failure by us to obtain, maintain or renew the necessary permits, licenses and certificates could disrupt our business, which in turn may have a material adverse effect on our business and operating results.

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Other than the risks relating to application of requisite licenses and permits, we could also face other risks in implementing our commercial manufacturing plan, including construction delays, failure to adopt new manufacturing techniques, implement effective quality control, recruit a sufficient number of qualified staff to support the increase in production capacity, or engage qualified subcontractors with sufficient manufacturing capacity in a cost-effective manner and on terms acceptable to us. Given the complexity of our product candidates, competition for qualified manufacturing staff is intense. New manufacturing staff are generally required to undergo sufficient training before they can commence work on our production lines. In addition, in the event of any significant increase in market demand, we may not be able to find sufficient external subcontractors to help produce our products, and even if we could engage third parties to produce a portion of our products, we would be exposed to the risks that the third parties may not manufacture products meeting our specifications or in sufficient volumes to meet market demand. Therefore, we cannot assure you that we will be able to establish or increase our commercial manufacturing capacity, develop advanced manufacturing techniques, process controls in the manner we contemplate, recruit a sufficient number of qualified manufacturing staff, or engage qualified subcontractors with sufficient production capacity, or at all. In the event of any aforementioned failure, we may not be able to capture the expected growth in demand for our products, which could materially and adversely affect our business prospects. Moreover, our plans to establish and increase our commercial manufacturing capacity require significant capital investment, and the actual costs of our commercial manufacturing plan may exceed our original estimates, which could materially and adversely affect the realization of expected return on our expenditures.

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

We rely on a limited number of third-party suppliers to supply key raw materials used in the research, development and manufacturing of our products and product candidates for reasons of quality assurance, cost effectiveness, availability, or constraints resulting from regulatory requirements. In 2020, 2021 and the eight months ended August 31, 2022, purchase from our five largest suppliers accounted for approximately 31.6%, 24.3% and 9.6% for our total purchases, respectively. We cannot assure you that we will be able to secure a stable supply of qualified raw materials at all times going forward, even though we believe we have built up stable relationships with our existing suppliers. We cannot assure you that we will be able to identify an alternative qualified supplier in a timely manner or at all, in the event any of our existing suppliers terminate their contracts with us or are no longer qualified.

Some of our suppliers are located outside China, therefore trade or regulatory embargoes imposed by foreign countries or China could result in delays or shortages of our raw materials. If we are forced to purchase raw materials from domestic suppliers whose prices are higher than those offered by foreign suppliers, our costs will increase and our business could be harmed. Furthermore, general economic conditions could also adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products. In addition, due to the rigorous regulations and requirements of the NMPA and/or foreign regulatory authorities regarding the manufacture of our products (including the need for approval of any change in supply arrangements), we may have difficulty establishing additional or replacement sources in a timely manner or at all if the need arises. Any change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology, and the loss of existing supply contracts could have a material adverse effect on us.

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

Our production processes require substantial amounts of raw materials and components, some of which may be susceptible to fluctuations in price and availability. Significant fluctuations in raw material and component prices and availability will have a direct and negative impact on our financial position. During the Track Record Period, our raw materials were generally available and sufficient for our demands, and their prices from our suppliers were generally stable. However, we cannot assure you that such situation will continue in the future. The prices of our raw materials may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, natural disasters such as fires, outbreak of epidemics or diseases such as COVID-19 and the PRC and global economic conditions. A significant increase in the costs of raw materials may increase our costs and negatively affect our financial position and, more generally, our business, financial conditions, results of operation and prospects. In addition, as we rely on certain overseas suppliers for some of our raw materials and components, any changes on the tariff policies, trade restrictions or barriers may adversely affect our business.

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

To manage our development progress appropriately and operate our business successfully, we need to manage our inventory for our product candidates effectively to ensure immediate delivery for clinical trial use when required. Our inventory consists of raw materials, work in progress, finished goods and goods shipped in transit. We regularly monitor our inventory to reduce the risk of overstocking and damages. We physically check and count all inventory twice a year to identify materials that are damaged, expired to soon-to-be expired. In particular, as our product candidates are highly exacting and complex medical devices, the inventories of our product candidates are exposed to risks associated with damages from outside environment such as accidental drop and squeeze. Although we have regularly checked and recorded the relevant statistics of our inventory of product candidates, we cannot assure you that such inventory will not be damaged or impaired, as our storage may encounter unforeseeable events including fires, floods, earthquakes, power outages, fuel shortages, mechanical breakdowns and other man-made or natural calamities. If our inventory of product candidates are damaged or impaired, our progress of clinical trials may be delayed, which in turn will have an adverse effect on our business and results of operation.

Risks Relating to Our Intellectual Property Rights

Failure to adequately protect our intellectual property rights may adversely affect our reputation and disrupt our business.

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

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infringing products to certain jurisdictions where we have patent protection but where enforcement rights are not as strong as those in certain other countries. These products may compete with our products and product candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Our success depends, in part, on our ability to protect our proprietary technologies. We have built an intellectual property portfolio in China and other overseas jurisdictions to protect our technologies, inventions and know-how and ensure our future success with commercializing our products. As of the Latest Practicable Date, we owned 110 registered patents and 44 pending patent applications in China and overseas. For more details, see "Business—Intellectual Property Rights" in this document. Due to the different regulatory bodies and varying requirements in these jurisdictions, we cannot assure you that we will be able to obtain patent protection for all or any aspects of our products in all or any of these jurisdictions. The process of seeking patent protection can be lengthy and expensive, and we cannot assure you that our patent applications will result in patents being issued, or that our existing or future issued patents will be sufficient to provide us with meaningful protection or commercial advantage. Since many of our current or potential competitors have substantial resources and have made substantial investments in competing technologies, we cannot assure you that they do not have, and will not obtain, patents that will prevent, limit or interfere with our ability to make, use or sell our products in either China or abroad. In addition, if we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our products and product candidates could be found invalid or unenforceable if being challenged in court or before the CNIPA or courts or related intellectual property agencies in other jurisdictions.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

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Defendant counterclaims alleging invalidity or unenforceability are commonplace, a third party can assert invalidity or unenforceability of a patent on numerous grounds. Third parties may also raise similar claims before administrative bodies in China or abroad, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we, our patent counsel, and the patent examiners could be unaware of invalidating prior art during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

Periodic maintenance fees on any issued patent are due to be paid to the CNIPA and other patent agencies in several stages over the lifetime of the patent. The CNIPA and various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

Depending on decisions by the National People's Congress of the PRC (the "NPC") and the CNIPA, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any.

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

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our product candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, corporate collaborators and other third parties. We also enter into employment agreements with our employees that include undertakings regarding

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assignment of inventions and discoveries. However, non-disclosure agreements with employees, contractors and other parties may not adequately prevent disclosures of our trade secrets and other proprietary information. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, some of our employees, including our senior management, were previously employed at other medical device companies, including our competitors or potential competitors. Some of these employees may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any material threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, and contractors involved in our research and development activities to execute agreements assigning all intellectual property rights to us, we may be unsuccessful in enforcing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks

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similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

Our current revenue is generated from sales of a limited number of medical consumables.

During the Track Record Period, the sales of certain medical consumables, such as the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform, contributed to a majority of our revenue. Prior to our successful commercialization of our cryotherapy devices, we expect to continue to derive all of our revenue from sales of medical consumables in the near future. Continued market acceptance and demand for these medical consumables are thus critical to our revenue in the near future. If we are unable to manufacture or sell these products due to commercial, regulatory, intellectual property or any other reasons, or if demand for these products is reduced due to the ever increasing competition or advances in alternative products, our revenue would significantly decline.

We had net cash outflows from our operating activities during the Track Record Period and we will need to obtain additional financing to fund our operations. Failure to obtain financing may materially affect the development of our product candidates and the commercialization of our approved products.

Our product candidates will require completion of clinical development, regulatory review and significant marketing efforts which require substantial investment before we can commercialize the future approved products and generate revenue. Since our inception, we have invested a significant portion of our financial resources in the development of our product candidates. We had net cash outflows from our operating activities of RMB34.2 million, RMB62.5 million and RMB60.0 million in 2020, 2021 and the eight months ended August 31, 2022, respectively. Whether we can generate profit from our operating activities largely depends on the successful commercialization of our future product candidates, and we cannot assure you that we will be able to generate positive cash flows in the future.

We expect to continue to spend substantial amounts of capital on conducting research and development activities, advancing the clinical development of our product candidates and commercializing our products upon approval. However, our existing capital resources may not be sufficient for us to complete all of our planned development and commercialization of our current product candidates for the anticipated indications and to initiate and conduct additional product development programs. Accordingly, we will need further funding through public or private offerings, debt financing and/or other sources. We cannot assure you that we will be able to secure sufficient financial resources to support our operations. Our future funding requirements will depend on many factors, including:

- the progress, timing, scope, costs and outcome of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials and the completion of clinical trials;

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- the outcome, timing and cost of regulatory approvals of our product candidates;
- the cost of filing, prosecuting, defending and enforcing any patent claims, trade secret and other intellectual property rights;
- the cost and timing of development and completion of commercial-scale manufacturing activities;
- selling and marketing costs associated with our existing or future product candidates, including the cost and timing of building up and expanding our sales and marketing team;
- cash requirements of any future acquisitions and/or the development of other product candidates;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish; and/or
- our headcount growth and associated costs.

We cannot assure you that we will have sufficient financing from other sources to fund our operations. Even if we resort to other financing activities, we may not be able to obtain the financing on terms acceptable to us, or at all, including financing costs and other commercial terms. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts, which may materially and adversely affect our continued business operations.

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

During the Track Record Period, our prepayments, other receivables and other assets primarily consisted of (i) amounts due from related parties; (ii) prepayment to suppliers; (iii) employee reserve fund; (iv) [REDACTED]; and (v) deposits. As of December 31, 2020, 2021 and August 31, 2022, our prepayments, other receivables and other assets amounted to RMB9.9 million, RMB19.8 million, and RMB30.6 million, respectively.

We conduct assessments on the recoverability of prepayments, other receivables and other assets based on, among others, our historical settlement records, our relationship with relevant counterparties, payment terms, current economic trends and to a certain extent, the larger economic and regulatory environment, which involve the use of various judgments, assumptions and estimates by our management. However, there is no assurance that our expectations or estimates will be entirely accurate, as we are not in control of all the underlying factors affecting such prepayments, other receivables and other assets. Therefore, if we are not able to recover the prepayments, other receivables and other assets as scheduled, our financial position and results of operations may be adversely affected.

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We have historically received government grants for our R&D activities and we may not receive such grants in the future.

We have historically received government grants for certain of our product development projects. For 2020, 2021 and the eight months ended August 31, 2022, we recognized government grants income of RMB3.6 million, RMB1.3 million and RMB3.5 million, respectively. For further details of our government grants, please refer to the section headed “Financial Information—Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income—Other Income and Gains” in this document. Our eligibility for government grants depends on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, the availability of funding at different granting authorities and the research and development progress made by other peer companies. In addition, the policies according to which we historically received government grants may be changed or halted by the relevant government entities at their sole discretion. There is no assurance that we will continue to receive such government grants or receive similar level of government grants, or at all, in the future.

Raising additional capital may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional funding through equity offerings, debt financings and/or other sources. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the [REDACTED] of our Shares to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Share-based payment may cause shareholding dilution to our existing Shareholders and have a material and adverse effect on our financial performance.

We adopted employee incentive schemes for the benefit of our employees (including directors) as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our Company. For details, please refer to the paragraphs headed “History, Development and Corporate Structure—Employee Incentive Platforms” in this document. During 2020, 2021 and the eight months ended August 31, 2022, we incurred equity-settled share award expense of RMB112.3 million, RMB17.8 million and RMB13.5 million, respectively. To further incentivize our employees to contribute to us, we may grant additional share-based payments in the future. Issuance of additional Shares with respect to such share-based payments may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payments may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

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Future tax payments or the discontinuation of any of the preferential tax treatments currently available to use could reduce our profitability.

During the Track Record Period, we recorded net losses, and as a result, we did not record any income tax expenses. We may be subject to PRC enterprise income tax in the future, which could reduce our profitability. We cannot assure you that we will continue to receive preferential tax treatment at historical levels, or at all. There may be situations where the Company is subject to additional tax obligations as required by related tax authorities, resulted from the Company's trading and capital activities. In the event that any of the preferential tax treatment currently enjoyed by us is reduced, discontinued or withdrawn by the government authorities, or in the event that we are subject to additional tax obligations, our results of operations and growth prospects may be materially and adversely affected.

RISKS RELATING TO OUR OPERATIONS

Our future success depends on our ability to retain key executives and to attract, hire, retain and motivate other qualified and highly skilled personnel.

We are highly dependent on Mr. LI Kejian, our executive Director and chairman of our Board, Mr. ZHU Jun, our executive Director and general manager, and other management members to help us successfully set and implement our business strategies. We do not maintain key person insurance for our management members. However, we provide competitive salary packages and equity incentive plans for our management members. If any of them leaves us for any reason including starting their own business that competes with our business, our business, results of operations and prospects may be materially and adversely affected.

The success of our business also relies on our ability to attract, hire, retain and motivate qualified scientific, technical, clinical, manufacturing, and sales and marketing personnel, as well as other advisers, including scientific and clinical advisers, who assist us in formulating our development and commercialization strategies. Although we have entered into employment agreements with each of our executives, employees, and advisers, they may terminate their agreements with us at any time. The loss of the services of any of them could impede the achievement of our research, development and commercialization objectives.

Furthermore, we have a strong executive team and R&D team, and other team members may temporarily take the place of the leaving employee before we find a suitable replacement; other than that, we do not have a particular contingency plan for unexpected departure of our key personnel. Replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may face difficulties for hiring and retaining talents and highly skilled personnel from time to time as our competitors may offer more attractive salary package, higher positions and better training opportunities to such talents. Therefore, we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous medical device companies for similar personnel. We also experience competition for the hiring of research and development and clinical personnel from research institutions, government entities and other organizations. As a result, we may incur additional expenses and devote significant time to recruit and train new personnel, which could severely disrupt our business and growth. In addition, our advisers may be engaged by our competitors and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We have a limited operating history compared to some of our competitors. Our operations to date have focused on business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials of our pipeline products and the commercialization of our products. As of the Latest Practicable Date, we only had six commercialized products. A majority of our products, including our Core Products, are still at various development stages, and we have not yet demonstrated ability to successfully obtain regulatory approvals for any such pipeline products.

As a result of our limited operating history, and particularly in light of the rapidly evolving nature of our industry, it may make it difficult to evaluate our current business and reliably predict our future performance. Our historical results may not provide a meaningful basis for evaluating our business, financial condition, results of operation and future prospects, and we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors, and may not be able to achieve promising results in future periods. If we cannot address these risks and overcome these difficulties successfully, our business and prospects will suffer.

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

As we seek to advance our product candidates through clinical trials and commercialization, and further commercialization of approved products, we plan to continue to expand our development, manufacturing, marketing and sales capabilities. Please refer to the paragraphs headed “Business—Our Strategies” in this document for more details. The success of our growth strategy will depend on, among other things, our ability to continue to innovate and develop advanced technologies in the highly competitive medical device market in China, maintain our efficient operating model, attract and retain skilled personnel who have the specialized skills needed to design, develop and manufacture medical devices, obtain and maintain regulatory approvals and effectively market our products using our network of distributors and our own sales and marketing team. However, we have limited operational, administrative and financial resources, which may be inadequate to sustain the growth we seek to achieve. In particular, in order to implement our growth strategy, we will need to increase our investment in, among other things, our research and development, manufacturing facilities, marketing and other areas of operations. If we are unable to manage our growth and expansion effectively, our business may be adversely affected.

We face substantial competition and rapid market changes, and our competitors may discover, develop or commercialize competing products before or more successfully than we do, or respond and adapt to the market changes more quickly and effectively.

The development and commercialization of new medical devices is highly competitive. We face competition primarily from other major companies focusing on the development of cryotherapy devices worldwide, some of which currently market and sell cryotherapy devices, or are pursuing the development of such products. Potential competitors also include government agencies, academic institutions and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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Our business opportunities could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer severe adverse events, are less expensive or are more convenient than our product candidates. Our competitors in the global market may also apply for marketing approvals in China or other countries for medical device products with the same intended use as our products and product candidates. The capacity of the relevant authorities, such as the NMPA, to concurrently review multiple marketing applications for the same type of innovative medical device may be limited, therefore such authorities' schedule to review our product candidates may be delayed when our product candidates are under the authorities' concurrent review with our competitors' products, and the registration process of our product may be prolonged. In addition, our competitors may obtain approvals from the NMPA or other comparable regulatory authorities more rapidly than we do.

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

We believe appropriate strategic partners will play an important role for our commercialization and help us strengthen our presence in both the domestic and global markets. We have entered into collaboration agreements with certain hospitals, medical institutions, academic institutions, CRO and SMO who are Independent Third Parties and may from time to time seek new strategic alliances, collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. However, we face competition in seeking appropriate strategic partners and the negotiation process for the collaboration, alliances or licensing arrangements can be time-consuming and complex, and other medical device companies may have greater resources and potentials than us which may lead us to a disadvantageous position in competing for an ideal strategic partner with extensive experience and abundant resources. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may deem our product candidates to be at too early of a development stage for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for the development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new design of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;

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- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and/or
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

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

We may seek strategic acquisition opportunities in the future for the purpose of advancing our clinical development and commercialization of our products in overseas markets. However, we may not be able to effectively identify appropriate businesses for strategic acquisitions, and the costs of identifying and consummating acquisitions may be significant. Even if appropriate opportunities arise, we may not be able to successfully complete the acquisitions. In addition, the acquisitions and the subsequent integration of new businesses and assets into our own require significant attention from our management and could result in a diversion of resources from our existing business, which in turn could materially and adversely affect on our operations. Acquired assets or businesses may not generate the financial results or realize the synergies as we expect. For example, we may not realize the intended synergies following our acquisitions of related businesses.

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Acquisitions or strategic partnerships may increase our capital requirements, dilute our Shareholders' ownership interest, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

To enhance our growth, we may acquire businesses, products, technologies or know-how or enter into strategic partnerships that we believe would benefit us in terms of product development, technology advancement or distribution network, among others. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses, including research and development expenses due to an increased number of product candidates, administrative expenses as well as selling and distribution expenses, which result in an increased cash requirements;
- the assumption of additional indebtedness or contingents;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- difficulty in retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products and product candidates and regulatory approvals;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and/or
- deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in the acquired business we discover after such acquisition, which may subject us to penalties, lawsuits or other liabilities.

Further, any difficulties in the integration of acquired businesses, product or technologies or unexpected penalties, lawsuits or liabilities in connection with such businesses, product or technologies could have a material adverse effect on our reputation, business, financial condition and results of operation. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

The medical device industry in China is rapidly evolving, and we may be unable to maintain or enhance our market share in this industry for a variety of reasons.

The medical device industry in China is rapidly evolving due to economic growth in China, changes in government policies and funding levels and other factors discussed in this document. We

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invest in research and development activities including various pre-clinical studies and clinical trials, build a robust distributor network, establish relationships with hospitals and physicians, implement necessary sales policies and discounts, as well as adjust our prices to distributors, from time to time depending on market conditions.

Our inability to adequately respond to changes in market conditions in a timely manner could have a material adverse effect on our business, financial condition, results of operation and return on capital expenditures, which could cause a decline in our growth rates, reduce our revenues, harm our ability to maintain our current market share in the cryotherapy device market or to achieve our targeted market share in future periods. If we cannot maintain our market position, our reputation may be materially and adversely affected which could adversely affect our relationships with physicians and hospital administrators and our long-term ability to effectively market and sell our products or conduct clinical trials for our new products.

If we fail to maintain effective internal controls, we may not be able to accurately report our financial results or prevent fraud.

We will become a [REDACTED] upon completion of the [REDACTED], and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our management, operational and financial resources and systems in the foreseeable future. In order to address our internal controls issues and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including establishing a compliance program, adopting new policies, and providing extensive and ongoing training on our controls, procedures and policies to our employees. In addition, in preparation for the [REDACTED], we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

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

We may from time to time become subject to various litigation, legal or contractual disputes, investigations or administrative proceedings arising in the ordinary course of our business, including but not limited to various disputes with or claims from our suppliers, customers, contractors, business partners and other third parties that we engage for our business operations. On-going or threatened litigation, legal or contractual disputes, investigations or administrative proceedings may divert our management's attention and consume their time and our other resources. In addition, any similar claims, disputes or legal proceedings involving us or our employees may result in damages or liabilities, as well as legal and other costs and may cause a distraction to our management. Furthermore, any litigation, legal or contractual disputes, investigations or administrative proceedings which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. If any verdict or award is rendered against us or if we settle with any third parties, we could be required

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to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business projects. In addition, negative publicity arising from litigation, legal or contractual disputes, investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

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

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

Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, we are subject to equivalents of each of the healthcare laws described above in other jurisdictions, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any source, not just governmental payors, including private insurers. There are ambiguities as to what is required to comply with these requirements, and if we fail to comply with an applicable law requirement, we could be subject to penalties.

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

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous

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materials and wastes. Our operations involve the use of hazardous and flammable chemical materials and special equipment. Our operations also produce hazardous waste. We have entered into hazardous waste disposal agreements with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We could also incur significant costs associated with civil or criminal fines and penalties.

Although we maintain insurance policies that cover losses arising from accidents in respect of our clinical trials, this insurance does not provide adequate coverage against accidents and natural calamities in respect of our machinery, equipment, inventory and other fixed assets in our research and manufacturing facilities, nor potential liabilities resulting from the use of or exposure to hazardous materials. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If we or our business partners fail to protect patient data and privacy, our reputation will be damaged and we might be subject to fines or other regulatory punishments.

During the process of clinical trials, we need to collect and store a large quantity of patients' personal data and information, which require us and our third-party vendors such as clinical trial institutions, hospitals, CROs and SMOs to maintain an effective control system to protect such personal data and information. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. Whilst we have adopted security policies and measures to protect our proprietary data and patients' privacy, misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of personal data might not be avoided due to human error, employee misconduct or system breakdown. We also cooperate with third parties including principal investigators, hospitals, CROs and SMOs for our clinical trials. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims. Whilst we have made efforts to ensure our compliance with the applicable privacy regulations in the relevant jurisdictions, we may not be capable of adjusting our internal policies in a timely manner and any failure to comply with applicable regulations could also result in regulatory enforcement actions against us.

In addition, the laws and regulations regarding cybersecurity, data privacy and protection in China are generally complex and evolving, with uncertainty as to the interpretation and application thereof. For example, on December 28, 2021, the Cyberspace Administration of China, or the CAC, and other twelve PRC regulatory authorities jointly revised and promulgated the Cybersecurity Review Measures (《網絡安全審查辦法》), which stipulates the applicable scope of the cybersecurity review and came into effect on February 15, 2022. Pursuant to the Cybersecurity Review Measures, critical information infrastructure

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operators that intend to purchase internet products and services and anticipate that its procurement of internet products and services affect or may affect national security after the network products and services being put into use and network platform operators engaging in data processing activities that affect or may affect national security must be subject to the cybersecurity review. The Cybersecurity Review Measures further stipulates that network platform operators with personal information data of more than one million users that seek for listing in a foreign country are obliged to apply for a cybersecurity review by the Cybersecurity Review Office. Although the number of individuals of which we process personal information are far below one million and we believe that our collection and handling of the personal information do not constitute "data processing activities" or any other activities that may affect national security under the Draft Data Security Regulations, the PRC government authorities may have discretion in the interpretation and enforcement of the laws and regulations. Any actual or alleged failure to comply with the evolving data privacy and protection laws and regulations could damage our reputation and negatively affect our business operation and financial position.

If our employees or distributors engage in bribery or corrupt practices or other improper conduct, we may be subject to liability and our reputation and business could be harmed.

We are subject to the anti-bribery laws of various jurisdictions, particularly in China. As our business expands, the applicability of the applicable anti-bribery laws to our operations has increased. Our procedures and controls to monitor compliance with anti-bribery law may fail to protect us from reckless or criminal acts committed by our employees or agents. We could be liable for actions taken by our employees or distributors that violate anti-bribery, anti-corruption and other related laws and regulations in China or other countries. The government authorities may seize the products involved in any illegal or improper conduct engaged in by our employees or distributors. We may be subject to claims, fines or suspension of our operations. Our reputation, our sales activities or the price of our Shares could be adversely affected if our Company is associated with any negative publicity as a result of illegal or improper actions, or allegations of illegal or improper actions, taken by our employees or distributors.

It is also possible that the Chinese government or other government authorities in countries where we sell our products could adopt new or different regulations affecting the way in which medical devices are sold to address bribery, corruption or other concerns. Any such new or different regulations could possibly increase the costs incurred by us, our employees or distributors in selling our products or impose restrictions on sales and marketing activities, which could in turn increase our costs. As we currently depend substantially on distributors for the sale of our products, any misconduct by our distributors or changes in the regulatory environment regarding the sale of medical devices could have a material adverse impact on our business, financial condition and results of operations.

Our internal computer systems as well as those of our service providers may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems are and those of our current or future CROs, SMOs and other service providers may be vulnerable to damage from computer viruses and unauthorized access. If such event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

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

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our Company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we may experience threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats may continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely.

We have limited insurance coverage which may not adequately cover all the risks and hazards associated with our operations.

We operate in the medical device industry, which involves numerous operating risks and occupational hazards. We maintain certain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice as of the Latest Practicable Date. For example, we maintain product liability insurance covering our clinical trials, we also maintain social welfare insurance and commercial insurance for our employees in accordance with relevant PRC laws and regulations. For more details of our insurance policies, please refer to the

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paragraphs headed “Business—Insurance” in this document. We cannot assure you that the existing insurance coverage is sufficient to compensate for actual losses suffered or incurred. To the extent that such losses or payments are not insured or the insured amount is not adequate, our business, results of operations and financial condition may be materially and adversely affected by such losses and associated liabilities. For the specific risks of inadequate insurance coverage in the event of product liability claims, please refer to the paragraphs headed “—Risks Relating to Manufacture and Supply of Our Products and Product Candidates—We may be exposed to potential product liability claims, and our insurance coverage may be inadequate to protect us from all the liabilities we may incur” in this section.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, suppliers and other business partners, could be subject to natural or man-made disasters, health epidemic, or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our and our partners’ operations and financial condition and increase our and their costs and expenses. Furthermore, our ability to obtain supplies of raw materials for producing our products and product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster, health epidemic, or other business interruption. Damage or extended periods of interruption to our administration, development, research or manufacturing facilities due to fire, natural disaster, health epidemic, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our product candidates.

For example, the ongoing COVID-19 pandemic and additional outbreaks in China could significantly affect our industry and cause temporary suspension of projects and shortage of labor and raw materials, which would severely disrupt our progress on research and development of our product candidates and have a material adverse effect on our business, financial condition and results of operations. Our operations could also be disrupted if any of our employees or employees of our distributors, suppliers and other business partners were suspected of contracting or contracted COVID-19, since this could require us and our distributors, suppliers and other business partners to quarantine some or all of these employees and disinfect facilities used for operations.

Our business significantly depends on our reputation and customer perception of us and any negative publicity on us, our Shareholders, Directors, officers, employees, suppliers, or other parties we cooperate with, or related to our industry, may materially adversely affect our business, financial condition and results of operations.

Our reputation and customer perception of our brand are critical to our business. Maintaining and enhancing our reputation and recognition depend primarily on the quality and consistency of our products, as well as continued promotion efforts. Our promotion efforts may be expensive and ineffective. In addition, our reputation and customer perception of our Company could suffer in events that:

- our products fail to gain acceptance by patients, doctors and hospitals;
- our products are defective or malfunction;
- lawsuits or regulatory investigations are instituted against us or relating to our future products or industry;

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- we provide poor or ineffective customer service; or
- we are subject to product liability claims.

If we are unable to maintain and further enhance our reputation and recognition, our ability to attract and retain customers may be impeded and our business prospects may be materially adversely affected. Any negative incident or negative publicity concerning us, our products, our management, our employees and our distributors, regardless of its veracity, could harm our image and diminish the trust from our customers and the market, which could in turn result in decreased sales of our products and materially and adversely affect our business. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our [REDACTED] and customers.

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

We and/or other parties related to our operations, such as landlords of premises on which we operate, are required to obtain and maintain various approvals, licenses, permits and certificates to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant governmental authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew such approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the regulatory authorities causing our operations to cease. In the event that such enforcement action is taken, we may be required to take corrective measures or remedial actions incurring additional capital expenditure, and our business operations could be materially and adversely disrupted.

Third parties including research institutions, CROs, SMOs, distributors and suppliers on whom we may rely to research, develop, produce, promote, sell and distribute our products, may be required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products. These third parties may also be subject to regular inspections, examinations, inquiries or audits by regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that third parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the business operation of such third parties, and if they fail to maintain or renew any such material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring these third parties to obtain any additional permits, licenses or certificates that were previously not required to operate their respective businesses, there can be no assurance that they will successfully obtain such permits, licenses or certificates. These third parties' failure to obtain the additional permits, licenses or certificates may in turn restrict the conduct of our business, decrease our revenues and/or increase our costs, which could materially reduce our profitability and impair our prospects.

RISK FACTORS

Fair value change of financial assets at fair value through profit or loss may affect the Group’s financial performance.

We had financial assets at fair value through profit or loss of RMB25.5 million, nil and RMB4.0 million as of December 31, 2020 and 2021 and August 31, 2022, respectively, which were wealth management products we purchased from banks in China. Pursuant to the Guidance on Regulating Financial Institution’s Asset Management Business (《關於規範金融機構資產管理業務的指導意見》) promulgated by the People’s Bank of China, the China Banking and Insurance Regulatory Commission, the China Security Regulatory Commission and the State Administration of Foreign Exchange on April 27, 2019, financial institutions selling wealth management products shall not guarantee the returns of principal and interest of such products. As a result, the returns of our investments on the wealth management products were not guaranteed, and therefore were measured at fair value through profit or loss. We are exposed to credit risks in relation to these financial assets, which may adversely affect their fair value. Net changes in their fair value are recorded as our other income or losses, and therefore directly affect our results of operations. We may continue to invest in wealth management products in the future when we believe that we have surplus cash on-hand and the potential investment returns are attractive. However, there can be no assurance that our internal management and investment strategy will be effective and adequate with respect to our purchased wealth management products. We cannot guarantee that we will not experience losses with respect to such investments in the future or that such losses or other potentially negative consequences due to such investments will not have material adverse effects on our business, results of operations and prospects.

We are exposed to risks relating to our failure to complete property leasing registrations for our leased properties.

As of the Latest Practicable Date, we leased ten properties in China, with an aggregate gross floor area of approximately 15,341 sq.m. Under the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. However, we had not completed the filings for nine of our lease agreements. We may be required by relevant government authorities to file these lease agreements for registration within a time limit, and may be subject to a fine ranging from RMB1,000 to RMB10,000 for each non-registration exceeding such time limit.

In addition, as our leases expire, we may fail to negotiate renewals, either on commercially acceptable terms or at all, which could require us to close such offices. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially adversely affect our business, results of operations and financial condition.

Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.

Certain of our cash and cash equivalents are denominated in foreign currencies. Therefore, we are exposed to foreign currency risk. The [REDACTED] from the [REDACTED] will be received in HKD. As a result, any appreciation of RMB against USD, HKD or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. The exchange rate of RMB against HKD and other foreign currencies is affected by, among other things, the policies of the PRC Government and changes in China’s and international political and economic conditions, as well as supply and

RISK FACTORS

demand in the local market. It is difficult to predict how market forces or government policies may impact the exchange rate between RMB, USD, HKD or other currencies in the future. There remains significant international pressure on the PRC Government to adopt a more flexible currency policy, which, together with domestic policy considerations, could result in a significant appreciation of RMB against USD, HKD or other foreign currencies.

In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Any of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our Shares in foreign currency terms.

We may be subject to penalties under relevant PRC laws and regulations due to failure in full compliance with social insurance and housing provident fund regulation.

According to the Social Insurance Law of the PRC promulgated in 2010 and most recently amended in 2018 and the Regulations on Management of Housing Provident Funds promulgated in 1999 and most recently amended in 2019, within a prescribed time limit, we need to register with the relevant social security authority and housing provident fund management center, and to open the relevant accounts and make full contributions to social insurance and housing funds for our employees, and this obligation cannot be delegated to any third party. During the Track Record Period, Ningbo SensCure did not make full contributions to the social insurance and housing funds for its employees in accordance with the relevant PRC laws and regulations. As a result, we may be required by competent authorities to pay the outstanding amount, and could be subject to late payment penalties or enforcement application made to the court. We made sufficient provisions in connection with our Track Record Period's shortfall amount of the social insurance and housing provident fund contribution.

During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any administrative actions, fines or penalties due to such non-compliance. We had not received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges with respect to social insurance and housing funds, nor had we received any administrative penalty or labor arbitration application from employees for our agency arrangement with third-party human resources agencies. We cannot assure you that the competent local government authorities will not require us to pay the outstanding amount within a specified time limit or impose late fees or fines on us, which may materially and adversely affect our financial condition and results of operations.

RISKS RELATING TO DOING BUSINESS IN CHINA

The medical device industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our products and product candidates.

We conduct substantially all of our operations in China. The medical device industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new devices. In recent years, the regulatory framework in China regarding the medical device industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our product candidates in China and reduce the benefits we believe are available to us from developing and manufacturing medical devices in China.

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Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, and control of foreign exchange and allocation of resources.

While the PRC economy has experienced significant growth over the past decades, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

PRC legal system embodies inherent uncertainties that may affect the protection afforded to our business and our Shareholders.

The PRC legal system is based on written statutes. Prior court decisions may be adduced for reference but have limited precedential value. Since the late 1970s, the PRC government has promulgated laws and regulations dealing with such economic matters as the issuance and trading of securities, shareholders' rights, foreign investment, corporate organization and governance, commerce, taxation and trade, with a view towards developing a comprehensive system of commercial law. However, as these laws and regulations are relatively new, the effect of these laws and regulations on the rights and obligations of the parties involved may involve uncertainty. As a result, the legal protections available to us under the PRC legal system may be limited.

Our operations in the PRC are subject to PRC regulations governing PRC companies. These regulations contain provisions that are required to be included in the articles of association of PRC companies and are intended to regulate the internal affairs of these companies. The PRC Company Law and regulations, in general, and the provisions for the protection of Shareholders' rights and access to information, in particular, may be considered less developed than those applicable to companies incorporated in Hong Kong, the United States and other developed countries or regions. In addition, PRC laws, rules and regulations applicable to companies listed overseas do not distinguish between minority and controlling shareholders in terms of their rights and protections. As such, our minority shareholders may not have the same protections afforded to them by companies incorporated under the laws of the United States and certain other jurisdictions.

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Additionally, the reform of the medical device approval system in 2017 may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our pipeline products in a timely manner. In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

You may experience difficulties in effecting service of legal process and enforcing judgments against us and our management based on Hong Kong or other foreign laws.

We are incorporated under the laws of the PRC, and substantially all of our assets are located in the PRC. In addition, a majority of our Directors, Supervisors and senior management personnel reside within the PRC, and substantially all their assets are located within the PRC. As a result, it may not be possible to effect service of process within the United States or elsewhere outside the PRC upon us or our Directors, Supervisors and senior management personnel. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions.

On July 14, 2006, the Supreme People’s Court of the PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “**Arrangement**”). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a PRC court is expressly selected as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in the PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. In addition, the Arrangement has expressly provided for “enforceable final judgement,” “specific legal relationship” and “written form.” A final judgement that does not comply with the Arrangement may not be recognized and enforced in a PRC court.

On January 18, 2019, the Supreme People’s Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排) (the “**2019 Arrangement**”). Under the 2019 Arrangement, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the effective judgments in civil and commercial cases subject to the conditions set forth in the 2019 Arrangement. Although the 2019 Arrangement has been signed, the outcome and effectiveness of any action brought under the 2019 Arrangement may still be uncertain. We cannot assure you that an effective judgment that complies with the 2019 Arrangement can be recognized and enforced in a PRC court.

RISK FACTORS

Gains on the sales of H Shares and dividends on the H Shares may be subject to PRC income taxes.

Under the applicable PRC tax laws, both the dividends we pay to non-PRC resident individual holders of shares (“**non-resident individual holders**”), and gains realized through the sale or transfer by other means of H shares by such shareholders, are subject to PRC individual income tax at a rate of 20%, unless reduced by the applicable tax treaties or arrangements.

Under applicable PRC tax laws, the dividends we pay to, and gains realized through the sale or transfer by other means of H shares by, non-PRC resident enterprise holders of H shares (“**non-resident enterprise holders**”) are both subject to PRC enterprise income tax at a rate of 10%, unless reduced by applicable tax treaties or arrangements. Pursuant to the Arrangements between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Incomes (內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排) dated August 21, 2006, any non-resident enterprise registered in Hong Kong that holds directly at least 25% of the shares of our Company shall pay Enterprise Income Tax for the dividends declared and paid by us at a tax rate of 5% if the Hong Kong non-resident enterprise is the beneficial owner of the equity and certain other conditions are met.

For non-resident individual holders, gains realized through the transfer of properties are normally subject to PRC individual income tax at a rate of 20%. However, according to the Circular of the Ministry of Finance and the State Administration of Taxation on Issues Concerning Individual Income Tax Policies (財政部、國家稅務總局關於個人所得稅若干政策問題的通知), income received by individual foreigners from dividends and bonuses of a foreign-invested enterprise are exempt from individual income tax for the time being. According to the Circular Declaring that Individual Income Tax Continues to Be Exempted over Individual Income from Transfer of Shares issued by the MOF and the SAT (關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知) effective as of March 30, 1998, income from individuals’ transfer of stocks of listed companies continued to be temporarily exempted from individual income tax. On February 3, 2013, the State Council approved and promulgated the Notice of Suggestions to Deepen the Reform of System of Income Distribution (國務院批轉發展改革委等部門關於深化收入分配制度改革若干意見的通知). On February 8, 2013, the General Office of the State Council promulgated the Circular Concerning Allocation of Key Works to Deepen the Reform of System of Income Distribution (國務院辦公廳關於深化收入分配制度改革重點工作分工的通知). According to these two documents, the PRC government is planning to cancel foreign individuals’ tax exemption for dividends obtained from foreign-invested enterprises, and the Ministry of Finance and the State Administration of Taxation should be responsible for making and implementing details of such plan. However, relevant implementation rules or regulations have not been promulgated by the Ministry of Finance and the State Administration of Taxation.

Considering these uncertainties, non-resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers of the H Shares.

RISK FACTORS

Governmental control of currency conversion, and restrictions on the remittance of Renminbi into and out of the PRC, may limit our ability to utilize our revenue effectively and adversely affect the value of your [REDACTED].

The Renminbi is not currently a freely convertible currency, as the PRC Government imposes controls on the convertibility of Renminbi into foreign currencies and in certain cases, the remittance of currency out of China. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our H Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under China’s current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses.

Our operations are subject to and may be affected by changes in PRC tax laws and regulations.

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. Although we believe that in the past we had acted in compliance with the requirements under the relevant PRC tax laws and regulations in all material aspects and had established effective internal control measures in relation to accounting regularities, we cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC government from time to time adjusts or changes its tax laws and regulations. For example, under the Individual Income Tax Law (“**IIT Law**”) which was last amended on August 31, 2018 and came into effect on January 1, 2019, foreign nationals which have domiciles in the PRC, or have no domicile in China but have resided in the PRC for one year or more, would be subject to PRC individual income tax at progressive rate on their income gained within or outside the PRC. The Standing Committee of NPC have approved the amendment of the IIT Law, which took effect on January 1, 2019. Under the amended IIT law, foreign nationals have no domicile in China but have resided in the PRC for a total of 183 days or more in a tax year, would be subject to PRC individual income tax on their income gained within or outside the PRC. Should such rule be strictly enforced, our ability to attract and retain highly skilled foreign scientists and research technicians to work in China may be materially affected, which may in turn have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. Further adjustments or changes to PRC tax laws and regulations, together with any uncertainty resulting therefrom, could also have an adverse effect on our business, financial condition and results of operations.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》), or the Scientific Data Measures, which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific

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data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, if and to the extent any data collected or generated in connection with our services will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our business, results of operations, financial conditions and prospects may be materially and adversely affected. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

The political relationships between China and other countries may affect our business operations.

During the Track Record Period, we purchased certain raw materials for our product candidates from overseas suppliers. In the event that China and/or the countries from which we import raw materials impose import tariffs, trade restrictions or other trade barriers affecting the importation of such components or raw materials, we may not be able to obtain a steady supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. We also might plan to commercialize some of our products in certain foreign jurisdictions, such as United States and EU in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions.

Furthermore, there can be no assurance that our existing or potential suppliers, service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Particularly, trade tension between the U.S. and China could place pressure on the economic growth in China as well as the rest of the world. The U.S. administration has advocated for and taken steps toward restricting trade in certain goods, particularly from China. There can be no assurance as to whether the U.S. will maintain or reduce tariffs, or impose additional tariffs on Chinese products in the near future. Trade tension between China and the U.S. may intensify and the U.S. may adopt even more drastic measures in the future. China has retaliated and may further retaliate in response to new trade policies, treaties and tariffs implemented by the U.S. Any further escalation in trade or other tensions between the U.S. and China or news and rumors of any escalation, could introduce uncertainties to China's economy and the global economy which in turn could affect activity levels on our research and development. Foreign policies of the U.S. tend to be followed by certain other countries, and those countries may adopt similar policies in their relationships with China and the Chinese companies.

In addition, those policies and measures directed at China and Chinese companies adopted by the U.S. government could have effect of discouraging U.S. persons from working for Chinese companies, which could hinder our ability to hire and retain qualified personnel for our business.

RISK FACTORS

RISKS RELATING TO THE [REDACTED]

No [REDACTED] currently exists for our H Shares, and an active [REDACTED] for our H Shares may not develop and the [REDACTED] for our H Shares may decline or become volatile.

No [REDACTED] currently exists for our H Shares. The initial [REDACTED] for our H Shares to the public will be the result of negotiations between our Company and the [REDACTED] (on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of the Shares following the [REDACTED]. We have applied for [REDACTED] of and permission to [REDACTED] our [REDACTED] on the [REDACTED]. On April 30, 2018, Stock Exchange adopted new rules under Chapter 18A of Listing Rules, or Chapter 18A. Chapter 18A permits for the first-time [REDACTED] on the [REDACTED] of pre-revenue, loss making Biotech Companies such as us. As required by Chapter 18A, our stock marker includes the letter "B" to denote we are a Biotech Company [REDACTED] pursuant to Chapter 18A.

A [REDACTED] on the [REDACTED], however, does not guarantee that an active and liquid [REDACTED] for the Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will not decline following the [REDACTED].

The [REDACTED] and [REDACTED] volume of our H Shares may be volatile, which could lead to substantial losses to [REDACTED].

The [REDACTED] and [REDACTED] volume of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the [REDACTED] and [REDACTED] volume of our H Shares. In addition to market and industry factors, the [REDACTED] and [REDACTED] volume of our H Shares may be highly volatile for specific business reasons, including but not limited to:

- the results of clinical trials of our product candidates;
- the results of our applications for approval of our product candidates;
- regulatory developments affecting our industry, healthcare, health insurance and other related matters;
- fluctuations in our revenue, earnings, cash flows, investments and expenditures;
- relationships with our suppliers;
- movements or activities of key personnel; and
- actions taken by competitors.

RISK FACTORS

Biotech Companies listed under Chapter 18A are generally viewed as being early stage and significantly riskier than those companies traditionally listed on the Stock Exchange. The trading market for Biotech Companies (including the depth and liquidity for that market) may take time to develop and could be subject to significant and adverse changes. Our shares and the shares of other Biotech Companies could be subject to significant volatility unrelated to company specific performance or corporate developments. For example, adverse announcements by another unrelated Chapter 18A Biotech Company could adversely impact the [REDACTED] for the Shares.

Normally, [REDACTED] acting on behalf of the [REDACTED] may [REDACTED] or effect [REDACTED] or any other [REDACTED] with a view to [REDACTED] of the [REDACTED] at a level higher than that which might otherwise prevail in the [REDACTED]. However, given that we will not grant any [REDACTED] to the [REDACTED], no [REDACTED] has been appointed by us in connection to the [REDACTED] and it is anticipated that no [REDACTED] activities will be conducted by any [REDACTED], which may result in substantial losses for [REDACTED] during the period when [REDACTED] activities would normally have been conducted.

Moreover, shares of other companies listed on the Hong Kong Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and our H Shares may be subject to changes in [REDACTED] not directly related to our performance.

You will incur immediate and significant dilution and raising additional capital may cause further dilution or restrict our operation.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] consolidated net tangible asset value. There can be no assurance that if we were to immediately liquidate after the [REDACTED], any assets will be distributed to Shareholders after the creditors' claims. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, limitations on our ability to acquire or license intellectual property rights or declaring dividends, or other operating restrictions.

Future [REDACTED] or perceived [REDACTED] of a substantial number of our H Shares in the [REDACTED] following the [REDACTED] could materially and adversely affect the [REDACTED] of our H Shares and our ability to raise additional capital in the future, and may result in dilution of your [REDACTED].

Prior to the [REDACTED], there has not been a [REDACTED] for our H Shares. Future [REDACTED] or perceived [REDACTED] by our existing Shareholders of our H Shares after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our H Shares. Only a limited number of the Shares currently outstanding will be available for [REDACTED] or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our H Shares in the [REDACTED] or the perception that these [REDACTED] may occur could significantly decrease the prevailing [REDACTED] of our H Shares and our ability to raise equity capital in the future.

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In addition, our Unlisted Shares may be converted into H Shares subject to regulatory approvals and compliance with relevant regulatory requirements. Any conversion of our Unlisted Shares will increase the number of H Shares available on the [REDACTED] and may affect the [REDACTED] of our H Shares.

We cannot assure you that we will declare and distribute any amount of dividends in the future.

There can be no assurance that we will declare and pay dividends because the declaration, payment and amount of dividends are subject to the discretion of our Directors, depending on, among other considerations, our operations, earnings, cash flows and financial position, operating and capital expenditure requirements, our strategic plans and prospects for business development, our constitutional documents and applicable law. For more details on our dividend policy, please refer to the paragraphs headed “Financial Information—Dividend” in this document.

We cannot make fundamental changes to our business without the consent of the Stock Exchange.

On April 30, 2018, the Hong Kong Stock Exchange adopted rules under Chapter 18A of its Rules Governing the Listing of Securities on the Stock Exchange. Under these rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Chapter 18A. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

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

Immediately following the [REDACTED], our Controlling Shareholders will be entitled to exercise approximately [REDACTED]% voting rights in our Company in aggregate. Our Controlling Shareholders will, through their voting power at the Shareholders’ meetings and their delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our Controlling Shareholders may not act in the best interests of our minority Shareholders. In addition, without the consent of our Controlling shareholders, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a sale of our Company and may significantly reduce the price of our Shares.

RISK FACTORS

Facts, forecasts and statistics obtained from official government sources in this document relating to our industry may not be fully reliable.

Facts, forecasts and statistics in this document relating to our industry are obtained from official government publications that have not been independently verified by our Company, the Joint Sponsors, [REDACTED], any of their respective directors, employees, agents or advisers or any other person or party involved in the [REDACTED]. Due to possibly flawed or ineffective collection methods or discrepancies between such published information and factual information and other problems, the information from official government sources in this document may be inaccurate and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from these sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong in making your [REDACTED] decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective [REDACTED] should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] in our [REDACTED]. By applying to [REDACTED] our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and the [REDACTED].

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

In preparation for the [REDACTED], our Company has sought [and has been granted] the following waivers from strict compliance with the relevant provisions of the Listing Rules and exemption from compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

WAIVER IN RELATION TO MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rule 8.12 and Rule 19A.15 of the Listing Rules, an issuer must have a sufficient management presence in Hong Kong. This normally means that at least two of its executive directors must be ordinarily resident in Hong Kong.

Our management, business operations and assets are primarily located outside Hong Kong. The principal management headquarters of our Group are primarily based in the PRC. Our Company considers that our Group’s management is best able to attend to its functions by being based in the PRC. Our executive Directors are not or will not be ordinarily resident in Hong Kong after the [REDACTED] of our Company. Our Directors consider that relocation of our executive Directors to Hong Kong will be burdensome and costly for our Company, and it may not be in the best interests of our Company and our Shareholders as a whole to appoint additional executive Directors who are ordinarily resident in Hong Kong. As such, we do not have, and for the foreseeable future will not have, sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules, provided that our Company implements the following arrangements to maintain effective communication between the Stock Exchange and us:

- (1) pursuant to Rule 3.05 of the Listing Rules, our Company has appointed and will continue to maintain two authorized representatives, namely, Mr. ZHU Jun (朱軍), our executive Director, and Ms. LEUNG Wai Yan (梁慧欣), our joint company secretary, to be the principal communication channel at all times between the Stock Exchange and our Company. Each of our authorized representatives will be available to meet with the Stock Exchange within a reasonable time frame upon the request of the Stock Exchange and will be readily contactable by telephone, facsimile and email;
- (2) as and when the Stock Exchange wishes to contact our Directors on any matters, each of our authorized representatives has the means to contact all of our Directors (including our independent non-executive Directors) promptly at all times;
- (3) each of our Directors not ordinarily residing in Hong Kong possesses or can apply for valid travel documents to visit Hong Kong and will be able to meet with the Stock Exchange within a reasonable period of time, when required;
- (4) we have appointed Maxa Capital Limited as our compliance adviser (the “**Compliance Adviser**”) pursuant to Rule 3A.19 of the Listing Rules, which will have access at all times to our authorized representatives, Directors and senior management, and will act as an additional channel of communication between the Stock Exchange and us for the period

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

commencing from the [REDACTED] to the date on which our Company complies with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED]. The Compliance Adviser will maintain constant contact with the authorized representatives, Directors and senior management through various means, including regular meetings and telephone discussions whenever necessary. Our authorized representatives, Directors and other officers of our Company will provide promptly such information and assistance as the Compliance Adviser may reasonably require in connection with the performance of the Compliance Adviser's duties as set forth in Chapter 3A of the Listing Rules;

- (5) we have provided the Stock Exchange with the contact details of each Director (including their respective mobile phone number, office phone number and e-mail address, if any), and in the event that any Director expects to travel or otherwise be out of the office, he/she will provide the phone number of the place of his/her accommodation to the authorized representatives; and
- (6) we will also retain legal advisers to advise on on-going compliance requirements as well as other issues arising under the Listing Rules and other applicable laws and regulations of Hong Kong after [REDACTED].

EXEMPTION IN RESPECT OF FINANCIAL STATEMENTS

Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all prospectuses to include matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and set out the reports specified in Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

Paragraph 27 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires a company to include in its prospectus a statement as to the gross trading income or sales turnover (as the case may be) of the company during each of the three financial years immediately preceding the issue of the prospectus, including an explanation of the method used for the computation of such income or turnover and a reasonable breakdown between the more important trading activities.

Paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance further requires the company to include in its prospectus a report by the auditors of the company with respect to (i) the profits and losses of the company and (ii) the assets and liabilities of the company for each of the three financial years immediately preceding the issue of the prospectus.

Section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance provides that the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from the compliance with the relevant requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance if, having regard to the circumstances, the SFC considers that the exemption will not prejudice the interests of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or would otherwise be unnecessary or inappropriate.

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

Rule 4.04(1) of the Listing Rules requires that the consolidated results of an issuer and its subsidiaries in respect of each of the three financial years immediately preceding the issue of the listing document or such shorter period as may be acceptable to the Stock Exchange be included in the accountants' report to the prospectus.

Rule 18A.03(3) of the Listing Rules requires that an eligible biotech company must have been in operation in its current line of business for at least two financial years prior to listing under substantially the same management. Rule 18A.06 of the Listing Rules requires that an eligible biotech company must comply with Rule 4.04 of the Listing Rules modified so that references to "three financial years" or "three years" in Rule 4.04 shall instead reference to "two financial years" or "two years", as the case may be. Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months from the date of the listing document.

In compliance with the abovementioned requirements under the Listing Rules, the Accountants' Report set out in Appendix I to this document is prepared to cover the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022.

As such, we have applied to the SFC for, [and the SFC has granted], a certificate of exemption from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance regarding the inclusion of the accountants' report covering the full three financial years immediately preceding the issue of this document on the following grounds:

- (a) our Company is primarily engaged in the R&D, application and commercialization of biotech products, and falls within the scope of a biotech company as defined under Chapter 18A of the Listing Rules. Our Company will fulfill the additional conditions for [REDACTED] required under Chapter 18A of the Listing Rules;
- (b) the Accountants' Report for each of the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;
- (c) given that our Company is only required to disclose our financial results for the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022 in accordance with Chapter 18A of the Listing Rules and preparation of the financial results for the year ended December 31, 2019 would require additional work to be performed by our Company and the reporting accountant of our Company, strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome for our Company;

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

- (d) notwithstanding that the financial results set out in this document are only for the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements; and
- (e) the Accountants' Report covering the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022, together with other disclosures in this document, have already provided the [REDACTED] with adequate and reasonable up-to-date information in the circumstances to form a view on the track record of our Company, and that all information which is necessary for the [REDACTED] to make an informed assessment of the business, assets and liabilities, financial position, management and prospects has been included in this document. Therefore, the exemption would not prejudice the interest of the [REDACTED].

The SFC has [granted] a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance on the condition that particulars of the exemption are set out in this document.

WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES

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

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

- (a) a member of The Hong Kong Chartered Governance Institute;
- (b) a solicitor or barrister (as defined in the Legal Practitioners Ordinance); or
- (c) a certified public accountant (as defined in the Professional Accountants Ordinance).

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

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

- (a) length of employment with the Company and other listed companies and the roles he/she played;
- (b) familiarity with the Listing Rules and other relevant laws and regulations including the Securities and Futures Ordinance, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;
- (c) relevant training taken and/or to be taken in addition to the minimum requirement of taking not less than fifteen hours of relevant professional training in each financial year under Rule 3.29 of the Listing Rules; and
- (d) professional qualifications in other jurisdictions.

Our Company considers that while it is important for the company secretary to be familiar with the relevant securities regulations in Hong Kong, he/she also needs to have experience relevant to our Company’s operations, a nexus to our Board and a close working relationship with the management of our Company in order to perform the function of a company secretary and to take the necessary actions in the most effective and efficient manner. It is for the benefit of our Company to appoint a person who has been a member of the senior management for a period of time and is familiar with our Company’s business and affairs as company secretary.

We have appointed Mr. LIU Wei (劉偉) (“**Mr. Liu**”) (our chief financial officer and Board secretary) and Ms. LEUNG Wai Yan (梁慧欣) (“**Ms. Leung**”) as the joint company secretaries of our Company. Ms. Leung is an associate member of The Hong Kong Chartered Governance Institute (formerly known as The Hong Kong Institute of Chartered Secretaries) and therefore meets the qualification requirements under Note 1 to Rule 3.28 of the Listing Rules and is in compliance with Rule 8.17 of the Listing Rules. Mr. Liu, however, does not possess the qualifications set out in Rule 3.28 of the Listing Rules. We believe that Mr. Liu, by virtue of his knowledge and experience in handling financial management and corporate development matters, is capable of discharging his functions as a joint company secretary. We therefore believe that it would be in the best interests of our Company and of the corporate governance of our Group to appoint Mr. Liu as a joint company secretary. For the biographical information of Mr. Liu and Ms. Leung, see “Directors, Supervisors and Senior Management” in this document.

We have therefore applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rules 8.17 and 3.28 of the Listing Rules on the conditions that: (i) Ms. Leung is appointed as a joint company secretary to assist Mr. Liu in discharging his functions as our joint company secretary and in gaining the relevant experience under Rule 3.28 of the Listing Rules; and (ii) the waiver will be revoked immediately if Ms. Leung, during the three-year period, ceases to provide assistance to Mr. Liu as our joint company secretary or if there are material breaches of the Listing Rules by our Company. We expect that Mr. Liu will acquire the qualifications or relevant experience required under Rule 3.28 of the Listing Rules prior to the end of the three-year period after the [REDACTED]. We will liaise with the Stock Exchange before the end of the

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

three-year period to enable it to assess whether Mr. Liu, having had the benefit of Ms. Leung’s assistance for three years, will have acquired the skills necessary to carry out the duties of a company secretary and relevant experience within the meaning of Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

WAIVER IN RELATION TO CONTINUING CONNECTED TRANSACTIONS

We have entered into and are expected to continue with certain transactions after the [REDACTED] which will constitute partially exempt continuing connected transactions under Chapter 14A of Listing Rules upon [REDACTED]. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver under Rule 14A.105 of the Listing Rules from strict compliance with the announcement requirement in respect of such transactions under Chapter 14A of the Listing Rules. For further details of our continuing connected transactions and the waiver, see “Continuing Connected Transactions” in this document.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
<i>Executive Directors</i>		
Mr. LI Kejian (李克儉)	Room 403 No. 24, Lane 110 Medical College Road Xuhui District Shanghai PRC	Chinese
Mr. ZHU Jun (朱軍)	Room 3801 Building 5, Lane 133 Linping Road Hongkou District Shanghai PRC	Chinese
<i>Non-executive Directors</i>		
Mr. LV Shiwen (呂世文)	Room 1102 Block 8, Lane 600 Miaopu Road Pudong New Area Shanghai PRC	Chinese
Mr. SUN Xiaolu (孫曉路)	Unit 903, Building 5 Lane 8, Qinzhou South Road Xuhui District Shanghai PRC	Chinese
Mr. ZHAO Chunsheng (趙春生)	Room 102 No. 60, Lane 200 Zi Long Road Minhang District Shanghai PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
<i>Independent non-executive Directors</i>		
Dr. GAO Dayong (高大勇)	No. 5651 152nd Ave SE Bellevue WA 98006 U.S.	American
Mr. LIANG Hsien Tse Joseph (梁顯治)	Unit D, 16/F, Block 6 City Garden 233 Electric Road North Point Hong Kong	Chinese (Hong Kong)
Dr. QIN Zheng (覃正)	Unit 101 No. 3, Lane 355 Jipu Road Yangpu District Shanghai PRC	Chinese
Dr. HU Henan (胡赫男)	Unit 301 No.9, Hanlan 3rd Street Yajule North Guangzhou Guangdong PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

SUPERVISORS

Name	Address	Nationality
Ms. LI Cuiqin (李翠琴)	Unit 501 No. 23, Lane 1333 Xinhuan North Road Pudong New Area Shanghai PRC	Chinese
Mr. ZHU Haorong (朱浩榮)	Room 201 No. 60, Lane 1800 Dongfang Road Pudong New Area Shanghai PRC	Chinese
Mr. QIU Junkang (邱軍康)	Room 102, No.10 Lane 260, Yongai Road Datuan Town Pudong New Area Shanghai PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

For details of the biographies and other relevant information of the Directors and Supervisors, see “Directors, Supervisors and Senior Management” in this document.

PARTIES INVOLVED IN THE [REDACTED]

**Joint Sponsors and
[REDACTED]**

Citigroup Global Markets Asia Limited

50/F, Champion Tower
3 Garden Road
Central
Hong Kong

Huatai Financial Holdings (Hong Kong) Limited

62/F, The Center
99 Queen’s Road Central
Central
Hong Kong

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

Legal Advisers to the Company

as to Hong Kong and U.S. laws:

O'Melveny & Myers

31/F, AIA Central
1 Connaught Road Central
Hong Kong

as to PRC law:

AllBright Law Offices

11/F and 12/F, Shanghai Tower
501 Yin Cheng Middle Road
Pudong New Area
Shanghai
PRC

as to PRC intellectual property law:

JunHe LLP Shanghai Office

26/F, HKRI Centre One
HKRI
Taikoo Hui
288 Shimen Road (No. 1)
Shanghai
PRC

**Legal Advisers to the Joint Sponsors
and [REDACTED]**

as to Hong Kong and U.S. laws:

Cooley HK

35/F, Two Exchange Square
8 Connaught Place
Central
Hong Kong

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

as to PRC law:

Zhong Lun Law Firm

8-10/F, Tower A, Rongchao Tower
6003 Yitian Road, Futian District
Shenzhen
Guangdong Province, 518026
PRC

Auditor and Reporting Accountant

Ernst & Young

*Certified Public Accountants and Registered Public
Interest Entity Auditor*
27/F, One Taikoo Place
979 King's Road
Quarry Bay
Hong Kong

Industry Consultant

Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.

2504 Wheelock Square
1717 Nanjing West Road
Shanghai 200040, PRC

Compliance Adviser

Maxa Capital Limited

Unit 1908
Harbour Center, 25 Harbour Road
Wanchai
Hong Kong

[REDACTED]

CORPORATE INFORMATION

**Registered Office, Headquarters
and Principal Place of
Business in the PRC**

Building 15
Lane 3399, Kangxin Road
Pudong New Area
Shanghai
PRC

**Principal Place of Business
in Hong Kong**

Room 1901, 19/F, Lee Garden One
33 Hysan Avenue
Causeway Bay
Hong Kong

Company Website

www.cryofocus.com

*(Information contained on this website does not form part
of this document)*

Joint Company Secretaries

Mr. LIU Wei (劉偉)

Unit 801
No. 31, Lane 1788, Hualing Road
Baoshan District
Shanghai
PRC

Ms. LEUNG Wai Yan (梁慧欣)

*Associate member of The Hong Kong Chartered
Governance Institute and The Chartered Governance
Institute in the UK*

Room 1901, 19/F, Lee Garden One
33 Hysan Avenue
Causeway Bay
Hong Kong

Authorized Representatives

Mr. ZHU Jun (朱軍)

Room 3801
Building 5, Lane 133
Linping Road
Hongkou District
Shanghai
PRC

Ms. LEUNG Wai Yan (梁慧欣)

Room 1901, 19/F, Lee Garden One
33 Hysan Avenue
Causeway Bay
Hong Kong

CORPORATE INFORMATION

Audit Committee

Mr. LIANG Hsien Tse Joseph (梁顯治) (*Chairperson*)
Mr. ZHAO Chunsheng (趙春生)
Dr. QIN Zheng (覃正)

Remuneration Committee

Dr. QIN Zheng (覃正) (*Chairperson*)
Mr. LIANG Hsien Tse Joseph (梁顯治)
Mr. LI Kejian (李克儉)

Nomination Committee

Mr. LI Kejian (李克儉) (*Chairperson*)
Dr. QIN Zheng (覃正)
Dr. HU Henan (胡赫男)

[REDACTED]

Principal Banks

China Merchants Bank (Shanghai Branch, Changyang Sub-branch)

2nd Floor, No. 1441
Changyang Road
Yangpu District
Shanghai
PRC

Bank of Ningbo (Shuangdongfang Sub-branch)

No. 2, Suiyuan Street
Jiangbei District
Ningbo City
Zhejiang Province
PRC

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from the report prepared by Frost & Sullivan, which was commissioned by us, and from various official government publications and other publicly available publications. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [REDACTED]. The information from official government sources has not been independently verified by us, the Joint Sponsors, [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy.

THE INTERVENTIONAL CRYOTHERAPY DEVICE MARKET

Overview of Interventional Cryotherapy

Cryotherapy is a treatment method that freezes and destroys abnormal cells or diseased tissue through extreme cold. When the temperature drops below -40°C and the tissue is frozen, the tissue fluid both inside and outside the cells will form iced crystals, the structure of the cells will be destroyed. After freezing, cell dehydration, lipoprotein degeneration of membrane system, ischemic infarction of the tissue, nutrition deficiency will happen, and finally, the cells necrosis will occur. Cryotherapy can be used to diagnose and treat various diseases, such as cardiovascular diseases, respiratory diseases, benign and malignant tumors.

Interventional cryotherapy is a minimally-invasive therapeutic or biopsy procedure that freezes and destroys abnormal tissue through extreme cold using imaging guidance. Depending on the purpose and outcome of freezing, interventional cryotherapy can be divided into cryoadhesion and cryoablation. Cryoadhesion uses the strong adhesion force brought by low temperature to remove the targeted diseased tissue. Cryoadhesion can be used for diagnostic purposes (e.g., cryobiopsy) and for removal of foreign bodies from natural lumens (e.g., bronchi). Cryoablation is based on the use of cryogenic techniques to freeze and destroy diseased tissue, causing necrosis or apoptosis and ultimately *in situ* inactivation of physical tissue. Cryoablation is applied to treat various diseases such as cardiovascular diseases, respiratory diseases, benign and malignant tumors, etc.

The interventional cryotherapy device market in China exhibits strong growth in recent years and is projected to continue to grow significantly in the near future. The factors that are driving the market growth include, among others, the accelerated aging population, the increased prevalence of chronic diseases, strong government policy support, continuous technological advancements, and advantages associated with the cryotherapy device and procedure. Catheter cryoablation, spray cryotherapy, percutaneous probe cryotherapy and probe cryoadhesion are among the most widely used cryotherapy and are expected to proliferate in the future.

INDUSTRY OVERVIEW

Overview of Cryoablation

Cryoablation is a type of interventional cryotherapy that utilizes extreme cold to freeze, destruct and destroy abnormal cells or diseased tissues. In cryoablation, cryogen is typically transmitted using a catheter or probe that creates extremely cold temperature at the site of treatment, thus freezing the target cells, causing cellular damage, death, and necrosis of diseased tissues. Cryoablation is also a type of ablation performed without open surgery. In contrast to surgical resection that removes an entire organ or part of it, ablation removes only a layer or multiple layers of tissue and does not damage the surrounding healthy tissue. Compared with open surgery, ablation therapy including cryoablation generally has a short recovery time, a short period of hospitalization and less bleeding as well as minimal risks. It can be used to treat a wide range of diseases across several medical domains such as cardiology and oncology.

According to Frost & Sullivan, cryoablation has received increased attention and research in recent years. Based on the estimation and assumption of Frost & Sullivan, cryoablation is expected to become one of the mainstream minimally-invasive treatment modalities. It offers benefits in the following aspects:

- ***Efficacy.*** Cryoablation forms uniform ablation and is able to preserve tissue architecture, in comparison with point-by-point circumferential lesions by radiofrequency ablation which generally shows a relatively higher recurrence rate.
- ***Safety.*** Cryoablation causes less patient pain and less damage to the adjacent tissue during the procedure and reduces scar hyperplasia, when compared to other types of ablation such as radiofrequency or microwave ablation. Its electrophysiological effects are completely reversible within seconds if halted properly.
- ***Operation.*** Catheter stability enables the ease of operation for cryoablation. In addition, cryoablation is less operator-dependent and features short learning curve and short operation time for physicians.

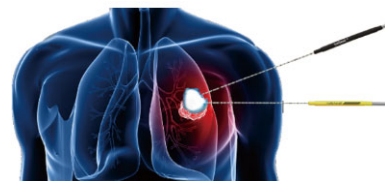
There are three major categories of cryoablation, namely cryoballoon ablation, spray cryotherapy and percutaneous probe cryotherapy:



Cryoballoon Ablation



Spray Cryotherapy



Percutaneous Probe
Cryotherapy

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During cryoballoon ablation or spray cryotherapy, cryoablation catheter enters a patient's body with the assistance of imaging tools such as fluoroscopy, endoscopy and advanced 3D mapping navigation system through blood vessel or natural cavity such as respiratory, digestive or urinary tracts. Cold liquid will be released by an inflated balloon in cryoballoon ablation or sprayed from the catheter in spray cryotherapy to freeze the target tissue and destroy diseased cells. Such cold liquid typically includes liquid nitrogen (N₂), nitrous oxide (N₂O) and carbon dioxide (CO₂). Liquid nitrogen (N₂) is obtainable and affordable and is attractive as a cryogen for its simplicity to use with relatively rapid cooling rate. Compared to nitrous oxide (N₂O) and carbon dioxide (CO₂), liquid nitrogen (N₂) can cool as low as -196°C to enable deeper ablation with adjustable energy supply and continuity, and it is hygienic and environment-friendly. Cryoballoon ablation and spray cryotherapy can be used in the treatment of various diseases such as cardiovascular diseases, respiratory diseases and cancers. In particular, vascular interventional cryoablation, in which the catheter is delivered via blood vessels, is typically indicated for treating cardiovascular diseases, whereas the NOTES interventional cryoablation, in which the catheter enters the body via natural cavity in a NOTES procedure, is generally used to treat tumors and respiratory diseases.

In comparison, percutaneous probe cryotherapy works by inserting a needle of cryoprobe into a patient's body through skin while using imaging tools, such as CT scan and ultrasound, to plan the puncture path. The percutaneous cryoprobe's extremely cold temperature will freeze and destroy the diseased cells, and the dead cells can serve as antigen to promote the body's immune response. It is suitable for treating solid tumors, such as liver, lung, breast and prostate cancer.

Overview of Cryoadhesion

Cryoadhesion utilizes the strong adhesion force created by low temperature to remove diseased tissue. Cryoadhesion can be used to perform diagnostic procedures (e.g., cryobiopsy) and to remove foreign bodies from natural lumens (e.g., bronchi). During cryoadhesion, the target tissue that contains enough water to freeze and adhere to the catheter is drawn out by the adhesion force created by freezing. Typically, cryoadhesion benefits the target tissue that is difficult to remove with standard forceps.

Market Size of Interventional Cryotherapy Devices

The market size of interventional cryotherapy devices reveals a rising trend. The global market size of interventional cryotherapy devices has increased from USD852.9 million in 2016 to USD1,476.7 million in 2020 at a CAGR of 14.7%, and is expected to reach USD13,877.2 million in 2030. In China, the market size of interventional cryotherapy devices has increased from RMB98.0 million in 2016 to RMB390.8 million in 2020, representing a CAGR of 41.3%. The market size of interventional cryotherapy devices in China is expected to further climb to RMB2,890.8 million in 2025 at a CAGR of 49.2% from 2020 to 2025, and to further increase to RMB11,233.9 million in 2030 at a CAGR of 31.2% from 2025 to 2030.

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Growth Drivers and Future Trend for Interventional Cryotherapy Device Market

The interventional cryotherapy device market in China and overseas, including Europe, is expected to grow significantly mainly due to the following factors:

- ***Accelerated aging population and patient pool expansion.*** According to the National Bureau of Statistics, the number of people over the age of 65 reached 190.6 million in 2020, accounting for 13.5% of the total population, which is expected to continue growing in the future. Europeans are also living longer than ever before, with the number of old people in Europe increasing. Furthermore, the prevalence of diseases such as atrial fibrillation, respiratory disease and cancer, increased rapidly in China and Europe over the last decade and is projected to continue to grow significantly in the future due to changes in lifestyle and the increased risk of diseases with age. The aging trend and changing disease patterns will create huge demands for interventional cryotherapy devices in China and Europe.
- ***Unmet medical needs.*** Cryotherapy has been clinically demonstrated its potential in a wide range of unmet medical needs. For certain challenging conditions, such as COPD, medications with limited effectiveness are still the dominant treatment. Novel treatments like cryoablation which provide patients with potentially better efficacy and safety compared with traditional medication therapies, are needed to address the unmet medical needs.
- ***Innovation of technology and higher acceptance.*** Well-developed technologies with simple operations can lower the learning curve for the surgeon and promote acceptance from patients. Cryoablation, as a relatively simple technology to perform when compared with traditional radiofrequency ablation, offers safe and low-pain therapy to benefit patients. Today, for the treatment of atrial fibrillation, European health authorities mainly recommend radiofrequency ablation or cryoablation as the first-line treatment, as an alternative to antiarrhythmic drug therapy. With proficient operation and advanced treatment methods, patients would have higher acceptance for interventional cryoablation, driving the growth of interventional cryotherapy device market in China and overseas.
- ***Favorable policy support and capital investment.*** In recent years, the PRC government has issued several policies to promote the development of interventional therapy, including interventional cryotherapy therapy. For example, the National Health Commission released the “14th Five-Year” *National Clinical Specialties Capacity Building Plan* (《「十四五」國家臨床專科能力建設規劃》) in 2021, which facilitates technological innovation of targeted therapy in the field of malignant tumors, encourages cutting-edge technology projects with specialty characteristics and core competitiveness, and vigorously supports the development of minimally invasive technologies including interventional therapy and local minimally invasive therapy, to realize full county coverage of interventional diagnosis and treatment technologies. Furthermore, the State Council issued “*Health China 2030*” (《「健康中國2030」規劃綱要》) in 2016 to strengthen early diagnosis, early treatment, and early rehabilitation, particularly for key cancers in high-incidence areas, and to gradually incorporate appropriate technologies for early diagnosis and treatment of major chronic diseases, including cancer, into the treatment routine. In addition, EU has favorable health insurance coverage policy that includes cryoablation for treatment of cancer and atrial fibrillation. Reduced financial burden for patients to undergo cryoablation will drive the growth of cryoablation procedures. With the support of government policies, domestic medical device companies have attracted capital in recent years, which is a substantial driving force of market growth.

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Entry Barriers for Interventional Cryotherapy Device Market

The development and commercialization of interventional cryotherapy devices require strong research capabilities, in-depth understanding of market trends and extensive management experience. Therefore, there are high entry barriers for new players to enter the interventional cryotherapy device market, including:

- ***Multi-disciplinary expertise for development of active medical devices.*** An active medical device refers to a device that requires a source of energy for its operation and has an output that is a function of present and past input signals, while passive medical devices don't need an external power source to function. The successful development of active medical devices requires multi-disciplinary expertise in mechanical engineering and advanced materials. For example, an active medical device must be electromagnetically compatible to function normally in its electromagnetic environment without causing an unbearable electromagnetic disturbance to anything in the environment. To prevent the use of electromagnetic interference or electromagnetic harassment and to ensure the safety and effectiveness of active medical devices, high expertise and accumulated industry know-how on product design and manufacturing are necessary to the development of active medical devices.
- ***Technical barriers of interventional cryotherapy device market.*** Effective and accurate control of volume expansion during vaporization is critical when using cryogenics like liquid nitrogen in cryoablation equipment. Especially when applied in cardiovascular intervention, it is important to control the temperature of nitrogen and energy transformation, and thus avoid massive volume expansion of nitrogen while pumping through small channels that might cause "vapor lock" or obstruction to further cryogen flow and lead to serious consequences. In addition, the design and manufacture of the long, thin and flexible catheter that introduces cryogen into the target ablated area is a high-end technology in the development of interventional cryotherapy devices. While ensuring the flexibility of the flexible catheter, retaining a certain degree of rigidity to support the catheter to reach the target position, and ensuring the temperature resistance of the catheter, are all technical barriers to consider in the design and development of catheter for cryoablation.
- ***Manufacturing, promoting and financial barrier.*** Quality control of cryotherapy equipment materials, such as catheters and balloons, is critical during manufacturing. Once the catheter is ruptured due to inability to withstand low temperature or bending during treatment, the leaked liquid nitrogen will cause damage to tissues and organs at extremely low temperatures. Currently, a lack of awareness or comprehensive understanding of the interventional cryotherapy device market is still a barrier to the commercialization of such devices. At the end of the day, it will be those with established and effective platforms to lead the way in the market. In-house development and use of specific materials increase the cost of R&D and manufacturing. As a result, well-capitalized companies have advantages when entering such highly innovative market.

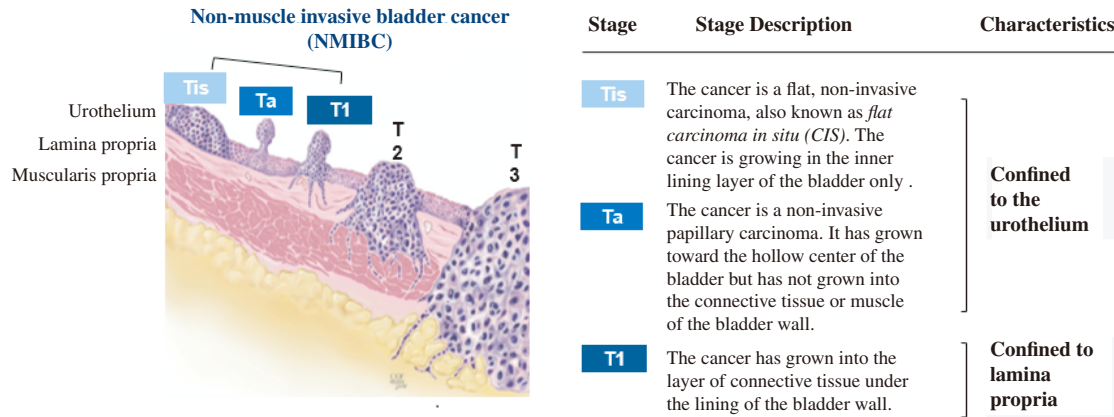
THE BLADDER CANCER INTERVENTIONAL CRYOTHERAPY DEVICE MARKET

Overview of Bladder Cancer

Bladder cancer is one of the several types of cancer arising from the tissues of the bladder, in which cells may grow abnormally and acquire the potential to metastasize. Urothelial carcinoma (UC), also known as transitional cell carcinoma (TCC), is by far the most common type of bladder cancer. UC originates in the urothelial cells that line the inner layer of the bladder. Patients treated with the traditional approaches often see a rapid disease progression and repeated relapses, and the 5-year overall survival rate is less than 50%. There is an urgent need for a novel UC treatment with higher efficacy. Non-muscle-invasive bladder cancer (NMIBC) is a heterogeneous subclassification of UC, in which the cancer is found in the tissues that lines the inner surface of the bladder but not yet invaded into bladder muscle.

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The bladder cancer can also be classified as non-muscle-invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer according to its extent of invasion into the muscular layer. NMIBC generally occurs during the earlier stages of cancer progression. It is papillary carcinoma confined to urothelium (Tis, Ta), and lamina propria (T1). NMIBC accounts for 75% of newly diagnosed bladder cancer. The chart below illustrates the clinical stages of bladder cancer:

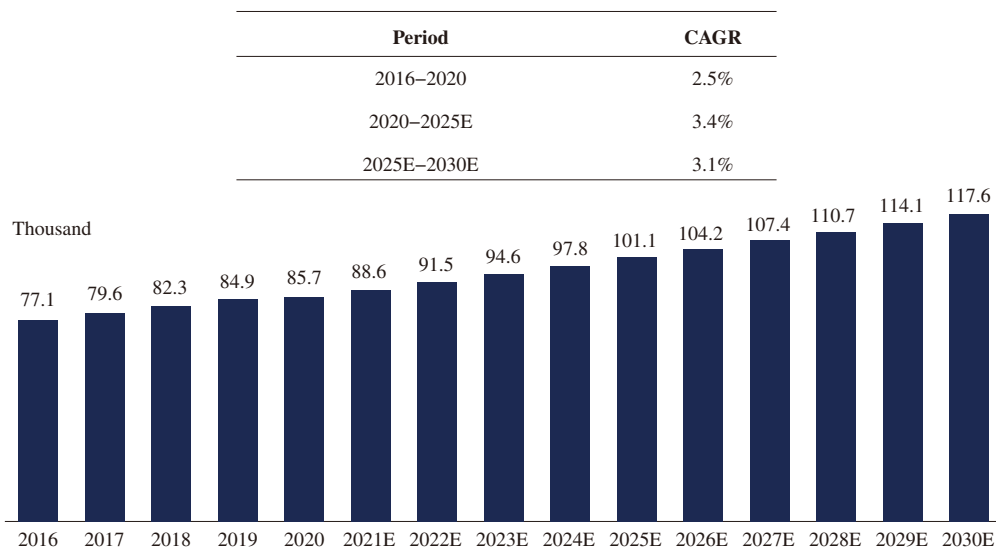


Source: Literature Research, Frost & Sullivan Analysis

Incidence of Bladder Cancer

The incidence of bladder cancer in China increased from 77.1 thousand in 2016 to 85.7 thousand in 2020, representing a CAGR of 2.5% from 2016 to 2020. The incidence of bladder cancer is expected to grow to 101.1 thousand in 2025 with a CAGR of 3.4% from 2020 to 2025, and further reach 117.6 thousand in 2030 with a CAGR of 3.1% from 2025 to 2030. The following chart illustrates the historical and forecasted incidence of bladder cancer in China:

Historical and Forecasted Incidence of Bladder Cancer in China 2016–2030E



Source: Frost & Sullivan Analysis

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According to *Diagnosis and Treatment Guidelines for bladder cancer (2022 edition) (China)*, the occurrence and development of bladder cancer is a complex, multifactorial and multi-step pathological change process, and both internal genetic factors and external environmental factors play an important role. Smoking and long-term exposure to industrial chemicals are two external risk factors for bladder cancer. About 50% of bladder cancer patients have a history of smoking, and the risk of bladder cancer among smokers increases by 2-3 times. The occurrence and development of bladder cancer are related to genetic and genetic abnormalities, and the risk of bladder cancer in those with a family history is significantly increased by two times. Bladder cancer occurs in all age groups, with a high incidence of 50-70 years old. As China’s aging population progresses, the number of people aged 50-70 will continue to increase. At the same time, considering the early detection of related oncogenes, the diagnosis rate of bladder cancer patients will be further improved. Therefore, the number of bladder cancer patients in China is expected to continue to grow.

Treatment of Bladder Cancer

Treatment of bladder cancer is based on the tumor’s clinical stage when it’s first diagnosed. A majority of newly diagnosed bladder cancer is NMIBC. TURBT is typically the first treatment for NMIBC, in which malignant tissue is removed with an electrocautery device during cystoscopy. For muscle-invasive bladder cancer, namely mid- to late-stage bladder cancer, cystectomy and chemotherapy are the main treatments. Major surgical and non-surgical options in bladder cancer management currently available on the market are set out in the table below:

Type of bladder cancer	Stage	Surgical options	Non-surgical options
NMIBC	<ul style="list-style-type: none"> • Ta • Tis or carcinoma in situ 	Transurethral resection of bladder tumor (TURBT)	<ul style="list-style-type: none"> • Intravesical chemotherapy within 24 hours after TURBT • For flat non-invasive (Tis) tumors, intravesical Bacillus Calmette-Guerin (BCG) is the treatment of choice after TURBT
	<ul style="list-style-type: none"> • T1 	<ul style="list-style-type: none"> • TURBT with fulguration is usually the first treatment • a second TURBT is often recommended several weeks later 	<ul style="list-style-type: none"> • If cancer tumors are completely removed after TURBT, intravesical BCG (preferred) or intravesical chemotherapy is usually given • If cancer tumors aren’t completely removed after TURBT, further treatment options can be intravesical BCG.
Muscle-invasive bladder Cancer	<ul style="list-style-type: none"> • T2a and T2b 	<ul style="list-style-type: none"> • TURBT is typically the first treatment for these cancers, but it’s done to help determine the extent or stage of the cancer rather than to try to cure it • If cancer is in only one part of the bladder, a partial cystectomy may be done instead. When the cancer has invaded the muscle, radical cystectomy (removal of the bladder) is the standard treatment. 	<ul style="list-style-type: none"> • Often given chemotherapy before surgery • For people who have had surgery, but the features of the tumor show it is at high risk of recurrence, the drug therapy might be offered.
	<ul style="list-style-type: none"> • T3 and T4 	<ul style="list-style-type: none"> • TURBT is often done first to find out how far the cancer has grown into the bladder wall. • Chemotherapy followed by radical cystectomy (removal of the bladder and nearby lymph nodes) is then the standard treatment. 	<ul style="list-style-type: none"> • Chemotherapy before surgery (with or without radiation) can shrink the tumor • Chemotherapy followed by radical cystectomy is the standard treatment
	<ul style="list-style-type: none"> • T4b 	<ul style="list-style-type: none"> • Urinary diversion or cystectomy as palliative therapy to relieve symptoms 	<ul style="list-style-type: none"> • Chemotherapy (with or without radiation) is usually the first treatment

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TURBT is the first and standard treatment for NMIBC. During TURBT, the cystoscope is passed inside the bladder through the urethra. The targeted tumor is removed using a high-energy laser through the cystoscope. The operation is minimally-invasive, involves minimal amount of bleeding and generally requires short recovery time after the operation. Intravesical immunotherapy through BCG perfusion or chemotherapy can be adjuvant to TURBT in preventing recurrence and progression of NMIBC in the immediate post-operative setting. Specifically, all patients with NMIBC require immediate postoperative perfusion chemotherapy or immunotherapy after TURBT; and more than 74% of patients with NMIBC require maintenance perfusion chemotherapy or immunotherapy after TURBT. NMIBC is characterized by a high rate of recurrence NMIBC. According to literature review, the overall recurrence rate of NMIBC post TURBT can reach 60%; the recurrence is influenced by several clinical and pathologic factors, such as clinical stage and tumor grade. For instance, patients with low-grade Ta lesions generally have a recurrence rate of about 55%, and those with high-grade T1 lesions generally have a recurrence rate of about 45%. There is an increasing need for a novel minimally-invasive treatment with low post-operative recurrence rate.

Based on the estimation and assumption of Frost & Sullivan, cryoablation would be a novel and promising therapy to potentially reduce bladder tumor recurrence after TURBT, though there is currently no recommendation by national or international guidelines of the use of cryoablation in the disease management of bladder cancer. Cryoablation performs several freeze cycles around the lesion, focused ablation on the target sites without damaging untargeted tissue significantly. A balloon is specifically designed on the tip of the catheter and could contact with the vesicle surface and then be inflated and transmitted with liquid nitrogen to form an ice ball. After removal of the bladder tumor, a cryoballoon was inserted into the bladder and placed on the surface of the resected area. After liquid nitrogen delivery, the cryoballoon is formed and its ice sphere is able to penetrate the thickness of the bladder wall. Three minutes of cryoablation is followed by natural thawing. Two to three freezing cycles are performed depending on the size of the tumor to ensure complete coverage of the tumor lesion. The greatest advantage of cryoablation is the ability to reduce persistent tumor to a large extent, Compared to percutaneous cryoablation, the cryoballoon can be inserted through the resectoscope or cystoscope sheath to prevent bladder wall damage and reduce the risk of tumor seeding. For further information on the tumor interventional cryotherapy device market, see “—The NOTES Interventional Cryotherapy Device Market—The Tumor Interventional Cryotherapy Device Market” in this section.

In addition, transurethral laser ablation is another ablation therapy for the treatment of bladder cancer, and it is typically used in conjunction with chemotherapy. According to the Interventional Procedures Guidance published by National Institute for Health and Care Excellence (NICE) in July 2019, despite no major safety concerns demonstrated for treating recurrent NMIBC, current evidence on the efficacy of transurethral laser ablation is limited in quality and quantity. As of the Latest Practicable Date, no medical device for such transurethral laser ablation had been approved for commercialization in China, according to Frost & Sullivan.

TURBT is now covered by provincial insurance reimbursement in some provinces in China. The reimbursement rate varies according to local policies. For example, the reimbursement rate for TURBT is 100% in Beijing and Henan province, but is 70% in Jiangsu province. Neither a national nor a provincial insurance reimbursement program currently covers BCG. The drugs used in perfusion chemotherapy include mitomycin C, epirubicin, pirarubicin, and hydroxycamptothecin, out of which, mitomycin C is fully covered by national insurance reimbursement program; epirubicin, pirarubicin and hydroxycamptothecin are covered by national insurance reimbursement but the reimbursement ratio varies according to provincial policies.

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The cost of a single TURBT procedure is approximately RMB12,171 in China, according to the “*Feasibility Study of Including BCG Vaccine in the Medicare Drug List and the impact on the health insurance fund budget*” (Qinmin et al., 2021). Most patients with NMIBC require maintenance perfusion chemotherapy or BCG perfusion therapy ranging from 2-3 years. Based on the estimation and assumption of Frost & Sullivan, cryoablation is a novel and promising therapy to potentially reduce bladder tumor recurrence after TURBT, which requires fewer patient visits and greater convenience and comfort. The following table sets forth the comparison of cryoablation with the Company’s Bladder Cryoablation System, perfusion chemotherapy and BCG perfusion therapy, in terms of annual drug costs, patients’ comfort and convenience.

	<u>Perfusion chemotherapy</u>	<u>BCG perfusion therapy</u>	<u>Cryoablation</u>
Number of annual procedures and annual costs	Drug cost for a single perfusion of chemotherapy generally ranges from RMB474 to RMB616. After an immediate post-operative chemotherapy following TURBT, maintenance chemotherapy for bladder cancer typically requires about 18 perfusions per year, with an annual drug cost ranging from RMB8,532 to RMB11,088.	Drug cost for a single BCG perfusion treatment is about RMB3,610. After an immediate post-operative BCG perfusion treatment following TURBT, maintenance BCG perfusion therapy typically requires about 19 treatments per year, with an annual drug cost ranging of about RMB68,590.	Cost for a cryoablation procedure with the Bladder Cryoablation System is expected to range from RMB10,000 to RMB15,000. After an immediate post-operative cryoablation following TURBT, the number of maintenance chemotherapy or BCG perfusion treatments per year is expected to decrease from 18 or 19 to about 12, with an annual drug cost ranging from RMB5,688 to RMB43,320.
Time required per operation	According to the results of the Company’s clinical trial, duration for immediate postoperative perfusion chemotherapy is about 28.2±13.35 minutes.	Comparable to perfusion chemotherapy	According to the results of the Company’s clinical trial, surgery time for the Bladder Cryoablation System was about 18.5 minutes.
Patients’ comfort and convenience	According to the <i>Bladder Cancer Guidelines (2022 Edition)</i> , bladder perfusion chemotherapy may result in side effect of chemical cystitis, which is related to the dose and frequency of perfusion.	According to the <i>Bladder Cancer Guidelines (2022 Edition)</i> , the overall adverse reaction rate of BCG intravesical bladder irrigation is 71.8%, which includes bladder irritation sign, hematuria and flu-like syndrome.	Cryoablation with the Bladder Cryoablation System typically has no significant adverse effects and is well tolerated by patients, as evidenced by the fact that no complications occurred in the confirmatory clinical trial for the Bladder Cryoablation System.

As illustrated in the above table, in terms of annual costs, perfusion chemotherapy is the cheapest therapy when compared to the other two; in terms of time required per operation, cryoablation is comparable to the other two therapies; in terms of patients’ comfort and convenience, cryoablation generally has fewer complications and is more convenient because it reduces the number of total procedures required when compared to perfusion chemotherapy and BCG perfusion.

Both the perfusion chemotherapy and BCG perfusion therapy are commonly used in patients with NMIBC after TURBT. Based on the risks of recurrence and the probability of progression to muscle-invasive disease, NMIBC can be classified into four categories, including low-risk NMIBC, intermediate-risk NMIBC, high-risk NMIBC, and very-high-risk NMIBC. By clinical stage, Tis generally

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falls under the low-risk group, Ta typically falls under the low-risk to high-risk groups, and T1 ranges from the low-risk group to very-high-risk group. According to the *Diagnosis and Treatment Guidelines for Bladder Cancer (2022 edition) (China) and European Association of Urology Guidelines on Non-muscle-invasive Bladder Cancer (Ta, T1, and Carcinoma in Situ) (2021 Edition)*, perfusion chemotherapy is recommended for low-risk to high-risk groups; BCG perfusion therapy is recommended for intermediate-risk to very-high-risk groups. Currently there is no guideline that recommends cryoablation for the treatment of NMIBC, because no relevant product has been commercialized yet.

Market Size of Bladder Cancer Interventional Cryotherapy Catheters

The cryotherapy device market is composed of catheter market and active device market (i.e. the device offering energy source). Because the energy source can be used in different departments of hospitals and thus cannot be split, it is difficult to estimate the market size of cryotherapy equipment in the field of bladder cancer treatment. Market size of cryotherapy catheters in the field of bladder cancer treatment is presented as follows.

According to Frost & Sullivan, the global market size of interventional cryotherapy catheters for the treatment of bladder cancer is predicted to arise from USD0.4 million in 2022 to USD363.5 million in 2030, and the market size of interventional cryotherapy catheters for the treatment of bladder cancer in China is expected to grow significantly from RMB2.7 million in 2022 to reach RMB355.7 million in 2030. Frost & Sullivan has estimated the market size for cryoablation catheters for bladder cancer in China and globally based on a variety of studies. Frost & Sullivan conducted market researches on both the demand side and the supply side of the cryoablation market indicated for use in the treatment of bladder cancer via multi-channel sources, including sales data and profiles of relevant medical device companies, literature research, interviews with relevant experts, and market trends. Frost & Sullivan anticipates that the estimated market growth will be primarily driven by the growth in the incidence of bladder cancer, growth in the population of patients with potential recurrence after TURBT, and the need for secondary surgical treatment to reduce recurrence rates.

Specifically, as the population ages, the incidence of bladder cancer is expected to increase annually. The incidence of bladder cancer in China was 85.7 thousand in 2020, and is expected to reach 117.6 thousand in 2030. As NMIBC accounts for approximately 75% of all bladder cancer incidences, the number of people with NMIBC in China was about 64.4 thousand in 2020, and is expected to reach 88.6 thousand by 2030. According to the *Expert Consensus on Bladder Perfusion Therapy for Non-Muscle Invasive Bladder Cancer (2021 Edition)* and expert interviews conducted by Frost & Sullivan, TURBT is the first-line treatment for NMIBC, and the proportion of NMIBC patients undergoing TURBT among those receiving surgical treatment was approximately 87.2% in 2020, which is expected to reach 94.8% by 2030. Thus, the number of NMIBC patients treated with TURBT in China was approximately 55.1 thousand in 2020, and is expected to increase to 82.9 thousand by 2030. On top of the above, the 5-year recurrence rate after initial TURBT is about 60%. Such patients are in need of new treatment modalities that can address the high recurrence rate.

Cryoablation, as an adjuvant therapy with TURBT for bladder tumors, has various potential benefits including its ability to eliminate the residual tumor to the greatest extent, ease of use, ease of learning by physician, relatively short learning curve and short operation time without complications as evidenced by the fact that no complications occurred in the confirmatory clinical trial for the Bladder Cryoablation System according to the final clinical trial report. Since cryoablation is a novel therapy for the treatment of bladder cancer, it may take time to educate the market and gain acceptance among

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physicians and patients. Similar to other medical procedures, cryoablation may carry some small risks such as infection, wounds and accidental damage to nearby, healthy tissues. Nevertheless, considering the aforesaid benefits such as ease of use and ease of learning by physicians that lower the hurdles of physicians to accept and perform cryoablation, Frost & Sullivan estimates that physician acceptance and market penetration of such cryoablation treatment will increase. Synthesizing expert interviews, Frost & Sullivan predicts that by 2030, the proportion of patients receiving cryoablation after a single TURBT treatment will be about 45%, and the number of patients expected to receive cryotherapy after TURBT will be about 37.4 thousand in 2030. Therefore, the volume of relevant cryotherapy procedures in 2030 is expected to be about 44.9 thousand. Theoretically, one cryotherapy catheter is used per procedure, and given that there is attrition, the volume of bladder cancer cryoablation catheters is anticipated to reach about 47.9 thousand in 2030.

For future price trends for cryotherapy catheters, since no cryoablation product specific for post-TURBT bladder cancer has been commercialized, Frost & Sullivan referenced the bidding prices of NMPA-approved cryotherapy catheters for the treatment of solid tumors and made certain assumptions and estimates for future average ex-factory prices. Taking into account the possibility of potential foreign products’ entry into the market and possible future technology introductions, technology updates and product iterations, Frost & Sullivan estimates that the ex-factory price of interventional cryotherapy catheters for the treatment of bladder cancer will increase in the future and rise to about RMB7,000 by 2030. The market size is obtained by multiplying the volume of catheters by the average ex-factory price. Based on the foregoing, Frost & Sullivan predicts that the market size of the interventional cryotherapy catheters for the treatment of bladder cancer in China will reach RMB355.7 million in 2030.

Our Company plans to increase physician acceptance and market penetration for the Bladder Cryoablation System through academic promotion, physician training, and publication of additional real-world clinical data based on further R&D activities. In particular, we plan to initially introduce the Bladder Cryoablation System to top Class III hospitals in provincial capitals or tier-one cities such as Beijing and Shanghai and then introduce it to the eligible hospitals in lower tier cities in China through providing training programs to physicians and organizing academic conferences. We will also provide general training and follow-up studies and training to physicians regularly to increase market penetration and market share. For further information on the competitive landscape and future trends of the relevant market, see the paragraphs headed “—Competitive Landscape of Interventional Cryotherapy Devices for Solid Tumor” below in this section.

Competitive Landscape of Interventional Cryotherapy Devices for Solid Tumor

As of the Latest Practicable Date, there were only seven commercialized interventional cryotherapy products for solid tumors in the world, and five of them were approved by the NMPA as detailed in the chart below. In addition, the Company’s Bladder Cryoablation System received the NMPA approval for commercialization in June 2022. According to Frost & Sullivan, the Company was the only market player that had spray cryotherapy and cryoballoon ablation devices under development for the treatment of solid tumors in China.

The products currently commercialized in China use a cryo-catheter that enters the body through percutaneous puncture to freeze and thaw targeted tissue, which involves the incision on the skin. The Company’s product candidates, including the Bladder Cryoablation System, the Esophageal Cryospray System, and the Gastric Cryoablation System, use cryoballoon or spray cryotherapy and flexible catheters via natural orifice instead of percutaneous cryoablation needles to achieve the ablation

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treatment with minimal invasion, which are generally safer, associated with less bleeding and fewer side effects as well as lower chances of post-operative complications compared to percutaneous cryoablation. In addition, none of these percutaneous intervention products listed in the chart below is specifically designed for the treatment of bladder cancer, and none of them is indicated for post-TURBT surgery to eliminate residue bladder tumors. Thus, the Company does not consider these percutaneous intervention products as direct competitors of the Bladder Cryoablation System. Furthermore, among these percutaneous intervention products, Siemens’s Cryocare and Boston Scientific’s Visual-Ice use argon-helium as cryogen. Compared to argon-helium, liquid nitrogen is less costly, more obtainable, safer and more environmentally friendly. Thus, the Bladder Cryoablation System enjoys advantages over these two products by using liquid nitrogen.

Percutaneous Intervention					
Manufacturer	Siemens	Hygea	Boston Scientific/ Galil Medical	AccuTarget	IceCure Medical
Product	Cryocare®	Kangbo Knife	Visual-Ice®	Disposable Cold Knife	IceSense® 3
NMPA Approval Time	2008	2017	2019	2019	2021
Technique	Cryo-probe	Cryo-probe	Cryo-probe	Cryo-probe	Cryo-probe
Intervention	Percutaneous Intervention	Percutaneous Intervention	Percutaneous Intervention	Percutaneous Intervention	Percutaneous Intervention
Application	<ul style="list-style-type: none"> The extremely low temperature at the tip of the ultra-cold surgical device is used to freeze and ablate tissues including prostate and kidney tissue, liver metastases and tumors. 	<ul style="list-style-type: none"> Cryotherapy for various solid tumors such as lung cancer, liver cancer, kidney cancer, prostate cancer, bone tumor, soft tissue tumor breast cancer, etc. 	<ul style="list-style-type: none"> Suitable for various malignant and benign tumors, such as prostate cancer, skin cancer, angiomas, rectal cancer, etc. 	<ul style="list-style-type: none"> The extremely low temperature of the disposable cold knife treatment section of this product is used to freeze and ablate the tissue and inactivate it for the treatment of solid tumors. 	<ul style="list-style-type: none"> A liquid nitrogen-based system for the destruction of benign and cancerous tumors by cryoablation in various solid tumors, including breast cancer.
Cryogen	Argon and helium	Liquid nitrogen	Argon and helium	Nitrogen gas	Liquid nitrogen

Source: FDA, NMPA, Company official website, Frost & Sullivan Analysis

In terms of the treatment of bladder cancer, as of the Latest Practicable Date, no cryoablation product for post-TURBT surgery had been commercialized, and there were only two cryoablation product candidates for post-TURBT surgery under development in the world, according to Frost & Sullivan. One is our Bladder Cryoablation System; the other one is under development of Vessi Medical, which completed a first-in-human case for superficial bladder cancer in July 2021. According to Frost & Sullivan, all the R&D activities of Vessi Medical in relation to its bladder cryoablation product candidate were conducted in Israel, and there was no sign that Vessi Medical was planning to commercialize its products in the China market in the short-to-mid-term, based on which, this product candidate is not a direct competitor of the Bladder Cryoablation System in China, but is expected to be a potential competing product of the Bladder Cryoablation System in Europe in the future.

The Company obtained the NMPA approval for the Bladder Cryoablation System in June 2022. Our Bladder Cryoablation System is a cryotherapy device specifically designed for the treatment of bladder cancer, and it is currently indicated for the treatment of NMIBC. As elaborated in the paragraphs headed “—Market Size of Bladder Cancer Interventional Cryotherapy Catheters” above in this section, the number of patients with NMIBC in China is expected to reach 88.6 thousand by 2030. According to the “*Best practice in the treatment of nonmuscle invasive bladder cancer*”(Anastasios et al. 2012), out of all newly diagnosed NMIBC, 70% present as stage Ta, 20% as T1 and 10% as Tis. Based on the foregoing, it is roughly estimated that the patient population applicable to use the Bladder Cryoablation System is expected to be about 88.6 thousand in China by 2030, including about 62.0 thousand at stage Ta, 17.7 thousand at stage T1, and 8.9 thousand at stage Tis.

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The Bladder Cryoablation System is simpler and easier for physicians to perform than re-TURBT; cryoablation is also effective, less painful, and associated with fewer complications while preserving the opportunity for further surgical intervention. Therefore, the Company expects the Bladder Cryoablation System to rapidly open up the market after its launch, with an estimated adaptation rate following TURBT of approximately 10% by 2025, which represents the number of patients who choose treatment with the Bladder Cryoablation System as a percentage of the total number of patients who need further treatment after TURBT. The Company forecasts that the Bladder Cryoablation System will take up a major share of the post-TURBT bladder cancer cryoablation market in 2023 and a few years thereafter. Even taking into account the possibility of foreign products' entry into the Chinese market, including Vessi Medical's cryoablation product, the Bladder Cryoablation System is still expected to maintain a large market share by leveraging its first-mover advantage. In addition, based on literature review, the penetration rate of cryoablation in atrial fibrillation surgery in Japan increased to 22.6% by 2021 since its introduction in 2015. Considering that cryoablation for atrial fibrillation shared advantages with cryoablation for bladder cancer, also based on the foregoing and the advantages of cryoablation over other adjuvant therapies after TURBT, the Company further expects the Bladder Cryoablation System to achieve an adaptation rate following TURBT of approximately 30% by 2030.

THE ENDOSCOPIC CLIP MARKET

Overview of Endoscopic Clips

Endoscopic clip is a form of the metal clip for flexible endoscopes. It has made their way into standard gastrointestinal endoscopic practice for common indications, such as ulcer, diverticular bleeding, or bleeding or high-risk polypectomy sites. It is also used for other indications, such as securing stents, feeding tubes and other devices; marking of endoscopic lesions for X-ray or magnets; closing fistulas and perforations, including sealing the luminal entry site in experimental NOTES.

Overview of Gastrointestinal Bleeding and Perforation

Indications of endoscopic clips mainly include gastrointestinal bleeding or perforation. According to Frost & Sullivan, the population of people suffering from gastrointestinal bleeding or perforation in China was 967.9 thousand in 2016, which increased to 1,008.2 thousand in 2020 and is predicted to reach 1,090.6 thousand in 2030.

Gastrointestinal bleeding and perforation are common complications of peptic ulcer diseases. A peptic ulcer disease is a sore in the inner lining of the stomach or upper small intestine. A peptic ulcer disease is common with a lifetime prevalence in the general population of 5-10% and an incidence of 0.1-0.3% per year. Ulcer bleeding is the most common complication of gastric ulcer and is more common in the elderly and in those on anti-platelet agents or anticoagulants; perforation is a serious complication of peptic ulcer disease and patients with perforated peptic ulcer often present with acute abdomen.

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According to the *Perforated and bleeding peptic ulcer: WSES guidelines*, endoscopy is the first-line investigation of choice for an undifferentiated upper gastrointestinal hemorrhage. In patients with bleeding peptic ulcer, non-operative management, namely endoscopic treatment, is recommended to be the first line of management after endoscopy. The following table sets forth the treatment paradigm for bleeding peptic ulcer:

Bleeding peptic ulcer	Non-operative management–endoscopic treatment	<ul style="list-style-type: none"> Spurting ulcer Oozing ulcer Ulcer with non-bleeding visible vessel 	Endoscopic hemostasis is recommended, 1C
		<ul style="list-style-type: none"> Bleeding peptic ulcer 	Dual modality for endoscopic hemostasis, 2B
	Angiography, embolization	<ul style="list-style-type: none"> Hemodynamically stable bleeding peptic ulcer Endoscopic hemostasis fails twice or is not possible/feasible 	Angiography with angioembolization where technical skills and equipment are available, 2D
		<ul style="list-style-type: none"> Rebleeding peptic ulcer 	Angioembolization as a feasible option, 2C
	Surgery	<ul style="list-style-type: none"> Failure of repeated endoscopy 	Surgical intervention with open surgery, 2D
	Antimicrobial therapy	<ul style="list-style-type: none"> <i>H. pylori</i>-positive 	Eradication therapy is recommended to avoid recurrent bleeding, 1C

1C: strong recommendation based on low-quality evidences

2B: weak recommendation based on moderate-quality evidences

2C: weak recommendation based on low-quality evidences

2D: weak recommendation based on very low-quality evidences

Source: WSES guideline 2020, Frost & Sullivan analysis

For the treatment of perforated peptic ulcer, endoscopic treatment could be considered when there is no contrast extravasation and signs of peritonitis or sepsis. Endoscopic clips are the most commonly used endoscopic modality in the closure of gastrointestinal perforations. The following table sets forth the treatment paradigm for perforated peptic ulcer:

Perforated peptic ulcer	Non-operative management–endoscopic treatment	<ul style="list-style-type: none"> No contrast extravasation No signs of peritonitis or sepsis 	Clipping, fibrin glue sealing, or stenting, 2C		
	Surgery	<ul style="list-style-type: none"> Significant pneumoperitoneum Extraluminal contrast extravasation 	Small perforation (< 2 cm)	No recommendation can be made whether the use of an omental patch can provide further protection of the repair, 2C	
			Large perforation (≥ 2 cm)	Large gastric ulcers	Resection with contextual operative frozen pathologic examination whenever possible, 2D
				Large duodenal ulcers	Resections or repair plus/minus pyloric exclusion/external bile drainage, 2D
Septic shock from a perforated peptic ulcer and signs of severe physiological derangement	A damage control strategy, 2D				
Antimicrobial therapy	In patients with perforated peptic ulcer, we recommend the administration broad-spectrum antibiotics, 1C				

1C: strong recommendation based on low-quality evidences

2C: weak recommendation based on low-quality evidences

2D: weak recommendation based on very low-quality evidences

Source: WSES guideline 2020, Frost & Sullivan analysis

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Endoscopic Management of Gastrointestinal Bleeding and Perforation

Endoscopic clips are the most commonly used endoscopic modality in the closure of gastrointestinal perforations. Two types of endoscopic clips are available, through-the-scope clip (“**TTS Clips**”) and over-the-scope clip (“**OTS Clips**”). TTS Clips are technically less demanding and can be used to close small defects of less than 1 cm while OTS Clips can provide full-thickness closure of defects of up to 2 cm in a single application, including those with everted edges. For further information, see the paragraphs headed “—Type of Endoscopic Clips” in this section. The following table sets forth the preferred endoscopic closure treatment for different perforations in gastrointestinal tract according to the *AGA Clinical Practice Update on Endoscopic Management of Perforations in Gastrointestinal Tract: Expert Review*:

AGA Clinical Practice Update on Endoscopic Management of Perforations in Gastrointestinal Tract: Expert Review

Location of perforation	Perforation Size	Preferred endoscopic closure techniques
Esophagus	• Small perforations (< 2 cm)	• TTS Clips or OTS Clips
	• Large perforations (> 2 cm)	• Self-expanding metal stent
	• Large or persistent esophageal perforations	• Endoscopic vacuum therapy
Stomach	• Small perforations (< 1 cm)	• TTS Clips
	• Defects of 1-3 cm in size	• OTS Clips
	• Defects of larger than 3 cm	• Combination of endoloop and TTS Clips, or endoscopic suturing
Duodenal and Periampullary	• Type 1 small perforations, caused by excessive shearing force or angle-related trauma to the bowel wall by the shaft or tip of the duodenoscope	• TTS Clips, OTS Clips, band ligation, or endoloops
	• Type 1 large perforations, caused by excessive shearing force or angle-related trauma to the bowel wall by the shaft or tip of the duodenoscope	• Endoscopic suturing
	• Type 2 perforations, caused by an overextension of a sphincterotomy beyond the intraduodenal portion of the ampulla	• Self-expanding metal stent
Colon	• Clean perforation site without spillage of colonic contents into the peritoneum	• TTS Clips, OTS Clips, or endoscopic suturing
	• Perforation in the cecum or a tortuous or unclear colon	• No safe and effective treatment currently available, and new suture-based device, X-Tack Endoscopic HeliX Tacking System, is lack of data from human studies

Source: Literature Review, Frost & Sullivan analysis

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Upper gastrointestinal bleeding refers to bleeding originating from sites in the esophagus, stomach, or duodenum. Endoscopic therapy is recommended for patients with upper gastrointestinal bleeding due to ulcers with active spurting, active oozing, and non-bleeding visible vessels. Patients who experience recurrent bleeding after endoscopic therapy for a bleeding ulcer are suggested to undergo another endoscopy and endoscopic therapy rather than surgery or transcatheter arterial embolization. The following table sets forth the recommended endoscopic management for different upper gastrointestinal bleeding according to the *ACG Clinical Guideline: Upper Gastrointestinal and Ulcer Bleeding*:

ACG Clinical Guideline: Upper Gastrointestinal and Ulcer Bleeding

Classification	Endoscopic Management	Recommendation
Upper gastrointestinal bleeding due to ulcers	<ul style="list-style-type: none"> • Bipolar electrocoagulation, heater probe, or injection of absolute ethanol 	<ul style="list-style-type: none"> • Strong recommendation, moderate-quality evidence
	<ul style="list-style-type: none"> • Clips, argon plasma coagulation, or soft monopolar electrocoagulation 	<ul style="list-style-type: none"> • Conditional recommendation, very-low- to low-quality evidence
Actively bleeding ulcers	<ul style="list-style-type: none"> • Hemostatic powder spray TC-325 	<ul style="list-style-type: none"> • Conditional recommendation, very-low-quality evidence
Recurrent bleeding due to ulcers after previous endoscopic hemostasis	<ul style="list-style-type: none"> • OTS Clips 	<ul style="list-style-type: none"> • Conditional recommendation, low-quality evidence
Failed endoscopic therapy	<ul style="list-style-type: none"> • Transcatheter arterial embolization 	<ul style="list-style-type: none"> • Conditional recommendation, very-low-quality evidence

Source: Literature Review, Frost & Sullivan analysis

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Management of Iatrogenic Endoscopic Perforations

Iatrogenic perforation is a rare but severe complication of endoscopy and its occurrences grow with the expansion of interventional endoscopy, so proper diagnosis and management are of importance. Endoscopic closure should be considered depending on the type and size of the iatrogenic perforation as well as the endoscopist’s expertise. The following table sets forth the treatment paradigm for iatrogenic endoscopic perforation according to the *Diagnosis and management of iatrogenic endoscopic perforations: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement – Update 2020*:

Diagnosis and management of iatrogenic endoscopic perforations: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement – Update 2020

Location of perforation	Recommendation
Esophagus	<ul style="list-style-type: none"> • First-step endoscopic treatment: TTS Clips can be used for perforations < 10mm, and OTS clips are recommended for perforations > 10mm. Stents can be used for larger defects (> 20mm)
Gastrointestinal tract	<ul style="list-style-type: none"> • Use TTS Clips for perforations ≤ 10mm, and OTS Clips, omental patching or the combined technique using endoloop and TTS Clips for perforations > 10mm
Periampullary and biliopancreatic ducts	<ul style="list-style-type: none"> • Non-surgical management in the majority of periampullary or biliopancreatic ductal iatrogenic perforations • TTC clips may be used for Stapfer types I and II* perforations
Duodenal and small-bowel	<ul style="list-style-type: none"> • Perforation is diagnosed immediately or early (< 12 hours) after the procedure: endoscopic treatment. Clips have been used to close Stapfer type I* perforations in the majority of cases • For large perforations, a combination of an endoloop and TTS Clips can enable successful closure • OTS Clips can be used for perforations of up to 20mm in diameter • Failed endoscopic treatment or perforation is diagnosed late (> 12 hours): surgery
Colorectum	<ul style="list-style-type: none"> • TTS Clips for iatrogenic perforation < 10mm • OTS Clip for defects > 10mm



* Stapfer types I: lateral or medial wall duodenal perforation
 Stapfer types II: perivaterian injuries

Source: Literature Review, Frost & Sullivan analysis

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Type of Endoscopic Clips

The endoscopic clipping systems consist of two main forms: TTS Clip and OTS Clip. The main differences between TTS Clips and OTS Clips are in the following aspects:

	TTS Clip	OTS Clip
Illustrative Diagram		
Product structure	A TTS Clip is an endoscopic surgical instrument with a metal clip for the anastomosis of tissues in the gastrointestinal tract.	An OTS Clip consists of an applicator cap, a mounted clip, a hand wheel, thread, and thread retriever. The mounted clip is made of a super-elastic alloy (Nitinol), which is a biocompatible and magnetic resonance imaging conditional material.
Working path	TTS Clips pass through the endoscopic clamp channel	OTS Clips are mounted on the outside of the endoscope.
Indication and clinical application	TTS Clips are used for closing smaller luminal defects, less than 20 mm. They are suitable to treat small perforations without inflammatory reaction and edema due to their small clamping diameter and clamping force.	OTS Clips can provide full-thickness closure of defects of up to 20-30 mm with single application. They have a larger wingspan, which can close more tissues and has stronger clamping force. They can pull all the peripheral tissues of the perforation or fistula into the cap, to close the perforation and even the whole layer of the digestive tract.
Patient population	Patients suffering from bleeding and perforated peptic ulcers, with relatively small luminal defects (less than 20 mm)	Patients suffering from bleeding and perforated peptic ulcers. OTS Clips suitable for closing larger luminal defects

TTS Clips are typically only used for closing small luminal defects of less than 20 mm, while OTS Clips can occlude more tissues and effectively close larger perforations. The classical indications for OTS Clips include closure or treatment of gastrointestinal perforations, leakages, fistulas including anorectal lesions, and uncontrolled bleedings. In addition, studies investigating OTS Clips showed their superiority over conventional endoscopic clips with regard to the closure capacity of iatrogenic perforations.

As early as 2014, the European Society of Gastrointestinal Endoscopy (ESGE) mentioned in its consensus on the *Diagnosis and management of iatrogenic endoscopic perforations* that in the case of perforations measuring 10 – 30 mm, use of OTS Clips or omental patching, or the combined technique using an endoloop and TTS Clips are recommended, and TTS Clips alone are not recommended. In its most recent update of the consensus (Update 2020), for iatrogenic endoscopic perforations, OTS Clips are the only technique recommended for esophageal perforation of 10 mm-20 mm, duodenal and small-bowel perforations of up to 20 mm in diameter and colorectum defects of more than 10mm. In this update of consensus, ESGE further highlighted the safety and efficacy of OTC Clips. It noted that “the OTS clip has become the most popular endoscopic tool for closing gastric perforations, giving the

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possibility of closing 30-mm diameter defects”, “recent systematic reviews based mainly on case series report that the OTS clipping system is a safe, easy to handle, and efficacious method to treat both diagnostic and therapeutic colorectal perforations”, “in the case of defects measuring 10 – 30 mm, the OTS clipping system has been the most evaluated technique and has already demonstrated its efficacy in clinical studies for the management of postoperative leaks or fistulas”, and that “in the case of OTS clipping unavailability, the combined technique using TTS clips plus endoloop can be recommended”. ESGE also specifically mentioned that “ESGE recommends first-step endoscopic treatment for endoscopy-related esophageal iatrogenic perforation. TTS clips can be used for perforations < 10 mm, and OTS clips are recommended for perforations > 10 mm”.

In addition, according to the *ACG Clinical Guideline: Upper Gastrointestinal and Ulcer Bleeding*, in the management of perforations in gastrointestinal tract, OTS Clips are the only recommendation in cases of recurrent bleeding due to ulcers after previous endoscopic hemostasis. Furthermore, according to the *AGA Clinical Practice Update on Endoscopic Management of Perforations in Gastrointestinal Tract: Expert Review*, OTS Clips can also be used to treat esophageal perforations with defects of less than 20 mm, gastric perforations with 10-30 mm defects, type I small perforations in duodenal and periampullary, and some cases of colon perforation. Other guidelines recommending OTS Clips include, among others, the *Endoscopic diagnosis and management of nonvariceal upper gastrointestinal hemorrhage (NVUGIH): European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2021* stating that OTS Clips can be considered as first-line therapy for actively bleeding ulcers, and the *Guidelines for the diagnosis and treatment of lower gastrointestinal bleeding (2020)* stating that OTS Clips can also be used as salvage treatment for bleeding after polypectomy.

According to Frost & Sullivan, based on literature review, the annual global incidence of peptic ulcer bleeding is about 57 per 100,000 people and the incidence of gastrointestinal perforations is about 10 per 100,000 people; the global incidence of gastrointestinal tumors is approximately 3.7 million people, accounting for approximately 18.6% of the incidence of tumors. Gastrointestinal fistula is a common complication after abdominal surgery, particularly when treating gastrointestinal tumors. For example, endoscopic clips are used to treat fistulas in approximately 45,000 new cases of esophageal cancer and approximately 641,000 new cases of colorectal cancer worldwide each year.

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Competitive Landscape and Market Size of Endoscopic Clips

As of the Latest Practicable Date, there were 32 endoscopic clips commercialized in China as detailed in the table below, out of which three products, namely the OTSC[®] System Set of Ovesco, the Disposable Hemostatic Closure Clip of Micro-Tech and the Company’s Endoscopic Clip for Anastomosis, were OTS Clips, and the other 29 products were all TTS Clips, according to Frost & Sullivan.

Company Name	Product Name	Type	Approval Year	Average End User Price/RMB
Cryofocus	Endoscopic Clip for Anastomosis	OTS Clip	2022	N/A
Ovesco	OTSC [®] System Set	OTS Clip	2013	15,727
Micro-Tech	Disposable Hemostatic Closure Clip (一次性使用止血閉合夾)	OTS Clip	2022	7,980
	Harmony Clip (可旋轉重複閉閉軟組織夾)	TTS Clip	2018	401
	Disposable Soft Tissue Clip (一次性使用軟組織夾)	TTS Clip	2022	Undisclosed
Boston Scientific	Disposable Tissue Clip for Gastrointestinal Tract (一次性使用消化道軟組織夾)	TTS Clip	2013	153
	Resolution Clip Device	TTS Clip	2016	759
Olympus	Resolution 360 Clip	TTS Clip	2019	1,440
	Clip Fixing Devices (夾子裝置)	TTS Clip	2015	935
	Clip Fixing Devices (夾子裝置)	TTS Clip	2015	1,297
	Clip Fixing Devices (夾子裝置)	TTS Clip	2015	1,297
	Clip Fixing Devices (夾子裝置)	TTS Clip	2014	2,631
Frankenman	Disposable Soft Tissue Clip with Applier (一次性使用帶推送器軟組織夾)	TTS Clip	2016	443
MEDNOVA	Disposable Hemoclip	TTS Clip	2019	502
Fuda Medical (富達醫療器械)	Disposable Soft Tissue Clip (一次性使用軟組織夾)	TTS Clip	2019	199
Vedkang	Endoscopic Hemoclip (麒麟夾)	TTS Clip	2018	519
Beijing ZKSK Technology	Disposable Hemoclip	TTS Clip	2018	320
Alton	Disposable Soft Tissue Clip for Gastrointestinal Tract (一次性使用消化道軟組織夾)	TTS Clip	2016	153
Anrei medica	Coagulate Grasper (一次性使用止血夾)	TTS Clip	2016	316
	Coagulate Grasper (一次性使用止血夾)	TTS Clip	2019	358
GRIT MEDICAL	Disposable Endoscopic Hemoclip	TTS Clip	2021	340
LANTEX	Clipping Device 一次性使用消化道用軟組織夾	TTS Clip	2017	347
	Clipping Device 一次性使用消化道用軟組織夾	TTS Clip	2017	347
AGS Medtech	Hemoclip (夾子裝置)	TTS Clip	2016	330
PENG Tian Medical	Disposable Hemoclips (夾子裝置)	TTS Clip	2021	323
Shangxian Medical (尚賢醫療)	Disposable Soft Tissue Clip for Gastrointestinal Tract System (一次性使用消化道軟組織夾系統)	TTS Clip	2015	682
U.Mair Medical	Disposable Soft Tissue Clip with Applier (一次性使用帶推送器軟組織夾)	TTS Clip	2021	Undisclosed
KeyiZhitou Medical (科醫智投)	Disposable Soft Tissue Clip (一次性使用軟組織夾)	TTS Clip	2021	Undisclosed
Microport Urocare (微創優通)	Disposable Hemoclips (一次性使用夾子裝置)	TTS Clip	2022	Undisclosed
AteTec Medical (安特爾醫療)	Disposable Hemoclips (一次性使用夾子裝置)	TTS Clip	2022	Undisclosed
RuiTian Medical (銳天醫療)	Disposable Hemoclips (夾子裝置)	TTS Clip	2022	Undisclosed
LeoMed (樂奧醫療)	Disposable Hemoclips (一次性使用夾子裝置)	TTS Clip	2022	Undisclosed

* The average end user price represents the average of published prices on the medical consumables centralized procurement platforms.

Source: NMPA, public medical procurement platform, Frost & Sullivan Analysis

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Ovesco, Micro-Tech and the Company were the market players that had commercialized OTS Clip products in China as of the Latest Practicable Date. However, Ovesco’s registration certificate for its OTS Clip product in China was expired, making the Disposable Hemostatic Closure Clip of Micro-Tech the only competing product of the Company’s Endoscopic Clip for Anastomosis in China.

Key players in the international OTS Clip market are Ovesco and Aponos Medical, which in aggregate had six OTS Clip products approved by the FDA or CE Marked as of the Latest Practicable Date. Details of the OTS Clips and major TTS Clips commercialized in the international market are set out in the table below:

Company Name	Product Name	Type	Approval Year	Average End User Price/USD
Ovesco	OTSC Clip	OTS Clip	2009 (CE) 2010 (FDA)	550
	OTSC Mini	OTS Clip	2010 (FDA)	550
	OTSC Stentfix	OTS Clip	2019 (FDA)	560
	Gastroduodenal FTRD Set	OTS Clip	2015 (CE) 2020 (FDA)	800
Aponos Medical	Padlock Clip	OTS Clip	2019 (FDA)	400
	Padlock Clip Pro-Select	OTS Clip	2019 (FDA)	400
Boston Scientific	Resolution Clip	TTS Clip	2003 (FDA)	80
	Resolution 360™ ULTRA Clip	TTS Clip	2020 (FDA)	120
Cook Medical	Instinct Plus	TTS Clip	2020 (FDA)	110
Olympus	QuickClip2	TTS Clip	2005 (FDA)	100
	QuickClip Pro	TTS Clip	2014 (FDA)	100
ConMed	DuraClip	TTS Clip	2016 (FDA)	80
Micro-Tech	SureClip Repositionable Hemostasis Clip	TTS Clip	2018 (FDA)	80
	Lockado Repositionable Hemostasis Clip	TTS Clip	2021 (FDA)	90

Source: Company Websites, FDA, Frost & Sullivan Analysis

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Compared to the OTS Clips currently commercialized in the market, the Company’s Endoscopic Clip for Anastomosis has a separable structure that makes its clamp detachable, allowing for easier clip removal and avoiding secondary damage to the tissue. Further comparison and analysis of OTS Clip products are set out in the table below:

Feature	The Company’s Endoscopic Clip for Anastomosis	Ovesco’s OTS Clips	Aponos Medical’s OTS Clips	Micro-Tech’s Disposable Hemostatic Closure Clip
Shape	Occlusion jaws with binding wire and detach ring, adopting bear claw-shaped design	Bear claw-shaped	Hexagonal-shaped	A plurality of outer ring members connected in order, a fillet, and an inner needle are included
Operating channel	Through the working channel of the endoscope	Through the working channel of the endoscope	Outside the operating channel of the endoscope	N/A
Invaginates tissue inside cap	By suction or by use of twin grasper or other instruments	By suction or by use of twin grasper or anchor	Only by suction	N/A
Hold of tissue	Parallel pressure on tissue, Anti-tissue necrosis design	Parallel pressure on tissue, Anti-tissue necrosis design	Circumferentially-placed inner prongs create firm hold of tissue and thorough closure	N/A
Deployment of clamps	By dual threads connected to reel of a releaser	By a thread connected to a rotating handle	Using lock-it delivery system	By a thread connected to a handle

Source: Company websites, Literature Review, Frost & Sullivan Analysis

Frost & Sullivan conducted comprehensive researches on the endoscopic clip market in China and globally via multi-channel sources (including literature review, enterprise sales data, publications of key players in the industry, among others), compared the pros and cons of various endoscopic clips including both commercialized products as well as product candidates that are under development, and analyzed the market development trends from both the demand side and the supply side. Based on these researches, Frost & Sullivan estimated the market sizes of the overall endoscopic clips market in China and globally, as well as the market shares of OTS clips.

The market size of endoscopic clips in China increased rapidly from RMB98.7 million in 2016 to RMB292.5 million in 2020, representing a CAGR of 31.2%, according to Frost & Sullivan. Frost & Sullivan estimates that the market size of endoscopic clips will increase to RMB571.1 million in 2025 at a CAGR of 14.3% from 2020 to 2025 and further reach RMB1,124.4 million in 2030 at a CAGR of 14.5% from 2025 to 2030. Frost & Sullivan further estimates that the size of the overall endoscopic clips market globally will increase from USD346.7 million in 2020 to USD1,317.7 million in 2030.

As the OTS Clip market is still in an early stage of development and due to the relatively high prices set by the market players, the current market share of the OTS Clips has been small within the overall endoscopic clip market. According to Frost & Sullivan, the size of the overall endoscopic clips market in China was RMB292.5 million in 2020, with the OTS Clip market occupying approximately 0.4% by value and 0.1% by volume; globally, the size of the overall endoscopic clips market was USD346.7 million in 2020, with the OTS Clip market occupying approximately 1.7% by value and 0.5% by volume.

Compared to TTS Clips, OTS Clips have several advantages such as the ability to close larger wounds. In the operation of closing large wounds, TTS Clips generally require more clips, whereas in the same case, the number of OTS Clips required is less, and the operation time is relatively shortened. More guidelines and academic articles recommend OTS Clips in recent years. Thus, it is anticipated that

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physicians will become increasingly willing to accept OTS Clips and the market share of OTS Clips will increase in the future if the price is reasonable and market promotion is strengthened. Considering the aforesaid, Frost & Sullivan estimates that OTS Clips will account for approximately 30.6% of the overall endoscopic clips market in China by volume in 2030. Based on literature review and expert interviews, Frost & Sullivan forecasts that the number of patients treated with endoscopic clips will rise from 155.4 thousand in 2020 to 765.9 thousand in 2030 in China. As more domestic OTS Clips are launched, Frost & Sullivan further predicts that the ex-factory price of OTS Clips will decrease from RMB7,300 in 2020 to about RMB1,600 in 2030. As a result, the market size of OTS Clips in China is expected to increase from RMB1.2 million in 2020 to RMB544.9 million in 2030, representing an increase of market share by value from 0.4% in 2020 to 48.5% in 2030 in China's overall endoscopic clips market. Globally, OTS Clips are expected to account for approximately 50.3% of the overall endoscopic clips market by value (and approximately 24.0% by volume) in 2030.

The Company obtained the Zhejiang MPA approval for the Endoscopic Clip for Anastomosis in August 2022. The Endoscopic Clip for Anastomosis is expected to capture a decent market share in the OTS Clip market in China after its launch, which is supported by (i) the competitiveness of the Endoscopic Clip for Anastomosis resulting from its innovative structure, and (ii) the anticipated advantages of the Endoscopic Clip for Anastomosis as we are a relatively early entrant in China's OTS Clip market, despite that the overall endoscopic clip market is highly fragmented and highly competitive. In particular, the innovative separable structure of the Endoscopic Clip for Anastomosis makes its clamp detachable and allows for easier clip removal. Such innovative feature, though without head-to-head study, differentiates the Endoscopic Clip for Anastomosis from competing products. The Company also plans to set appropriate prices for the Endoscopic Clip for Anastomosis and enhance market promotion to quickly capture the market and establish industry barriers.

Growth Drivers and Future Trend for Endoscopic Clip Market

The endoscopic clip market in China and overseas, including Europe, is expected to grow significantly mainly due to the following factors:

- ***Accelerated Aging Population and Patient Pool Expansion.*** The number of elderly people in China and Europe is growing, and this trend is expected to continue in the coming decades. Furthermore, according to the *Perforated and bleeding peptic ulcer: WSES guidelines 2020*, A peptic ulcer disease is common with a lifetime prevalence in the general population of 5-10% and an incidence of 0.1-0.3% per year. In China, the population of people suffering from gastrointestinal bleeding or perforation increased from 967.9 thousand in 2016 to 1,008.2 thousand in 2020, with a projected increase to 1,090.6 thousand in 2030. The prevalence of peptic ulcer disease in EU also grew rapidly over the last decade, and is expected to further increase in the future due to changes of lifestyle and increased risk of diseases with age. Endoscopic clips, including OTS Clips, will be in high demand in China and the EU due to the aging trend and changing disease pattern.
- ***Relevant Expert Review and Clinical Guideline Recommendation.*** More guidelines and academic articles recommend endoscopic clips, particularly OTS Clips, in recent years, which will increase physician acceptance and market penetration and drive the market growth. According to the *Perforated and bleeding peptic ulcer: WSES guidelines*, endoscopy remains the first-line investigation of choice for an undifferentiated upper gastrointestinal hemorrhage. According to *AGA Clinical Practice* guideline, OTS Clips can also be used to

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treat esophageal perforations with defects of less than 20 mm, gastric perforations with 10-30 mm defects, type I small perforations in duodenal and periampullary, and some cases of colon perforation. For further information of relevant expert review and guidelines, see the paragraphs headed "—Type of Endoscopic Clips" in this section.

THE VASCULAR INTERVENTIONAL CRYOTHERAPY DEVICE MARKET

Atrial Fibrillation and Treatment

Overview of Atrial Fibrillation

Atrial fibrillation is a quivering or irregular heartbeat, namely arrhythmia, which can lead to blood clots and stroke. During atrial fibrillation, the heart's two upper chambers (the atria) beat chaotically and irregularly, out of coordination with the two lower chambers (the ventricles).

Atrial fibrillation patients are expected to experience fatigue, and rapid and irregular heartbeats. Blood clots, which often form in the left atrial appendage, can travel to the brain and cause a stroke. Compared to those without atrial fibrillation, the incidence of stroke and the disability and mortality rates of patients with atrial fibrillation are significantly higher. According to the China National Stroke Registry, the recurrence rate, disability rate, and fatality rate of stroke patients with atrial fibrillation are approximately 32.35%, 51.58%, and 34.23%, respectively. Stroke patients with atrial fibrillation have a 3.7-times higher risk of recurrence than patients without atrial fibrillation.

Prevalence of Atrial Fibrillation

Atrial fibrillation affects a large number of people in China. According to the literature data quoted in China Cardiovascular Health and Disease Report 2019, the standardized prevalence of atrial fibrillation in China is about 0.7% in the population over the age of 35. The number of patients with atrial fibrillation in China increased from 10.8 million in 2016 to 11.6 million in 2020, which is estimated to reach 13.6 million at a CAGR of 3.2% from 2020 to 2025, and further climb to 16.6 million at a CAGR of 4.1% from 2025 to 2030.

Treatment for Atrial Fibrillation

Treatments for atrial fibrillation are divided into two categories: medical treatment and non-medical treatment. In terms of medical treatment, anticoagulants and cardioversion drugs can effectively treat atrial fibrillation in some patients, but they may cause serious side effects. Ventricular rate control drugs is also a common medical treatment. However, they sometimes may not be effective and are used due to fewer side effects. Non-medical treatments mainly include ablation, implanted pacemaker, defibrillator and occluder. Ablation works by accurately ablating tissues that affect heart rates using external energy. Implanted pacemaker treatment involves using an artificial pacemaker that sends current to make the heart beat normally. Defibrillator can automatically recognize malignant arrhythmia and discharge defibrillation. Occluder can block the potential thrombosis part and left atrial appendage to prevent cardioembolic stroke.

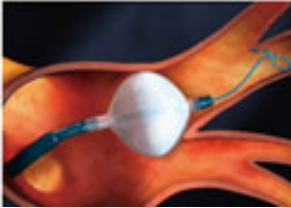




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Medical guidelines recommend interventional surgery for patients with symptomatic atrial fibrillation, including paroxysmal and persistent atrial fibrillation, if drug therapy is not effective. Short-term application of antiarrhythmic drugs can control the heartbeat disorder produced by atrial fibrillation. However, drug therapy hardly cure atrial fibrillation, and long-term use of antiarrhythmic drugs may cause arrhythmogenic effects and many side effects. As a result, treatment of atrial fibrillation with antiarrhythmic drugs may not be a long-term solution. In addition, the overall effect of non-medical treatment is significantly better than that of medical treatment, considering that (i) multiple clinical trials have shown that ablation is more effective than medical treatment in maintaining sinus rhythm and preventing reoccurrence of atrial fibrillation; (ii) patients’ adherence to medications is generally poor. For example, the compliance rate of anticoagulation therapy in China is only about 32.3%, according to Zhao et al. (2017); and (iii) medical treatment is not always effective, particularly for patients with severe symptoms. Interventional and/or surgical treatment can be used if there is no improvement after medical treatment, and some patients with severe symptoms can directly use interventional treatment.

Ablation therapy, in particular, outperforms antiarrhythmic drug therapy in maintaining sinus rhythm and improving the patient’s quality of life. Ablation is used to treat atrial fibrillation by destroying target heart cells, causing tissue death and blocking abnormal electrical signals. Its safety and efficacy have been further confirmed by clinical studies. Currently, radiofrequency ablation is the standard clinical treatment for atrial fibrillation. In radiofrequency ablation, the front end of the radiofrequency ablation catheter is delivered to a specific site within the heart to produce an impedance thermal effect locally, causing localized myocardial cell desiccation and necrosis for the treatment of tachyarrhythmias. Radiofrequency ablation relies on extensive surface heating to allow heat transfer to the myocardial tissue. The main catheters currently used in radiofrequency ablation include temperature-controlled radiofrequency ablation catheters and cold saline-infused radiofrequency ablation catheters. Patients with atrial fibrillation may also have a pacemaker implanted after the ablation of the atrioventricular node to restore sinus rhythm, or a defibrillator implanted to prevent sudden death from malignant ventricular arrhythmias. Cryoablation is another common ablation treatment for atrial fibrillation, and pulse field ablation is a promising new ablation modality for atrial fibrillation treatment. See “—Cryoablation for Atrial Fibrillation” below and “—The Pulse Field Ablation Device Market—Pulse Field Ablation for Atrial Fibrillation” in this section for more details.

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The chart below illustrates the comparison of cryoablation and radiofrequency ablation used in cardiac ablation:

Techniques	Cryoablation	Radiofrequency Ablation
Diagram		
 Efficacy	<ul style="list-style-type: none"> • Form uniform ablations and able to preserve tissue architecture • Suitable for patients on dialysis • Low recurrence rate of atrial fibrillation 	<ul style="list-style-type: none"> • Point-by-point circumferential lesion ablation with a wide range of applications • Higher recurrence rate of atrial fibrillation than cryoablation
 Safety	<ul style="list-style-type: none"> • Less pain during operation, local anesthesia • Its electrophysiological effects are completely reversible within seconds if halted properly • Reduce damage to the endocardial surface and thus reduce the formation of mural thrombus 	<ul style="list-style-type: none"> • High risk of post-ablation atrial flutter, cardiac tamponade, gastrointestinal bleeding and thromboembolic events like stroke
 Operation	<ul style="list-style-type: none"> • Catheter stability enabling ease of operation • Barely operator-dependent • Shorten learning curve • Shorten operation time 	<ul style="list-style-type: none"> • Point-by-point ablation • Highly dependent on the operators • Relatively long learning curves • Relatively long operation time (~2 hours)

Source: Literature Review, Frost & Sullivan Analysis

Cryoablation offers various benefits over radiofrequency ablation, mainly including ease of operation, low recurrence rate of atrial fibrillation, less pain during operation. Specifically, radiofrequency ablation employs “point-by-point” ablation, which is long and operationally demanding, whereas cryoablation requires a shorter operation time and is less operator dependent. In addition, according to Frost & Sullivan, radiofrequency ablation for the treatment of atrial fibrillation generally has a high recurrence rate and a high risk of thromboembolic events, based on publicly available clinical data. In contrast, cryoablation can lead to a low recurrence rate of atrial fibrillation, with a low incidence of serious complications, according to the “*Clinical analysis of 12 cases of atrial fibrillation treated by cryoballoon catheter ablation*” (Biming et al., 2016).

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Cryoablation for Atrial Fibrillation

Cryoablation is one of the common ablation treatments for atrial fibrillation that utilizes extreme cold to freeze and destroy the diseased tissue. It can be applied in the first-line treatment as an alternative to antiarrhythmic drug therapy as an initial rhythm control strategy of symptomatic paroxysmal and persistent atrial fibrillation. Cryoablation offers various benefits over the other types of ablation treatment, such as ease of operation, low recurrence rate of atrial fibrillation, less pain during operation. According to the Chinese Expert Consensus on Cryoballoon Ablation and Atrial Fibrillation published in 2020, cryoballoon ablation is safe and effective in patients with paroxysmal atrial fibrillation and may have better clinical results than radiofrequency ablation.

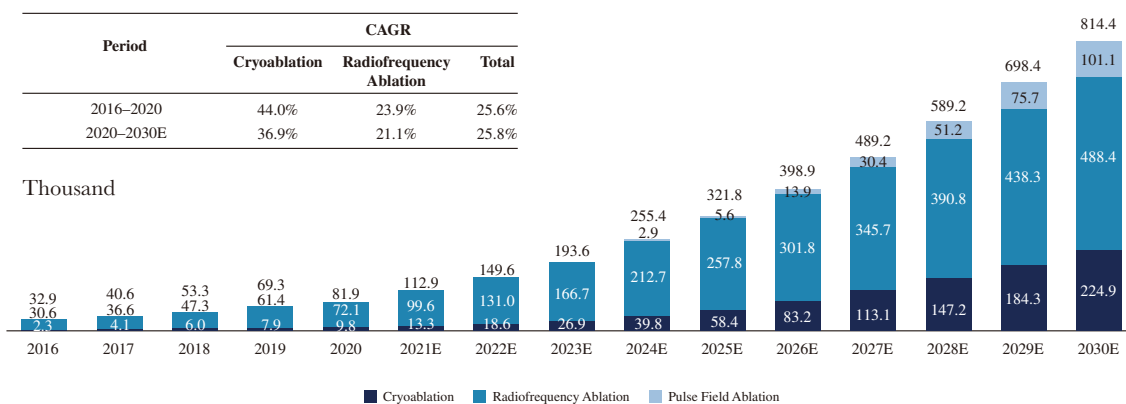
There are certain limitations of cryoablation therapy for the treatment of atrial fibrillation. For example, the potential complications of cryoballoon ablation for atrial fibrillation include persistent phrenic nerve injury, phrenic nerve palsy, stroke, oesophageal injury, pericardial effusion and atrio-oesophageal fistula. Cryoablation therapy currently has not been commonly used for the treatment of atrial fibrillation in China, mainly due to the market's early stage of development, as well as Medtronic's pricing strategy as the only manufacturer with an approved product in China. There are certain limitations of cryoablation therapy for the treatment of atrial fibrillation. Among all potential complications, phrenic nerve injury and phrenic nerve palsy are the two most common ones, and many phrenic nerve injuries following cryoballoon ablation are short-lived, as evidenced by many cases recovering before hospital discharge. In addition, it takes time for doctors who are more familiar with radiofrequency ablation to learn and master the operation method of cryoablation, despite that cryoablation is less operator-dependent and features short learning curve. Besides, cryogen is required for cryoablation, but the cryogen may not be available at any time.

The first cryoballoon system for treating paroxysmal atrial fibrillation in the world was launched by Medtronic in the U.S. in 2010. The cryoablation systems of Medtronic were initially used for drug-refractory recurrent symptomatic paroxysmal atrial fibrillation. As of the Latest Practicable Date, atrial fibrillation cryoablation has been used in patients with different types of atrial fibrillation. In China, the cryoablation system of Medtronic has been approved to treat not only drug-refractory recurrent symptomatic paroxysmal atrial fibrillation, but also recurrent symptomatic paroxysmal atrial fibrillation and drug-refractory persistent atrial fibrillation. Besides, the cryoablation system of Medtronic has also been approved to treat recurrent symptomatic paroxysmal atrial fibrillation and drug-refractory symptomatic persistent atrial fibrillation in the U.S. by FDA and in Japan by PMDA. According to literature review, the population with paroxysmal atrial fibrillation, persistent atrial fibrillation, and longstanding persistent atrial fibrillation represents around 50%, 30% and 20% of all patients with atrial fibrillation, respectively, in China. Drug-refractory rate among paroxysmal AF and persistent AF patients is around 75% and 80%, respectively, and the incidence of AF recurrence could reach 50% in total.

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In China, the market of atrial fibrillation cryoablation devices is still in its early stage of development, with significant growth potential. Against the backdrop of a yearly increase in the atrial fibrillation population in China, a total of 81.9 thousand ablation procedures for atrial fibrillation were performed in China in 2020, of which 9.8 thousand was cryoablation and 72.1 thousand utilized radiofrequency. The number of cryoablation procedure for atrial fibrillation in China increased from 2.3 thousand in 2016 to 9.8 thousand in 2020 representing a CAGR of 44.0%, and is expected to rise further to 224.9 thousand in 2030 at a CAGR of 36.9% from 2020 to 2030. Cryoablation’s share of total atrial fibrillation ablation procedures increased from 7.0% in 2016 to 12.0% in 2020, which is expected to reach 27.6% in 2030. The diagram below shows the historical and forecasted number of ablation procedures (including cryoablation and others) for atrial fibrillation in China:

Historical and Forecasted Volume of Atrial Fibrillation Ablation Procedures in China, 2016–2030E



Source: Frost & Sullivan Analysis

Market Size of Atrial Fibrillation Cryoablation Catheters

The global market size of atrial fibrillation cryoablation catheters has increased from USD726.6 million in 2016 to USD1,201.3 million in 2020 at a CAGR of 21.2%, and is expected to reach USD7,735.0 million in 2030. In China, the market size of atrial fibrillation cryoablation catheters increased from RMB48.4 million in 2016 to RMB255.0 million in 2020 at a CAGR of 51.5%. Driven by the rising prevalence of atrial fibrillation and increasing penetration of cryoablation treatment, the market size of atrial fibrillation cryoablation catheters in China is estimated to increase to RMB5,103.0 million in 2030.

Competitive Landscape of Atrial Fibrillation Cryoablation Devices

As of the Latest Practicable Date, there were four commercialized cryoablation devices for atrial fibrillation in the world, according to Frost & Sullivan. In China, there was only one NMPA-approved cryoablation device for atrial fibrillation on the market in China, the Arctic Front Advance of Medtronic. No domestically-manufactured atrial fibrillation cryoablation device has been approved for commercialization in China.

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As of the Latest Practicable Date, the Company was one of the four companies conducting clinical trials in China for atrial fibrillation cryoablation devices. Details of the atrial fibrillation cryoablation devices in China are set out in the table below:

Manufacturer	Medtronic	Cryofocus	MicroPort	Artechmed	HeartCare
Product	Arctic Front Advance (Second generation cryoballoon)	AF Cryoablation System	IceMagic® Cardiac Ablation System	Unknown	CryoAblation Console
Clinical Stage	NMPA approved in (2016)	Registration application submitted	Enrollment completed	Clinical trial initiated	Registration Application Submitted
Actual/Estimated Indications	Drug refractory recurrent symptomatic paroxysmal atrial fibrillation, recurrent symptomatic paroxysmal atrial fibrillation and drug referential persistent atrial fibrillation	Paroxysmal atrial fibrillation ⁽¹⁾	Paroxysmal atrial fibrillation ⁽¹⁾	Paroxysmal atrial fibrillation ⁽¹⁾	Paroxysmal atrial fibrillation ⁽¹⁾
Energy Source	Liquified Nitrous Oxide (N ₂ O)	Liquid Nitrogen (N ₂)	Liquified Nitrous Oxide (N ₂ O)	Liquified Nitrous Oxide (N ₂ O)	N/A
Clinical Outcomes	<ul style="list-style-type: none"> Over 80% Efficacy at 12 months: single procedure freedom from AF, AT, and AFL (n ~ 2,100 patients) Shorter procedure times compared with radiofrequency ablation 	N/A	N/A	N/A	N/A
Bidding Price	<ul style="list-style-type: none"> Balloon catheter: ~RMB36,500 	/	/	/	/
National Reimbursement Coverage	Covered	/	/	/	/

Source: Company official website, NMPA website, Frost & Sullivan Analysis

Note:

- (1) Represents an estimate of indications based on publicly available information about these product candidates, which may differ from the indications ultimately approved by the NMPA.

Most cryoablation products use nitrous oxide as the cryogen, while the Company’s AF Cryoablation System uses liquid nitrogen. According to literature review, liquid nitrogen as an energy source allows for rapid cooling and adjustable energy supply, and compared to nitrous oxide-based cryoablation that needs to meet the demand for high pressure resistance, liquid nitrogen-based cryoablation requires low pressure resistance and therefore ensures the operational safety. Using liquid nitrogen or liquefied nitrous oxide as cryogen in cryoablation procedures is technically demanding due to the following potential risks and challenges. When liquid nitrogen is introduced into the freezing zone of cryoprobe and in contact with surrounding warm biological tissues, the nitrogen may evaporate and expand several hundred-fold in volume at atmospheric pressure if its temperature rises above the boiling temperature (-196°C). The Company’s liquid nitrogen cryoablation technology resolves the excessive volume change associated with vaporization while maintaining the benefits of liquid nitrogen. Nitrous oxide systems typically achieve cooling by expansion of the pressurized gases through a Joule-Thomson expansion element such as a small orifice and throttle. However, cryosurgical applications using nitrous oxide are limited due to the insufficiently low operating temperature and relatively high initial pressure. The returning gas also requires insulation to avoid freezing non-target tissues. If the exhaust gas from the probe is improperly vented, nitrous oxide concentrations in air can reach several thousand parts per million during a cryosurgical procedure and may remain elevated following the procedure, possibly affecting short-term behavioral and long-term reproductive health. Based on such literature research, it is estimated that the first-movers in this market with advanced liquid nitrogen technologies will have more chances to capture large market shares in the future, according to Frost & Sullivan.

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In addition, according to Frost & Sullivan, there were ten manufacturers that had commercialized radiofrequency ablation catheters for the treatment of atrial fibrillation in China as of the Latest Practicable Date, details of which are set out below.

Manufacturer	Product	First approval year	Indications
Abbott	Therapy Cool Flex Ablation Catheter	2016	Arrhythmia
	Ablation Catheter	2016	Atrioventricular node regurgitation tachycardia, bypass ablation and complete AV conduction block due to arrhythmia
Medtronic	Steerable Electrode Catheters for Intracardiac Ablation (RF)	2015	Endocardial ablation procedure
Japan Lifeline	Radiofrequency ablation catheter	2018	Arrhythmia
C.R. Bard	Cardiac radiofrequency ablation catheter	2017	Tachyarrhythmia
Biosense Webster	nMARQ Irrigated Catheter	2015	Drug-refractory, recurrent symptomatic paroxysmal atrial fibrillation
APT Medical (惠泰醫療)	Cold saline Irrigated radiofrequency ablation catheter (冷鹽水灌注射頻消融導管)	2017	Tachycardia
	Controlled radiofrequency ablation electrode catheter (可控射頻消融電極導管)	2016	Tachycardia
LEPU Medical (樂普醫療)	Cardiac Radiofrequency Ablation Catheter (心臟射頻消融導管)	2012	Tachyarrhythmias
Visee Medical (維心醫療)	Radiofrequency ablation catheter (射頻消融導管)	2014	Arrhythmias, including atrioventricular re-entry tachycardia (AVRT) and atrioventricular nodal reentry tachycardia (AVNRT)
Shanghai MicroPort EP MedTech (上海 微創電生理)	Disposable magnetically positioned microelectrode radiofrequency ablation catheter (一次性使用磁定位微電極射頻消融導管)	2021	Drug-refractory persistent atrial fibrillation
	Magnetically positioned radiofrequency ablation catheter (磁定位型射頻消融導管)	2017	Tachyarrhythmias, including atrioventricular re-entry tachycardia (AVRT) and atrioventricular nodal reentry tachycardia (AVNRT)
	Cardiac Radiofrequency Ablation Catheter (心臟射頻消融導管)	2016	Arrhythmias, including atrioventricular re-entry tachycardia (AVRT) and atrioventricular nodal reentry tachycardia (AVNRT)
	Cold saline Irrigated radiofrequency ablation catheter (冷鹽水灌注射頻消融導管)	2016	Tachyarrhythmias, including atrioventricular re-entry tachycardia (AVRT) and atrioventricular nodal reentry tachycardia (AVNRT)

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According to Frost & Sullivan, there were six manufacturers that had commercialized radiofrequency ablation catheters for the treatment of atrial fibrillation in the international market as of the Latest Practicable Date, details of which are set out below.

Manufacturer	Product	First approval year	Indications
Medtronic	DiamondTemp Ablation Catheters	2021 (FDA) 2017 (CE)	Atrial fibrillation
	Therapy Cardiac Ablation Catheters	2008 (FDA)	AV nodal re-entrant tachycardia (AVNRT); or creation of complete AV nodal block in patients with a difficult to control ventricular response to an atrial arrhythmia
Abbott	Therapy Cool Path Ablation Catheters	2007 (FDA) 2007 (CE)	Arrhythmia
	Safire BLU Duo Catheter	2012 (FDA)	Arrhythmia
	Flexability Ablation Catheters	2015 (FDA) 2014 (CE)	Arrhythmias
	TactiCath irrigated ablation catheter	2014 (FDA) 2012 (CE)	Atrial fibrillation and supra ventricular tachycardia ablation
C.R. Bard	Stinger Ablation catheter	2000 (FDA)	Arrhythmias
	nMARQ Irrigated Catheter	2013 (CE)	Cardiac Ablation
Biosense Webster	Ez Steer Thermocool Nav Catheters	2008 (FDA) 2010 (CE)	Arrhythmias, including atrial flutter and ventricular tachyarrhythmia and atrial fibrillation
	Navistar Thermocool Catheter	2006 (FDA) 2010 (CE)	Arrhythmias, including atrial flutter and ventricular tachyarrhythmia and atrial fibrillation
Boston Scientific	Blazer Prime HTD Temperature Ablation	2009 (FDA)	Arrhythmia
	IntellaTip MiFi Open-irrigated Ablation Catheter	2017 (FDA) 2014 (CE)	Drug refractory, recurrent, symptomatic, Paroxysmal Atrial Fibrillation (PAF)
	IntellaNav ST Ablation Catheters	2018 (FDA)	Arrhythmia
	IntellaNav Open-irrigated Ablation Catheters	2016 (FDA) 2015 (CE)	Sustained or recurrent type 1 Atrial Flutter, drug refractory, recurrent, symptomatic, Paroxysmal Atrial Fibrillation (PAF)
Japan Lifeline	Radiofrequency ablation catheter	2017 (PMDA)	Arrhythmias
	Irrigated Tip Ablation Catheter	2017 (PMDA)	Arrhythmias

INDUSTRY OVERVIEW

Hypertension and Treatment

Overview of Hypertension

Hypertension is defined as having an average SBP of 140 mmHg or higher or an average DBP of 90 mmHg or higher, or currently using antihypertensive medication.

Uncontrolled hypertension is defined as having an average SBP of 140 mmHg or higher, or an average DBP of 90 mmHg higher despite the use of three antihypertensive medication of different classes, according to National Center for Cardiovascular Disease. Resistant hypertension refers to hypertension irresponsive to aggressive medical treatment. Hypertension is considered resistant when all of the following conditions are met: (i) the patient's blood pressure is constantly above the treatment goal (usually 140/90 mmHg); (ii) the patient is taking three or more different antihypertensive medications at the maximally tolerated doses; (iii) one of the antihypertensive medications is a diuretic, and (iv) the hypertension requires four or more medications to be controlled. Patients with uncontrolled or resistant hypertension generally have higher risk of end-organ damage and complications, such as stroke, heart attack, heart failure, kidney damage, memory damage, vision damage and erectile dysfunction, when compared to those with controlled blood pressure.

Prevalence of Hypertension

Due to factors such as aging population and people's unhealthy lifestyle, the number of hypertension patients rises steadily at a CAGR of 2.3% from 297.1 million in 2016 to 325.9 million in 2020, and is projected to continue to grow to 390.1 million in 2030. In particular, the incidence of hypertension among young and middle-aged patients has increased rapidly in the past decade, and its increasing trend is more rapid and visible than that of the elderly.

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According to Frost & Sullivan, approximately 15.0% and 62.5% of hypertension patients in China suffered from resistant hypertension and uncontrolled hypertension, respectively. Such rates are greatly affected by age and other genetic factors, and do not significantly fluctuate over time. The number of patients with resistant hypertension increased from 44.6 million in 2016 to 48.9 million in 2020 at a CAGR of 2.3%, and is expected to reach to 54.0 million in 2025 and further climb to 58.5 million in 2030. The number of patients with uncontrolled hypertension grew from 191.6 million in 2016 to 203.7 million in 2020. This number is projected to increase at first to 214.1 million in 2025 and to reduce slightly to 212.6 million in 2030 with improved health awareness and advanced treatment methods.

Treatment of Hypertension

In China, according to the Chinese Hypertension Health Management Specification (2019 edition) and the Chinese Hypertension Prevention and Treatment Guidelines (2018 edition), there are three main treatment methods for resistant hypertension, including lifestyle intervention, pharmacotherapy and interventional or instrumental therapy, such as renal denervation (RDN). Interventional or instrumental therapy has great application potential in the future and is still under clinical research.

Healthier lifestyle changes are always advised, but they are difficult to treat uncontrolled or resistant hypertension. Pharmacotherapy alone is also difficult to treat resistant hypertension, and it is inconvenient to many patients, since patients are required to take large amounts of medications frequently and for a long time. Antihypertensive drugs can cause side effects which led to poor adherence to pharmacotherapy in hypertension patients. Thus, effective long-term alternative therapies are needed, and RDN is gaining increasing attention as a promising therapy.

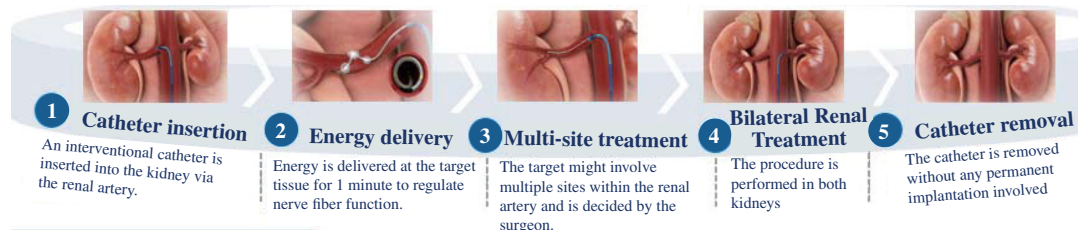
Renal Denervation Therapy

RDN is a minimally invasive procedure in which energy released through the ablation catheter acts on the sympathetic nerve fibers in the perivascular wall of the renal artery, reducing the hyperactivity of the renal artery sympathetic nerve and, as a result, lowering the blood pressure.

RDN is currently the most widely followed and well-studied interventional therapy for hypertension. Clinical trials in recent years suggest that RDN provides general safety and clear efficacy in lowering blood pressure. The SPYRAL HTN-OFF MED (SPYRAL Pivotal) trial has shown the superiority of catheter-based RDN compared with a sham procedure to safely lower blood pressure in the absence of antihypertensive medications. More future research will also concentrate on identifying patients with well-responding hypertension and clarifying relevant predictors.

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RDN can lower blood pressure by reducing sympathetic hyperexcitability. The procedure involves the spiral ablation of bilateral renal arteries, and is carried out via the femoral artery route. Energy is delivered to damage the nerve fibers in the adventitia and hence to remove the renal sympathetic innervation and to inhibit the renal sympathetic nerves. The procedure is highly target-selective, minimally invasive, involves short post-operative recovery duration, and does not require a permanent implantation. There are also no systemic adverse reaction and only a few operation-related side effects, while future research may shed light on reducing complications and relapse. The following diagrams illustrate the RDN procedure:



Most RDN studies employ radiofrequency current and ultrasound as the energy sources for ablating the renal sympathetic nerves. For radiofrequency ablation, accurate catheter placement and proper contact with the vessel wall are necessary. Furthermore, radiofrequency ablation are applied discretely, and there are probably functional fibers remained after treatment and diffuse visceral abdominal pain caused by tissue heating. Therefore, a device with higher stability and less side effect is demanded. Recently, RDN with catheter-based cryoablation has been used in animal experiments and human trials. These studies suggest that cryoablation RDN is efficient and safe, with lower blood pressures and reduced sympathetic nervous system activity. The chart below demonstrates the comparison of different ablation techniques used in RDN:

	Radiofrequency Ablation RDN	Cryoablation RDN
Thoroughness	<ul style="list-style-type: none"> RF catheters ablate lesions circumferentially but the lesions vary in shape, area, and diameter depending on the adjacent tissue substructures 	<ul style="list-style-type: none"> Cryoablation RDN is more penetrating, resulting in fewer NFL (neurofilament)¹ positive nerves remaining in Sheep Model
Efficiency	<ul style="list-style-type: none"> In Swine Model, the NE (norepinephrine)² content of the renal cortex dropped by 73% by radiofrequency ablation 	<ul style="list-style-type: none"> In Swine Model, the NE content of the renal cortex dropped by nearly 90% by Cryoablation RDN
Safety	<ul style="list-style-type: none"> RF ablation RDN produces tissue disruption, which increases the risk of perforation and thromboembolism 	<ul style="list-style-type: none"> Cryoablation EDN is associated with less endothelial damage and thrombus formation

Notes:

- The above information was derived and summarized from different clinical trials for different products without the support of controlled, head-to-head comparison between radiofrequency and cryoablation RDN.
- The content of renal NE (norepinephrine) is a surrogate biomaker of denervation efficiency.
- The attenuation of NFL-positive nerves density is a marker for the reduction of sympathetic hyperinnervation in a rat infarct model.

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Competitive Landscape and Market Size of RDN Product Market

The RDN product market is still at its early stage of development. As of the Latest Practicable Date, seven RDN product had been commercialized in the world. In China, there were only seven market players that had RDN product candidates in clinical trial stage, out of which, the Company’s Cryofocus Renal Denervation System (“**Cryo-RDN System**”) is the only cryoablation-based RDN product candidate. Details of the RDN product candidates under development in China are set out in the table below:

Technology	Cryoballoon	Radiofrequency					
Manufacturer	Cryofocus	Bioheart	Golden Leaf	SyMap	Medtronic	MicroPort	Synaptic Medical
Product Name	Cryo-RDN System	Iberis	N/A	SyMapCath	Symplicity Spyral	FlashPoint	N/A
Clinical Status	RCT ongoing	RCT ongoing	RCT ongoing	RCT ongoing	FIM ongoing	RCT ongoing	RCT ongoing
Primary Outcome Measures	Reduction on average 24-hour ambulatory systolic blood pressure at 6 months follow-up	Reduction in average 24-hour ambulatory systolic blood pressure at 3 months follow-up	Average 24-hour ambulatory systolic blood pressure changes at 6 months	The control rates of office systolic blood pressure (SBP<140mmHg) at 6 months after the treatment	N/A	N/A	N/A

Note:

- This table only includes RDN products with public information of clinical progress within three years.

Source: Clinical trials, Company official website, Literature Review, Frost & Sullivan Analysis

According to Frost & Sullivan, the Cryo-RDN System manufactured by the Company is expected to be among the world’s first cryoablation products that specifically focus on the treatment of hypertension. According to Frost & Sullivan, considering the prevalence of hypertension, the limitations of currently available therapies and the benefits of RDN over traditional treatment, the size of the RDN product market in China is expected to grow rapid after the product candidates of the aforementioned forerunners are approved by the NMPA. Frost & Sullivan estimates that the global market size of the RDN catheters for the treatment of hypertension will reach USD736.9 million in 2030 with a high CAGR of 257.2% from 2025 to 2030. Frost & Sullivan further estimates that the market size of the RDN catheters for the treatment of hypertension in China will reach RMB6.5 million and RMB1,069.9 million by 2025 and 2030, respectively, which represents a CAGR of 177.2% from 2025 to 2030.

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THE NOTES INTERVENTIONAL CRYOTHERAPY DEVICE MARKET

The Tumor Interventional Cryotherapy Device Market

Overview of Tumor Interventional Cryotherapy

Cryoablation can be used to treat pain and other symptoms associated with abnormal tissue spread. This therapy might be used alone to alleviate cancer symptoms when a mass is too risky to operate on, or it could be part of a larger, multi-therapy treatment plan. Therefore, cryoablation benefits patients who are unable to undergo surgical tumor removal. Compared with the other types of ablation, cryoablation demonstrates several benefits, such as local anesthesia, less pain and tumor immunogenicity kept. Moreover, the frozen area formed by cryoablation has clear boundary and uniform temperature, making it easy to monitor the ablation area. See “—The Interventional Cryotherapy Device Market—Overview of Interventional Cryotherapy” and “—The Bladder Cancer Interventional Cryotherapy Device Market” in this section for more details.

Esophagus Cancer and Treatment

Overview of Esophagus Cancer

Esophagus cancer, one of the most common cancers around the world, arises from the lining cells of esophagus. Esophagus cancer cells that derived from different layers of esophagus wall behave differently. There are two main types of esophagus cancer based on the type of cell it starts in, namely esophageal adenocarcinoma and esophageal squamous-cell carcinoma. The esophageal squamous-cell carcinoma is more common in the developing world while the esophageal adenocarcinoma is more common in developed countries. Trouble swallowing is the most common symptom of esophagus cancer.

Incidence of Esophagus Cancer

The incidence of esophagus cancer increased from 254.4 thousand in 2016 to 289.6 thousand in 2020 at a CAGR of 3.3%. The incidence is expected to grow to 339.5 thousand in 2025 with a CAGR of 3.2% from 2020 to 2025, and further to 389.2 thousand in 2030 with a CAGR of 2.8% from 2025 to 2030.

Treatment of Esophagus Cancer

For the esophagus cancer patients, treatments should be based on their status, pathological type, invasion of the tumor and the possible prognosis. Surgery is one of the most important radical treatment to treat esophageal carcinoma. Other treatments include radiotherapy, chemotherapy and supportive and palliative treatment.

Although esophageal stent placement, the most common treatment, facilitates patients maintaining oral intake and improving life quality, it is accompanied by substantial limitations and a significant risk of adverse events, such as bleeding, pain, fistulas and, in a high proportion of patients, dislocation of the esophagus and recurrent dysphagia, which reduces the survival expectations of patients. Thus, it becomes important to seek alternatives to esophageal stenting such as cryoablation.

Cryoablation is a minimally-invasive treatment for esophagus cancer with an aim of improving symptoms of advanced esophagus cancers such as difficulty in swallowing. Spray cryotherapy is a

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non-contact procedure in which the cryogen is sprayed directly onto the targeted mucosa, causing necrosis of the superficial esophageal mucosal layers. It can be used to shrink tumors and make swallowing simpler for patients.

Market Size of Esophagus Cancer Interventional Cryotherapy Catheters

According to Frost & Sullivan, the global market size of esophagus interventional cryotherapy catheters increased steadily from USD3.3 million in 2017 to USD4.8 million in 2020, and is expected to reach USD105.3 million in 2030. Frost & Sullivan further estimates that the market size of esophagus cancer interventional cryotherapy catheters in China is expected to grow increasingly from RMB9.0 million in 2025 to reach RMB176.8 million in 2030 at a CAGR of 81.4%.

For further information on the competitive landscape and future trends of the relevant market, see the paragraphs headed “—The Bladder Cancer Interventional Cryotherapy Device Market—Competitive Landscape of Interventional Cryotherapy Devices for Solid Tumor” in this section.

The Respiratory Interventional Cryotherapy Device Market

Overview of Respiratory Interventional Cryotherapy

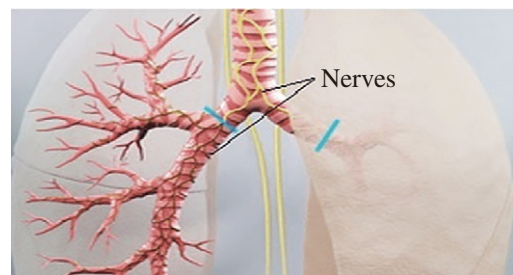
Cryotherapy is a proven therapy that can be applied in the treatment of various respiratory diseases.

Currently, respiratory interventional cryoablation includes two types, spray cryotherapy or bronchial cryoballoon ablation. Spray cryotherapy works by spraying cold liquid to ablate the diseased mucosa of the airway and restore it to normal mucosa. It involves placing a small catheter in an endoscope to destroy unwanted cells using measured blasts of extremely cold liquid nitrogen. Spray cryotherapy destroys targeted cells but preserves the underlying collagen structure, thereby providing a scaffold for healthy tissue to regrow. In contrast, bronchial cryoballoon is typically used in targeted lung denervation (TLD) procedures, which is a bronchoscopic procedure intended to disrupt pulmonary parasympathetic inputs and is an experimental treatment for COPD. Bronchial cryoballoon delivers extreme cold to freeze parasympathetic efferent innervation of the lung and disrupts unwanted electrical signals. It can reduce tension of smooth muscle to decrease COPD acute attack. Bronchial cryoballoon can also deliver extreme cold to freeze tissue lesion in the treatment of airway stenosis. For more details of spray cryotherapy and cryoballoon ablation, see “—The Interventional Cryotherapy Device Market—Overview of Cryoablation” in this section. The diagrams below illustrate the aforesaid spray cryotherapy or bronchial cryoballoon ablation:

Types of Respiratory Interventional Cryoablation



Spray Cryotherapy



Bronchial Cryoballoon Ablation

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COPD and Treatment

Overview of COPD

COPD is a common respiratory disease characterized by persistent respiratory symptoms and airflow restrictions, including chronic cough, sputum production, progressive dyspnea.

The diagnosis of COPD is predicated upon the recognition of its two major forms: (i) emphysema, a lung condition that causes shortness of breath, and (ii) chronic bronchitis, inflammation (swelling) and irritation of the bronchial tubes. These two different manifestations of COPD frequently coexist in the same individual.

The diagnosis of COPD is verified when the FEV1/FVC ratio, which measures the proportion of a person’s vital capacity they are able to expire in the first second of forced expiration (“FEV1”) to the whole forced vital capacity (“FVC”), is less than 70% after utilising bronchodilator. The FEV1/FVC ratio in healthy people is usually greater than 80%. The severity of airway limitation will be determined when the diagnosis has been verified. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD), there are four COPD lung function classifications as illustrated below:

GOLD I (mild)	FEV1 \geq 80% predicted value ¹
GOLD II level (moderate)	50% \leq FEV1<80% predicted value
GOLD III level (severe)	30% \leq FEV1<50% predicted value FEV1<30% predicted value
GOLD IV (extremely severe)	or FEV1<50% expected value with respiratory failure

Note:

1. A derived value of FEV1% is FEV1% predicted, which is defined as FEV1% of the patient divided by the average FEV1% in the population for any person of similar age, sex, and body composition.

Prevalence of COPD

In China, the number of COPD patients increased from 101.7 million in 2016 to 105.3 million in 2020 at a CAGR of 0.9%. The number of COPD patients in China is expected to reach 109.6 million in 2025 with a CAGR of 0.8% from 2020 to 2025, and further climb to 113.3 million in 2030 representing a CAGR of 0.7% from 2025 to 2030.

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The majority of the COPD patients in China have a moderate, severe or extremely severe disease (GOLD Stage II – IV). About 29.8%, 43.1%, 26.1% and 0.9% of the total number of COPD patients in China are in Stage I, II, III and IV, respectively, according to Frost & Sullivan. In patients with severe and extremely severe COPD (GOLD Stage III & IV) in China, the five-year mortality rate is reported to be 54.0%. Since COPD is a chronic disease that deteriorates over time, effective early treatment that can not only control the disease but also improve life quality is important and needed for patients with COPD in the early stages.

The number of COPD patients in China is enormous, but the actual diagnosis rate is less than 30%, and the control rate is far lower than the same indicator data in the U.S. Although COPD cannot be cured, it can be effectively controlled. The actual number of deaths in China is close to one million, far exceeding lung cancer. In 2020, the mortality rate of COPD is the largest in China among all China, the U.S., and the European Union, leading to 72.9 deaths per 100,000 people.

Treatment of COPD

According to different symptoms and degree of exacerbation history, COPD drug treatment can be divided into four categories, namely bronchodilators, long-acting β 2 receptor agonist, long-acting cholinergic drug and inhaled glucocorticoid. There are also non-pharmacological treatments for COPD such as education, self-management, and respiratory rehabilitation, vaccination, intervention bronchoscopy, surgery and nutrition.

Interventional therapy is appropriate for patients with severe emphysema who have not responded well to drug therapy. As one of the interventional therapies, cryoablation can be a promising therapy to treat COPD with its benefits such as low occurrence of complication and good survival rate, based on the estimation and assumption of Frost & Sullivan.

Asthma and Treatment

Overview of Asthma

Asthma is a long-term inflammatory disease of the airways of the lungs characterized by variable and recurring symptoms, reversible airflow obstruction, and easily triggered bronchospasms. Asthma is thought to be caused by a combination of genetic and environmental factors. The symptoms of asthma mainly include coughing, wheezing, chest tightness and shortness of breath. Some asthma symptoms can be relieved with medication. However, severe asthma can lead to death from suffocation if left untreated.

Prevalence of Asthma

The number of patients with asthma is increasing in China. The number of patients suffering asthma in China grew from 60.4 million in 2016 to 65.0 million in 2020 at a CAGR of 1.8% from 2016 to 2020. This number is expected to further increase to 72.2 million with a CAGR of 2.1% from 2020 to 2025, and eventually reach 78.5 million in 2030 with a CAGR of 1.7% from 2025 to 2030.

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Treatment of Asthma

There is currently no cure for asthma, but treatment can help control the symptoms and enable patients to live a normal, active life. At present, the main control means are drug control, such as inhalers or Leukotriene receptor antagonists (“**LTRAs**”). The inhaler, the most commonly used treatment, is effective for treating mild to moderate asthma and has some advantages, such as portability. However, drug control has limited effects on severe asthma. For severe asthma, non-pharmacy treatments, such as cryoablation and bronchial thermoplasty, are still needed to help patients relieve asthma symptoms. Among all adult asthma patients, 3.6% qualify as patients diagnosed of severe refractory asthma. Based on the estimation and assumption of Frost & Sullivan, cryoablation, which destroys vagus nerves, can be a promising therapy for treating severe asthma, with advantages such as less scarring and a shorter surgery time. At present, the clinical study of cryoablation is mainly carried out for asthma patients with severe symptoms.

Airway Stenosis and Treatment

Overview of Airway Stenosis

Airway stenosis is the narrowing of the airways caused by neoplastic or nonneoplastic processes, which may develop with several diseases. Airway stenosis may be malignant, as occurs with narrowing from a tumor, or benign, such as those caused by inflammatory diseases. When the narrowing impedes flow and increases resistance within the airways, symptoms like cough and dyspnoea develop. Dyspnoea caused by airway stenosis can seriously affect the patient’s quality of life, and in severe cases, death may result from respiratory failure.

Specifically, malignant airway stenosis is caused by malignant diseases, including lung cancer and extratracheal lesions. The symptoms of malignant airway stenosis mainly include dyspnoea, cough, polynea, bronchospasm. Benign airway stenosis refers to the airway stenosis caused by nonneoplastic diseases. The symptoms of benign airway stenosis include dyspnoea, cough, haemoptysis and phlegm.

Treatment of Airway Stenosis

Malignant airway stenosis is mainly treated by tumor elimination and tracheoscopic intervention, and is closely related to the decreased quality of life and increased mortality of many patients with advanced lung cancer. Therefore, effective treatment methods are needed to relieve the pain of patients. Interventional therapy like ablation has been recognized by professional as a promising way to provide patients with more chances to survive, prolong their life and provide opportunities for follow-up treatment.

Traditional treatment for benign airway stenosis in China mainly includes surgical excision and surgical reconstruction. However, due to surgical trauma, high risk, or poor physical condition, the indications of surgical operation are very limited, and postoperative anastomotic scar formation leads to restenosis.

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During the treatment process of benign airway stenosis, cryoablation is commonly applied to clean residual lesions after the diseased region is treated by thermal ablation or balloon dilation. Such cryoablation can reduce the rate and degree of scar restenosis. In addition, cryotherapy is less likely to cause cartilage damage and less prone to perforation than thermal ablation, so there are fewer complications of airway softening and collapse.

Chronic Cough and Treatment

Overview of Chronic Cough

Chronic cough is a symptom developed during several diseases such as cough-variant asthma and COPD. It is defined as the cough lasts more than eight weeks in adults or four weeks in children. Clinical misdiagnosis and mistreatment are common due to its complex aetiology and clinicians' lack of understanding of chronic cough in the past, which seriously affect patients' life. According to Chung and Pavord (2008), 70% patients with COPD would develop chronic cough with 46% reporting daily symptoms, and cough-variant asthma mainly presents with a dry and chronic cough.

Treatment of Chronic Cough

For the chronic cough of definite aetiology, treatment usually customized according to the aetiology. Diseases causing chronic cough include COPD, asthma, eosinophilic bronchitis, gastro-oesophageal reflux disease, postnasal drip syndrome or rhinosinusitis, pulmonary fibrosis, and bronchiectasis. Cryoablation can target and ablate the obstructed airways in a way that is not possible with pharmacological treatment.

Competitive Landscape and Market Size of Respiratory Interventional Cryotherapy Devices

In China, there were three market players in the respiratory interventional cryotherapy market as of the Latest Practicable Date, out of which, the Company is the only company that had cryoballoon and spray therapy product candidates, according to Frost & Sullivan. The other two players' products are cryoprobes for biopsy, recanalization and devitalization in bronchoscopy.

The Company's products cover a wider range of indications in the field of respiratory interventional cryotherapy. For the treatment of COPD, spray therapy can improve airway remodelling and reduce cough receptors in airway mucosa to relieve cough symptoms and sensitivity. Cryoballoon delivers extreme cold to freeze parasympathetic efferent innervation of the lung and disrupts unwanted electrical signals, which is suitable for the treatment of asthma, and airway stenosis. The Company also has a cryoadhesion product candidate for biopsy, stenosis recanalization and foreign body retrieval.

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According to Frost & Sullivan, the Company is expected to be among the first market players that develop cryotherapy products utilizing spray and cryoballoon ablation technologies for treating respiratory diseases in China.

Details of the respiratory interventional cryotherapy products in China are set out in the table below:

	Cryoablation		Cryoadhesion			
Manufacturer	Cryofocus		Erbe		Beijing Kooland	Cryofocus
Product	COPD Cryospray System, Cough Cryospray System and Tuberculosis Cryospray System	Asthma Cryoablation System, Malignant Stenosis Cryoablation System, Benign Stenosis Cryoablation System, Peri-Pulmonary Nodule Cryoablation System	ERBOKRYO CA	ERBOKRYO 2	Kooland Cryotherapy Device	Cryoadhesion System
NMPA Approval	/	/	2005	2017	2016	/
Technique	Cryo-spray	Cryoballoon	Cryo-probe	Cryo-probe	Cryo-probe	Cryo-probe
Application	<ul style="list-style-type: none"> Suitable for cryoablation of the lesion tissue for the treatment of chronic cough, COPD II-IV and tuberculosis. 	<ul style="list-style-type: none"> Suitable for cryoablation of pulmonary parasympathetic inputs the lesion tissue for the treatment of asthma, airway stenosis and peri-pulmonary nodules. 	<ul style="list-style-type: none"> Suitable for biopsy, recanalization and devitalization in bronchoscopy. 	<ul style="list-style-type: none"> Suitable for biopsy, recanalization and devitalization in bronchoscopy. 	<ul style="list-style-type: none"> Suitable for biopsy, recanalization and devitalization in bronchoscopy. 	<ul style="list-style-type: none"> Suitable for biopsy, recanalization and devitalization in bronchoscopy.
Principle	Tissue-targeted	Tissue-targeted Targeted Lung Denervation (TLD)	Tissue-targeted	Tissue-targeted	Tissue-targeted	Tissue-targeted
Features	<ul style="list-style-type: none"> Improving airway remodelling and reducing cough receptors in airway mucosa to relieve cough symptoms and sensitivity. 	<ul style="list-style-type: none"> Destroying diseased cells for treatment by freezing the target tissue. To deliver extreme cold to freeze parasympathetic efferent innervation of the lung and disrupt unwanted signaling transduction. 	<ul style="list-style-type: none"> It is used to remove foreign bodies, mucous plugs, necrotic tissue, benign and malign tumors by cryoadhesion. 	<ul style="list-style-type: none"> ERBECRYO®2 cryosurgical device have upgraded the probe unit to make it more suitable for biopsies. 	<ul style="list-style-type: none"> It is used to remove foreign bodies, mucous plugs, necrotic tissue, benign and malign tumors by cryoadhesion. 	<ul style="list-style-type: none"> It is used to remove foreign bodies, mucous plugs, necrotic tissue, benign and malign tumors by cryoadhesion.

Source: NMPA, Company official website, Frost & Sullivan Analysis

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The global market size of respiratory interventional cryotherapy catheters has increased steadily from USD2.5 million in 2016 to USD4.5 million in 2020 at a CAGR of 16.4%, which is expected to increase rapidly to reach USD2,032.3 million in 2030, according to Frost & Sullivan. The market size of respiratory disease interventional cryotherapy catheters in China also reveals a rising trend. It has increased from RMB0.9 million in 2016 to RMB2.1 million in 2020, representing a CAGR of 24.4%, according to Frost & Sullivan. With the development of novel technique, the market will further expand. According to Frost & Sullivan, the market size of respiratory disease interventional cryotherapy catheters in China is expected to reach RMB109.8 million in 2025 with a CAGR of 120.2% from 2020 to 2025, and to further increase to RMB1,731.8 million in 2030, with CAGR of 73.6% from 2025 to 2030.

THE PULSE FIELD ABLATION DEVICE MARKET

Pulse Field Ablation for Atrial Fibrillation

Pulsed field ablation (PFA) destabilizes cell membranes by forming irreversible nanoscale pores, which leads to cell death and achieve therapeutic effect. PFA is a promising new ablation modality for the treatment of atrial fibrillation. For details of atrial fibrillation and its treatment, see “—The Vascular Interventional Cryotherapy Device Market—Atrial Fibrillation and Treatment” in this section. PFA employs a train of nanosecond-duration, high-amplitude electrical pulses, and ablate myocardium by electroporation of the sarcolemmal membrane without measurable tissue heating.

PFA offers certain benefits including high speed and safety. Thermal ablation requires several seconds to minutes to achieve steady-state temperature, while a single PFA delivery is accomplished within one heartbeat, and typically a lesion is created with 3 to 4 PFA deliveries. Moreover, PFA can be applied in position of high risk. According to Frost & Sullivan, PFA exhibits tissue specificity in ablation, targets on cell membrane and spares extracellular matrix, which results in good therapeutic effect. PFA procedures need relatively short operation time compared to other types of ablation, and it is more approachable to the operators than radiofrequency ablation. Unlike radiofrequency ablation, PFA does not lead to pulmonary vein stenosis.

According to clinical trial results published by Farapulse, PFA is generally efficient and safe in treating paroxysmal atrial fibrillation. The trial result also sheds light on the extensive application of PFA beyond paroxysmal atrial fibrillation to persistent atrial fibrillation, as a promising technology with potential in application of non-cardiac ablation due to its unique tissue specificity.

The atrial fibrillation PFA device market is still at the early stage of development. As of the Latest Practicable Date, there was only one commercialized PFA device for the treatment of atrial fibrillation in the world, which has not been approved for commercialization in China, leaving significant room for future growth. Forerunners in this market are expected to enjoy significant first mover advantages. The Company’s Atrial Fibrillation Pulsed Field Ablation System was in the stage of pre-clinical study. According to Frost & Sullivan, eight PFA product candidates from eight companies were in the clinical trial stage for the treatment of atrial fibrillation in China, and eight PFA product candidates from eight companies were in the clinical trial stage for the treatment of atrial fibrillation in the overseas market.

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THE PULMONARY NODULE LOCALIZATION NEEDLE MARKET

Overview of Video-Assisted Thoracoscopic Surgery

Video-assisted thoracoscopic surgery (VATS) is a minimally-invasive surgical technique used to diagnose and treat problems in chest. During the VATS procedure, a tiny camera (thoracoscope) and surgical instruments are inserted into the chest through one or more small incisions in the chest wall. The thoracoscope sends images of the inside of the patient's chest to a video monitor, which guides the surgeon in performing the procedure.

VATS is currently the gold standard procedure for the diagnosis and treatment for pulmonary nodules. Compare to traditional surgery, VATS benefits patients with less postoperative pain, more rapid recovery, a lower risk of infection bleeding and a shorter hospital stay. However, it might be difficult in locating deep nonpalpable nodules in the pulmonary parenchyma, and the outcome of VATS might be jeopardized. As a result, medical devices that aid in the identification and localization of small and deep pulmonary nodules are still needed.

Overview of Pulmonary Nodule Localization

Nodule localization is widely used in aiding the identification and excision of impalpable nodule lesions. During pulmonary nodule localization, a fine wire is placed in the lung to guide the surgeon to the exact excision area, enabling the removal of abnormal tissue identified on X-ray, ultrasound or MRI scans. From the early 2000s, preoperative CT-guided breast nodule localization has been experimentally applied to assist VATS.

Although the current application of nodule localization is largely limited to impalpable breast lesions, research and clinical trials have indicated the feasibility of applying nodule localization techniques in the management of pulmonary nodules. It is shown to be safe, effective, and able to provide accurate visualization and localization of pulmonary nodules buried deep within the pulmonary parenchyma, overcoming the caveats in VATS diagnosis and treatment.

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Competitive Landscape of Nodule Localization Devices

As of the Latest Practicable Date, three nodule localization products in China, including the Company’s Pulmonary Nodule Localization Needle, are for lung nodules, and the others are all indicated for breast nodules, according to Frost & Sullivan. Details of the nodule localization products commercialized in China are set out in the table below:

Company Name	Product Name	Application	Approval Year
Cryofocus	Pulmonary Nodule Localization Needle (肺結節定位針)	Lung	2019
Cook	Jabczenski Ductogram Cannula (乳腺定位針)	Breast	2017
	X-Reidy Breast Lesion Localization Needle (乳腺病灶定位針)	Breast	2017
Bard	Ghiatas Beaded Breast Localization Wire (乳腺定位針)	Breast	2017
	Chesbrough Breast Localization Wire (乳腺定位針)	Breast	2017
	Ultra Clip Dual Trigger Breast Tissue Marker (乳腺組織標記定位針)	Breast	2015
	Bard Dualok Breast Lesion Localization Wire (乳腺穿刺定位針)	Breast	2016
Argon	Accura Needle (乳腺定位針)	Breast	2015
SOMATEX	Q-Wire System (一次性使用乳腺定位絲及其導引針)	Breast	2020
Beckdal Medical	Disposable breast locator wire and guiding needle (一次性使用乳腺定位絲及其導引針)	Breast	2021
German Medical	Disposable breast locator wire and guiding needle (一次性使用乳腺定位絲及其導引針)	Breast	2019
Curaway	Disposable breast locator wire and guiding needle (一次性使用乳腺定位絲及其導引針)	Breast	2021
Xinsid	Disposable Lung Nodule memory alloy Localization Needle (一次性使用肺結節記憶合金定位針)	Lung	2022
Polymer	Disposable Lung Nodule Localization Needle (一次性使用肺結節定位針)	Lung	2022
Argon	Hawkins Breast Localization Needle (乳腺定位針)	Breast	2022
Argon	Hawkins Breast Localization Needle (一次性使用乳腺定位絲及其導引針)	Breast	2022
Cryofocus	Disposable Breast Localization Wire (一次性使用乳腺定位針)	Breast	2022
Xinke (南京欣科醫療)	Disposable breast locator wire and guiding needle (一次性使用乳腺定位絲及其導引針)	Breast	2022

Source: Company Website, NMPA, Frost & Sullivan Analysis

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THE LAPAROSCOPY MARKET

Overview of Laparoscopy

Laparoscopy is a type of surgical procedure that allows a surgeon to access the inside of the abdomen (tummy) and pelvis without having to make large incisions in the skin. This procedure is also known as keyhole surgery. Large incisions can be avoided during laparoscopy because the surgeon uses laparoscope, which is a small tube that has a light source and a camera and relays images of the inside of the abdomen or pelvis to a television monitor. The advantages of this technique over traditional open surgery include a shorter hospital stay and faster recovery time, less pain and bleeding after the operation and reduced scarring.

Overview of Single-Port Laparoscopy

Single-port laparoscopy (SPL), is a recently developed technique in laparoscopic surgery. It is a minimally-invasive surgical procedure in which the surgeon operates almost exclusively through a single-entry point, typically the patient's navel. Compared to multiport laparoscopy, SPL uses only one port, single-port surgery leaves little to no scarring and may reduce complications that commonly occur after traditional open and even traditional laparoscopic abdominal surgery. Patients in SPL are reporting less discomfort and faster recovery compared with those undergoing traditional laparoscopy.

Overview of Single-Port Multi-Channel Operation Puncture Outfit

Although there is a growing trend towards SPL, due to the complexity and stiffness of traditional laparoscopic channels, it is not convenient for surgeons to operate surgical instruments quickly and flexibly, especially to reach the lesions that deviate far from the incision laterally. Therefore, the single-port multi-channel puncture outfit was developed in order to smoothly reach the lesions with a long lateral deviation distance and adapt to the needs of multiple instruments entering from the same incision.

The single-port multi-channel laparoscopic operation puncture outfit is typically composed of three parts: an inner sleeve ring, a membrane channel and a porous platform. In the process of minimally-invasive laparoscopic surgery, the surgeon firstly makes a small incision in the human umbilicus, and then installs the inner sleeve ring on the inner side of the human abdomen. The laparoscope and surgical instruments are inserted from the porous platform through the membrane channel to enter the body to perform surgery. After the operation, the product was withdrawn, and the incision was sutured. According to Frost & Sullivan, the single-port multi-channel operation puncture outfit has advantages including leaving little to no scarring, avoiding mutual interference between instruments and reducing the number of surgical incisions.

Competitive Landscape of Single-Port Multi-Channel Operation Puncture Outfits

According to Frost & Sullivan there were 42 single-port multi-channel operation puncture outfits approved by the NMPA in China, as of the Latest Practicable Date. The Company's Laparoscopic Single Port Multi-Channel Access Platform is made of uniquely-formulated gel material that offers good flexibility and stability, allowing for better handling during delicate operations, particularly in general surgery. In addition, the Company's Laparoscopic Single Port Multi-Channel Access Platform is detachable. Its membrane channels can be placed with greater flexibility based on physicians' usage habits and needs.

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THE FROST & SULLIVAN REPORT

In connection with the [REDACTED], we commissioned Frost & Sullivan, an Independent Third Party, to prepare a report on the markets of interventional cryotherapy devices and surgical consumables. We have agreed to pay a total of RMB0.8 million in fees for the preparation of the Frost & Sullivan Report. Frost & Sullivan is a market research and consulting company founded in 1961 that provides market research on a variety of industries including healthcare. In preparing the report, Frost & Sullivan collected and reviewed publicly available data such as government-derived information, annual reports and industry association statistics, as well as market data collected by conducting interviews with key industry experts and leading industry participants. Frost & Sullivan has exercised due care in collecting and reviewing the information so collected and believes that the basic assumptions are factual and correct and the interpretations are reasonable. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected.

The market projections in the commissioned report are based on the following key assumptions:

- the overall social, economic and political environment in the PRC is expected to remain stable during the forecast period;
- China's economic and industrial development is likely to maintain steady growth over the next decade;
- key industry drivers, such as the increasing use of medical devices, growing health expenditures and patient affordability, the increasing incidence of chronic diseases, aging population growth, and stricter regulatory policies are likely to drive the growth of China's medical device market during the forecast period; and
- no extreme force majeure or industry regulation will dramatically or fundamentally affect the market.

Except as otherwise noted, all data and forecasts in this section come from the Frost & Sullivan Report. Our Directors confirm that, to the best of their knowledge, after taking reasonable care, there has been no adverse change in market information since the date of the Frost & Sullivan Report which may qualify, contradict or impact the information disclosed in this section.

REGULATORY OVERVIEW

PRC REGULATORY OVERVIEW

Our business operations in the PRC are subject to a large number of laws and regulations as well as extensive government supervision. This section sets out a summary of the major laws, regulations, rules and policies that may have a significant impact on our business operations in the PRC.

LAWS AND REGULATIONS RELATING TO ADMINISTRATION OF MEDICAL DEVICES

Our business operations in the PRC are subject to a number of laws and regulations relating to administration of medical devices. The principal regulator of the medical device industry of the PRC is the National Medical Products Administration (the “NMPA”) and its local branches, formerly known as the State Food and Drug Administration (the “former SFDA”) and its local branches.

Classification, Registration and Filing of Medical Devices

Pursuant to the *Regulations on Supervision and Administration of Medical Devices* (《醫療器械監督管理條例》) promulgated by the State Council on January 4, 2000, last amended on February 9, 2021 and effective on June 1, 2021, medical devices are subject to classified management in the PRC and are classified into three categories by their degree of risk. Class I refers to low-risk medical devices with their safety and effectiveness ensured through routine administration. Class II refers to medium-risk medical devices with their safety and effectiveness under strict control and administration. Class III refers to high-risk medical devices which require special measures for strict control and administration to ensure their safety and effectiveness. Class I medical devices are subject to filing-based product administration, while Class II and Class III devices are subject to registration-based product administration. Drug supervision and administration authorities under the State Council formulate the rules and catalogs for medical device classification, timely analyze and assess the changes of risks concerning medical devices, and adjust their classification rules and catalogs based on their production, operation and use. According to the most updated Catalogue of Medical Device Classification (醫療器械分類目錄) published by the NMPA, each of the Bladder Cryoablation System and the Atrial Fibrillation Cryoablation System is classified as a Class III medical device in China and the Endoscopic Clip for Anastomosis is classified as a Class II medical device in China.

Pursuant to the *Regulations on Supervision and Administration of Medical Devices* and the *Measures for the Administration of Registration of Medical Devices* (《醫療器械註冊管理辦法》) promulgated by the former SFDA on July 30, 2014 and effective on October 1, 2014 (repealed after the *Measures for the Administration of Registration and Filing of Medical Devices* (《醫療器械註冊與備案管理辦法》) became effective on October 1, 2021), for filing domestic Class I medical devices, filing materials shall be submitted to the local drug supervision and administration authorities of the municipal people’s government, with any amendment to the record matters to be filed with the original filing authorities. Domestic Class II and Class III medical devices are subject to registration-based administration, under which Class II medical devices shall be examined by the drug supervision and administration authorities of a people’s government at provincial, autonomous region and municipal level; and Class III medical devices shall be examined by the drug supervision and administration authorities of the State Council, with a medical device registration certificate (醫療器械註冊登記證) to be issued upon approval.

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For registered Class II or Class III medical devices, the registrant shall apply to the original registration authorities for registering any substantive changes to the design, raw material, production technology, scope and methodology of application of such devices which may affect their safety and effectiveness. In addition, for any expansion of the scope of application, the registrant shall apply for an update on the relevant part of the registration certificate with the original registration authorities. The medical device registration certificate is valid for five years, and the registrant shall apply to the original registration authorities for registration renewal at least 6 months prior to the expiration date.

Clinical trials are not required for the filing of Class I medical devices, but required for the application for registering Class II and Class III medical devices. Medical devices may be exempt from clinical trial under either of the following circumstances: (i) with a clear working mechanism, established design, mature manufacturing processes, years of application of similar medical devices on the market with no record of material adverse events, and no change to the general purpose of the device; (ii) safety and effectiveness of the medical device proven through non-clinical evaluation; (iii) safety and effectiveness of the medical device proven through the analysis and evaluation of the data obtained from the clinical trial or application of similar medical devices.

The NMPA shall prepare, adjust and release the catalog of medical devices exempt from clinical trial. For products not included in such catalog, the applicant may specify in the registration application and submit relevant proofs in relation to the safety and effectiveness of the medical device proven through the analysis and evaluation of the data obtained from the clinical trial or application of similar medical devices. For certain Class III medical devices that are subject to clinical trials with high risk to human body, approval from the NMPA is required before clinical trials. The original catalog of Class III medical devices subject to clinical trial approval was amended under the Notice of the Catalog of Class III Medical Devices Requiring Clinical Trial Approval (2020 Amendment) (《需進行臨床試驗審批的第三類醫療器械目錄(2020年修訂版)的通告》) promulgated by the NMPA on September 14, 2020, which came into effect on September 14, 2020.

In addition, the Measures for the Administration of Registration of Medical Devices stipulates the technical requirements for product registration inspection, clinical evaluation, product registration application and examination, and the inspection and approval of product registration shall be conducted in accordance with the requirements of the NMPA.

On August 26, 2021, the State Administration for Market Regulation issued the *Measures for the Administration of Registration and Filing of Medical Devices* (《醫療器械註冊與備案管理辦法》). The Measures came into effect on October 1, 2021, with the Measures for the Administration of Registration of Medical Devices repealed at the same time. Pursuant to the notice issued by the NMPA on September 29, 2021, for such registration applications that were accepted but not yet approved prior to the implementation of the Measures for the Administration of Registration and Filing of Medical Devices, drug supervision and administration authorities shall continue with their assessment in accordance with the original regulations and issue medical device registration certificates if the conditions are met for launch on the market.

Similar to the Measures for the Administration of Registration of Medical Devices, the Measures for the Administration of Registration and Filing of Medical Devices divides medical devices into three categories with classified regulation. Class I medical devices are subject to filing-based product administration. Class II and Class III medical devices are subject to registration-based product administration.

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Pursuant to the Measures for the Administration of Registration and Filing of Medical Devices which came into effect on October 1, 2021, the registrant of medical devices shall actively conduct post-launch studies on the devices to further confirm their safety, effectiveness and quality controllability and strengthen the continuous management of the launched medical devices. For registered Class II and Class III medical devices, the registrant shall apply to the original registration authorities for registering any substantive changes to the design, raw material, production technology, scope and methodology of application of such devices which may affect their safety and effectiveness; other changes shall be filed with the original registration authorities within 30 days from the date of such changes.

The Measures for the Administration of Registration and Filing of Medical Devices stipulates that, except for the circumstances exempt from clinical evaluation, clinical evaluation shall take place for the registration and filing of medical device products. On September 16, 2021, the NMPA issued the Notice on the Issuing the Catalog of Medical Devices Exempt from Clinical Evaluation (《關於發佈免於臨床評價醫療器械目錄的通告》), which came into effect on October 1, 2021.

In addition, the Measures for the Administration of Registration and Filing of Medical Devices sets out the details of product development, clinical evaluation, registration system verification, product registration, registration of changes, renewal registration and product filing, as well as special registration procedures such as innovative product registration procedures, priority registration procedures and emergency registration procedures.

Good Clinical Practice for Medical Devices

Jointly promulgated by the former SFDA and the former National Health and Family Planning Commission on March 1, 2016 and effective from June 1, 2016, the *Good Clinical Practice for Medical Devices* (《醫療器械臨床試驗質量管理規範》) covers the entire process of clinical trial of medical devices, including, among others, the protocol design, execution, monitoring, verification and inspection, as well as data collection, recording, analysis and conclusion and reporting procedure of a clinical trial. To carry out clinical trials of medical devices, the applicant shall organize to prepare a scientific and reasonable clinical trial protocol based on the categories, risks and intended uses of the medical devices for clinical experiment. The applicant shall be responsible for (i) organizing the preparation and modification of the researcher's manual, clinical trial protocol, informed consent form, case report form, relevant standard operating procedures and other relevant documents, and (ii) organizing necessary training for the clinical trials. The applicant shall select a clinical trial institution and its researchers from qualified clinical trial institutions for medical devices based on the characteristics of such medical devices to be used in the experiment. Applicants for the clinical trials of medical devices are responsible for initiating, applying for, organizing and monitoring such clinical trials, and shall be responsible for the authenticity and reliability of the clinical trials. If the safety and performance of a new product that has not been approved for marketing in or outside the PRC have not been medically verified, the clinical trial protocol shall be designed with a small sample feasibility test as the start. After initial confirmation of its safety, the sample size shall be determined according to statistical requirements for subsequent clinical trials.

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Special Examination Procedures for Innovative Medical Devices (“Green Path”)

On October 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Medicine and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the “**Innovation Opinions**”), which aims to encourage the innovation of medical devices. Pursuant to the Innovation Opinions, priority review and approval will be granted to innovative medical devices supported by the Major National Science and Technology Projects and the Key National Research and Development Program of the PRC, clinically trialed by the National Clinical Research Center, and approved by the management department of the National Clinical Research Center.

Pursuant to the *Special Examination Procedures for Innovative Medical Devices* (《創新醫療器械特別審查程序》) promulgated by the NMPA on November 2, 2018 and effective from December 1, 2018, special procedures are applicable to the examination of medical devices in the following circumstances:

- (i) the applicant legally owns the invention patent of the core technology of the product through its technological innovation activities in the PRC, or legally obtains the invention patent or the right of use thereof through transfer in the PRC, and the interval shall not exceed five years from the date of application for the special examination and approval of innovative medical devices to the date of announcement of patent license; or the patent administration authorities of the State Council has disclosed the application for the invention patent of the core technology and the Patent Search and Consultation Center of China National Intellectual Property Administration (國家知識產權局專利檢索諮詢中心) has issued a patent search report setting out the novelty and innovation of the core technology solution of the product;
- (ii) the applicant has completed preliminary research and developed a preliminary product, through a true and controlled research process with complete and traceable research data;
- (iii) the product has (a) pioneering major working mechanism or mechanism of action domestically, (b) fundamental improvement in performance or safety compared with similar products, (c) internationally leading technology and significant value for clinical application.

The Center for Medical Device Evaluation of the NMPA (國家藥監局醫療器械技術審評中心) shall prioritize innovative medical devices in their technical review of the registration applications received, after which the NMPA shall prioritize such products in their administrative approval.

According to the Measures for the Administration of Registration and Filing of Medical Devices effective from October 1, 2021, an applicant for innovative product registration procedures shall submit an application for review of the innovative medical device to the NMPA after the preliminary product is developed. The NMPA will organize experts to review the application and, if the requirements are met, will include it in the registration procedures for innovative products. For medical device registration applications subject to the innovative product registration procedures, the NMPA and the institutions that undertake relevant technical work will designate special personnel for timely communication and guidance according to their respective responsibilities. For medical devices included in the innovative product registration procedures, the Center for Medical Device Evaluation of the NMPA can communicate with the applicant on major technical issues in product development, major safety issues, clinical trial protocols, summaries and evaluations of phased clinical trial results, etc. before the registration application is accepted and during the technical review process.

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Production Permit of Medical Devices

Pursuant to the *Measures for the Supervision and Administration of Medical Device Production* (《醫療器械生產監督管理辦法》) promulgated by the former SFDA on July 20, 2004 and last amended and effective on November 17, 2017, a medical device manufacturer shall have all the following conditions:

- (i) production sites, environmental conditions, production equipment and professional technicians suitable for such medical devices produced;
- (ii) organizations or professional examination staff and examination equipment to carry out quality examination for such medical devices produced;
- (iii) management systems to ensure the quality of such medical devices;
- (iv) after-sale services capabilities suitable for such medical devices produced; and
- (v) requirements in line with the provisions of the product research and development and production technique documents.

An enterprise engaged in the production of Class I medical devices shall file for the production of such devices with the municipal food and drug supervision and administration authorities in the district where the enterprise is located, and submit proofs of qualifications for production of such medical devices. Any changes to the contents of such filing proofs shall be filed. Enterprises engaged in the production of Class II and Class III medical devices shall apply for a Medical Device Production Permit (《醫療器械生產許可證》) with the drug supervision and administration authorities of the province, autonomous region or municipality where the enterprise is located, and submit proofs of qualifications for production of such medical devices and the registration certificates for such medical devices produced. For any changes to the contents of the Medical Device Production Permit, an application shall be made to the original issuing authorities for registering such changes. The Medical Device Production Permit is valid for five years, and the registrant shall apply to the original issuing authorities for renewal at least 6 months prior to the expiration date.

Medical Device Production and Quality Management Standards

Pursuant to the *Quality Management Standards for Medical Device Production* (《醫療器械生產質量管理規範》) (the “**Production Quality Management Standards**”) promulgated by the former SFDA on December 29, 2014 and effective on March 1, 2015, an enterprise engaged in medical device production shall establish a sound quality management system as required under the Production Quality Management Standards and shall ensure its effective operation. The enterprise shall establish procurement control procedures and a supplier audit system to evaluate its suppliers and ensure that the products purchased meet statutory requirements. The enterprise shall keep a true, accurate, complete and traceable record of the purchase, production and inspection of raw materials. The enterprise shall manage its risks throughout the process of design and development, production, sales and after-sales services. The measures taken shall be appropriate to the risks associated with the product.

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According to the Notice on Issuing On-site Inspection Guidelines of Medical Device Production Quality Management Standards and Three Other Guidelines (《關於印發〈醫療器械生產質量管理規範現場檢查指導原則〉等四個指導原則的通知》) promulgated by the former SFDA on September 25, 2015 and effective on the same date, during the on-site verification of medical device registration and the on-site inspection of production licensing (including changes), the inspection team shall issue conclusive recommendations for on-site inspection according to such guidelines. The recommendations are divided into three categories, namely "pass", "fail" or "review after rectification". During supervision and inspection, the enterprise shall be required to suspend production for rectification if found to breach the requirements on key items or on general items which may have a direct impact on product quality; the enterprise shall be required to rectify within a prescribed period if only found to breach the requirements on general items which have no direct impact on product quality. Regulators shall issue the final inspection results upon reviewing the conclusive recommendations and on-site inspection information submitted by the inspection team.

Management of Medical Device Operations

Pursuant to the *Measures for the Supervision and Administration of Medical Devices Operation* (《醫療器械經營監督管理辦法》) promulgated by the former SFDA on July 30, 2014 and amended on November 17, 2017, an enterprise engaged in medical devices operation shall align its operation and storage premises with the scope and scale of operation, and engage quality management agencies or personnel in line with medical devices operation. An enterprise engaged in the operation of Class II medical devices shall file with the municipal drug supervision and administration authorities in the district where the enterprise is located, and submit proofs that the enterprise has met the conditions on the operation of such medical devices; and an enterprise engaged in the operation of Class III medical devices shall apply for a Medical Device Operation Permit (《醫療器械經營許可證》) with the municipal drug supervision and administration authorities in the district where the enterprise is located, and submit proofs that the enterprise has met the conditions on the operation of such medical devices.

The drug supervision and administration authorities that have received the application for an operation permit shall issue the Medical Device Operation Permit to the enterprise which has met the requirements. The Medical Device Operation Permit is valid for five years and renewable in accordance with relevant provisions. Enterprise engaged in medical device operation shall not operate or use medical devices that are not registered or filed, or without qualification proofs, or have expired or become invalid or eliminated.

Medical device registrants, filers or manufacturers who sell medical devices at their residential or production address do not need to apply for an operation permit or undergo filing; those who store and conduct spot sale of medical devices at other venues shall apply for an operation permit or undergo filing in accordance with the regulations.

Pursuant to the *Quality Management Standards for Medical Device Operation* (《醫療器械經營質量管理規範》) promulgated by the former SFDA and effective on December 12, 2014, an enterprise engaged in the operation of medical devices shall take effective quality control measures in procurement, inspection and acceptance, storage, sales, transportation, after-sales service and other aspects, to ensure product quality and safety.

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Pursuant to the Regulation for Supervision and Administration of Medical Devices, an enterprise engaged in medical device operation shall check the qualifications of the supplier and the qualification proofs of the medical devices, as well as establish an inspection record system for goods when it purchases medical devices. An enterprise engaged in the wholesale business of Class II and Class III medical devices and the retail business of Class III medical devices shall also establish a sales record system. Matters on the record shall include: (1) the name, model, specification and quantity of medical devices; (2) the production batch number, expiration date and date of sale of medical devices; (3) the name of the manufacturer; (4) the name, address and contact information of the supplier or purchaser; (5) the serial numbers of relevant license proofs. The inspection records of goods purchased and sales records shall be true and kept for a period of time as prescribed by the food and drug supervision and management authorities of the State Council.

Tender Management for Medical Device Procurement

Pursuant to the Notice of the Ministry of Health on Further Strengthening the Administration of Centralized Procurement of Medical Devices promulgated on June 21, 2007, all non-profit medical institutions organized by governments, industries and state-owned enterprises at all levels shall participate in the centralized procurement of medical devices.

Pursuant to the Notice of Opinions on Reform of Pricing System of Pharmaceuticals and Medical Services (《關於印發改革藥品和醫療服務價格形成機制的意見的通知》) issued on November 9, 2009, the state shall strengthen the regulation on the pricing of medical devices. For high-value medical devices, especially implantable (interventional) medical devices, efforts shall be made to result in reasonable pricing by such measures as limiting the price difference rate during circulation and publishing market price information. High-value medical devices usually refer to medical devices that act directly on the human body with strict safety requirements, considerable clinical consumption and relatively high prices.

According to the *Work Standards on Centralized Procurement of High-Value Medical Supplies (Trial)* (《高值醫用耗材集中採購工作規範(試行)》) issued on December 17, 2012, online centralized procurement of high-value medical supplies (“**Centralized Procurement**”) shall be led by the government and carried out in provinces (autonomous regions and municipalities). Medical institutions, medical supplies manufacturers and operators shall engage in such procurement through the centralized procurement work platform established by provinces (autonomous regions and municipalities). The centralized procurement authorities of each province (region or municipality) are responsible for preparing a catalog of high-value medical devices for centralized procurement in their respective administrative region. The high-value medical supplies listed in the centralized procurement catalog can be procured through open bidding, invitation for tendering or other means prescribed by state laws and regulations. After the purchase price is determined, the public medical institutions in the region concerned shall engage in procurement strictly at public bidding prices.

On July 19, 2019, the General Office of the State Council issued the Notice on Issuing the Reform Plan for the Management of High-value Medical Supplies (《關於印發〈治理高值醫用耗材改革方案〉的通知》) (“**High-Value Medical Supplies Notice**”). Pursuant to the High-Value Medical Supplies Notice, high-value medical supplies are medical supplies that act directly on the human body, with strict safety requirements, high clinical use, relatively high prices and heavy financial burden on the public. The High-value Medical Supplies Notice sets out reform plans on regulating high-value medical supplies, including: (i) the National Healthcare Security Bureau, the National Medical Products Administration

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and the National Health Commission will gradually unify the classification and numbering of high-value medical supplies for national medical insurance by the end of 2020, and explore the application for connecting the registration, procurement and use of high-value medical supplies; (ii) an access system will be established for the high-value medical supplies under basic medical insurance, with management based on the high-value medical supplies catalog and improvement of the dynamic adjustment mechanism for the catalog. The National Health Commission and the Ministry of Finance (the "MOF") shall introduce access management measures by the end of June 2020; (iii) the mark-ups of medical supplies in public medical institutions shall be abolished by the end of 2019, with procurement prices applied to all medical supplies (including high-value medical supplies) in public medical institutions; and (iv) the National Healthcare Security Bureau, the MOF and the National Health Commission shall prepare and implement policies on medical insurance payment. Meanwhile, efforts shall be made to prepare the standards for medical insurance payment regarding high-value medical supplies, and establish a dynamic adjustment mechanism. Medical insurance funds and patients shall bear their respective expenses for high-value medical supplies under medical insurance payment standards. Medical institutions shall be guided to further reduce procurement prices according to the guidelines in the High-Value Medical Supplies Notice.

Pursuant to the Guidelines of the National Healthcare Security Administration on Establishing a Credit Evaluation System for Pharmaceutical Prices and Tender-based Procurement (《國家醫療保障局關於建立醫藥價格和招採信用評價制度的指導意見》) issued by the National Healthcare Security Administration on August 28, 2020, the credit evaluation scope of pharmaceutical prices and tender-based procurement shall take into account any illicit benefits under the catalog of improprieties obtained by pharmaceutical enterprises (including pharmaceutical production permit holders, manufacturers of medicine and medical supplies, their entrusted distribution agents, and delivery companies) during the pricing, bidding, performance and marketing processes. A catalog shall be established for improprieties regarding pharmaceutical prices and tender-based procurement matters, with dynamic adjustment in place. The catalog shall include behaviors of dishonesty and discredit, such as offering rebates or other illicit benefits during pharmaceutical purchase and sale, tax-related breaches, monopoly, improper pricing, disruption of centralized procurement order, malicious breach of contractual agreements, etc. Based on the credit ratings of pharmaceutical enterprises, written warnings and the centralized procurement platform shall be used to provide purchasers with risk information, restrict or suspend the launch of relevant medicine or medical supplies online, restrict or suspend the procurement of relevant medicine or medical supplies, and disclose the information of any impropriety. If the number of provinces involved in such impropriety meets the prescribed conditions, the Medical Price and Tender-based Procurement Guidance Center (醫藥價格和招標採購指導中心) of the National Healthcare Security Bureau shall initiate nationwide action to address the issue.

"Two Invoice System" (兩票制) for Medical Devices

Pursuant to the Notice on Opinions on the Implementation of the "Two Invoice System" in Pharmaceutical Procurement by Public Medical Institutions (for Trial Implementation) (《印發關於在公立醫療機構藥品採購中推行兩票制的實施意見(試行)》) issued on December 26, 2016, the "Two Invoice System" refers to one invoice from the pharmaceutical manufacturer to the distribution enterprise and one invoice from the distribution enterprise to the medical institution. Wholly-owned or holding commercial company (limited to one commercial company nationwide) and domestic general agent of foreign pharmaceutical products (limited to one domestic general agent nationwide) set up by a drug manufacturer or an integrated science, industry and trade group-type enterprise that only sells the pharmaceutical products of the enterprise (group) can be treated as a production enterprise. The transfer

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of pharmaceutical products between a pharmaceutical distribution group-type enterprise and its wholly-owned (holding) subsidiaries or between its wholly-owned (holding) subsidiaries can be considered not as one invoice, but is allowed to be issued one invoice at most.

Pursuant to the Notice on Consolidating the Achievements of Cancelling Pharmaceutical Markups and Deepening Comprehensive Reforms in Public Hospitals (《關於鞏固破除以藥補醫成果持續深化公立醫院綜合改革的通知》) issued on March 5, 2018, the classified centralized procurement of high-value medical supplies shall be implemented, and the “Two Invoice System” for the purchase and sale of high-value medical supplies shall be gradually implemented.

On July 19, 2019, the General Office of the State Council issued the Notice of the General Office of the State Council on Issuing the Reform Plan for the Management of High-value Medical Supplies (《國務院辦公廳關於印發〈治理高值醫用耗材改革方案〉的通知》), local authorities are encouraged to reduce the processes for the circulation of high-value medical supplies and promote open and transparent purchase and sale through means such as the “Two Invoice System” after considering the actual situation.

At present, some provinces in the PRC have issued relevant regulations on the “Two Invoice System” for medical supplies. Nevertheless, there is no clear regulation and exact implementation timeline on the “Two Invoice System” for medical devices, with the reform still in progress. Going forward, implementation of the “Two Invoice System” for medical devices in the PRC will bring uncertainties to the Company’s business development and operations.

Advertising Supervision of Medical Devices

The State Administration for Market Regulation (SAMR) promulgated the *Interim Administrative Review Measures for the Advertisements of Pharmaceutical Products, Medical Devices, Dietary Supplements and Formulated Foods for Special Medical Purposes* (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) (the “**Interim Review Measures**”) on December 24, 2019, which became effective on March 1, 2020. The Interim Review Measures stipulates that medical device advertising shall not be released without review, with the content of medical device advertising subject to the registration certificate or filing proof or the product description of registered or filed products approved by pharmaceutical supervision and administrative authorities. Medical device advertising involving medical device name, scope of application, mechanism of action or structure and composition, etc., shall not exceed the scope of the registration certificate or filing proof or the product description of registered or filed products. The validity period of advertising approval number of pharmaceutical products, medical devices, dietary supplements, formulated foods for special medical purposes shall be consistent with the shortest validity period prescribed in product registration documents, filing proofs or production license documents. If the product registration documents, filing proofs or production license documents do not specify the validity period, the advertising approval number shall be valid for two years.

Medical Device Recall, Monitoring and Re-evaluation of Adverse Events

Pursuant to the *Administrative Regulations for Medical Device Recall* (《醫療器械召回管理辦法》) promulgated by the former SFDA on January 25, 2017 and effective on May 1, 2017, medical device recalls shall be classified, according to the severity of medical device defects, as: (i) Class I recall: where the use of the medical device is likely to cause or has caused serious health hazards; (ii) Class II recall: where the use of the medical device may or has caused temporary or reversible health hazards; or (iii) Class III recall: where the use of the medical device is less likely to cause harm but still need to be

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recalled. Medical device manufacturers should determine the class of recall according to the circumstances, and design and implement the recall plan scientifically according to the sales and use of medical device. If Class I recall is implemented, a medical device recall announcement shall be published on the website of the State Drug Administration and the main media. If Class II or Class III recall is implemented, a medical device recall announcement shall be published on the website of the pharmaceutical supervision and administrative authorities of the province, autonomous region or municipality.

Pursuant to the *Administrative Measures for the Monitoring and Re-evaluation of the Adverse Events on Medical Devices* (《醫療器械不良事件監測和再評價管理辦法》) issued by the State Administration for Market Supervision and the National Health Commission on August 13, 2018 and effective on January 1, 2019, a medical device marketing licensee (the “**Licensee**”) shall be capable of quality management and assuming corresponding responsibilities to ensure the safety and effectiveness of medical devices, establish a monitoring system of medical device adverse events, and report such events directly to the monitoring technical institution for such events (the “**Monitoring Institution**”).

The enterprises in operation authorized by the Licensee to sell and the units that use medical devices should report the adverse events of medical devices to the Licensee and monitoring agencies. The Licensee shall evaluate the adverse events identified, improve product quality according to the evaluation results and report such results and quality improvement measures to the monitoring body; if approval from the original registration authority is required, an application shall be submitted in accordance with regulations.

NMPA has established a national monitoring information system for medical device adverse events, to strengthen the monitoring information network and database construction on medical device adverse events. A monitoring agency designated by NMPA is responsible for the unified management of information collected on medical device adverse events and providing the feedback of information on the monitoring of such events to relevant monitoring agencies, the Licensee, enterprises in operation or the units that use such devices.

Export of Medical Device Products

According to the Measures for the Supervision and Administration of Medical Device Production, manufacturers of medical devices for export shall ensure that such medical devices meet the requirements of the importing country (region) and file the relevant information on the products with local municipal food and drug administration authorities.

According to the *Regulations on the Application and Issuance of Medical Device Exporting Certificates* (《醫療器械產品出口證明申辦規定》) promulgated on January 6, 1996, the SFDA (currently known as the NMPA) examines the safety and legality of medical device products manufactured by enterprises in the PRC, and issues export certificates in accordance with international practices to certify that the products have been legally manufactured in the PRC.

Pursuant to the *Regulations on the Administration of Export Sales Certificates of Medical Devices* (《醫療器械產品出口銷售證明管理規定》) promulgated on June 1, 2015 and effective on September 1, 2015, if the registration certificate and production permit for a medical device have been obtained in the PRC, or the medical device registration and production filing have been completed, the drug supervision and administration authorities may issue an Export Sales Certificate for Medical Device Product (醫療器

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械產品出口銷售證明) to the relevant manufacturing enterprise. The validity term of the Export Sales Certificate for Medical Device Product shall not exceed the earliest deadline for the various documents submitted by the enterprise in the application materials, with the maximum validity term not to exceed two years.

Human Genetic Resources Filing

Pursuant to the *Regulations for the Administration of Human Genetic Resources of the People's Republic of China* (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council on May 28, 2019 and effective on July 1, 2019, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, and improvement of diagnosis and treatment technology, the PRC's capabilities of protecting biosafety and people's health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources in the PRC, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall conform to ethical principles and undergo ethical review in accordance with relevant regulations. At the same time, the privacy rights of the providers of human genetic resources shall be respected, with their prior informed consent obtained and their legitimate rights and interests protected.

On October 17, 2020, the NPC Standing Committee promulgated the *Biosecurity Law of the People's Republic of China* (《中華人民共和國生物安全法》), which came into effect on April 15, 2021. The law reaffirms the PRC's sovereignty over its human genetic resources and biological resources, and sets out more detailed provisions for the regulatory requirements contained in the *Regulations for the Administration of Human Genetic Resources of the People's Republic of China*.

Pursuant to the *Notice on the Implementation of the Administrative License for the Gathering, Collection, Dealing, Export and Exit of Human Genetic Resources* (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated and implemented by the Ministry of Science and Technology on August 24, 2015, the gathering and collection of human genetic resources through clinical trials shall be filed for record with the Human Genetic Resources Administration Office of the PRC (中國人類遺傳資源管理辦公室) through an online system.

OTHER LAWS AND REGULATIONS

Laws and Regulations on Customs

According to the *Customs Law of the People's Republic of China* (《中華人民共和國海關法》) promulgated by the Standing Committee of the NPC on January 22, 1987, last amended and came into effect on April 29, 2021, the Customs of the People's Republic of China is the PRC's entry and exit customs supervision and administration authority and is responsible for the supervision of the transport vehicles, goods, freight items, postal items and other items entering into and departing from the PRC, and collecting tariff and other duties and charges. Where a consignee or consignor of import or export goods or a customs clearing enterprise handles customs declaration procedures, they shall register with the customs in accordance with law.

According to the *Provisions of the Customs of the People's Republic of China on the Administration of Registration of Customs Declaration Entities* (《中華人民共和國海關報關單位註冊登記管理規定》) last amended by the General Administration of Customs on May 29, 2018 and came into

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effect on July 1, 2018, registration of declaring entities shall be divided into the registration of declaring enterprises which shall not go through the custom declaration procedures at the customs unless it has been approved by the relevant competent authority directly under the General Administration of Customs or the authorized customs affiliate, and the registration of consignee or consignor of imported or exported goods which requires no additional approval.

Laws and Regulations on Environmental Protection

Pursuant to the *Environmental Protection Law of the People's Republic of China* (《中華人民共和國環境保護法》) promulgated by the Standing Committee of the NPC on December 26, 1989 and last amended on April 24, 2014 and came into effect on January 1, 2015, the waste discharge licensing system has been implemented in the PRC and entities that discharge medical sewage to water directly or indirectly shall obtain a waste discharge license. Furthermore, installations for the prevention and control of pollution at a construction project must be designed, built and commissioned simultaneously with the principal part of the project.

Pursuant to the *Environmental Impact Assessment Law of the People's Republic of China* (《中華人民共和國環境影響評價法》) promulgated by the Standing Committee of the NPC on October 28, 2002 and last amended and came into effect on December 29, 2018, the *Regulations on the Administration of Construction Project Environmental Protection* (《建設項目環境保護管理條例》) amended by the State Council on July 16, 2017 and came into effect on October 1, 2017, and the *Interim Measures for the Acceptance of Environmental Protection on Completion of Construction Project* (《建設項目竣工環境保護驗收暫行辦法》) promulgated by the Ministry of Environmental Protection and came into effect on November 20, 2017, the PRC implements classification administration on the environmental impact assessment of construction projects according to the level of impact on the environment. The construction unit shall prepare an environmental impact report, or an environmental impact form or complete an environmental impact registration form (the "EIA Documents") for reporting and filing purpose. If the EIA Documents of a construction project have not been reviewed by the approving authority in accordance with the law or have not been granted approval after the review, the construction unit is prohibited from commencing construction works. Unless otherwise stipulated by laws and regulations, enterprises which are required to provide an environmental impact report and an environmental impact form shall undertake the responsibility of acceptance of the environmental protection facilities by itself upon the completion of the construction project. A construction project may be formally put into production or use only if the corresponding environmental protection facilities have passed the acceptance procedure. The competent authorities may carry out spot check and supervision on the implementation of the environmental protection facilities.

Pursuant to *Law of the People's Republic of China on Prevention and Control of Environmental Pollution Caused by Solid Wastes* (《中華人民共和國固體廢物污染環境防治法》) promulgated by the Standing Committee of the NPC on October 30, 1995 and amended on April 29, 2020 and came into effect on September 1, 2020, the construction of projects which discharge solid wastes and the construction of projects for storage, use and treatment of solid wastes shall be carried out upon the appraisal regarding their effects on environment and in compliance with the relevant state regulations concerning the management of environmental protection in respect of construction projects. The necessary supporting facilities for the prevention and control of environmental pollution caused by solid wastes as specified in the EIA Documents of the construction project shall be designed, constructed and put into operation simultaneously with the principal construction works of the construction project. No construction project shall be permitted to be put into operation or to use before its facilities for the prevention and control of

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environmental pollution caused by solid wastes have been inspected and accepted by the competent department of environmental protection that examined and accepted the EIA Documents.

Pursuant to the *Law of the People's Republic of China on Prevention and Treatment of Water Pollution* (《中華人民共和國水污染防治法》) promulgated by the Standing Committee of the NPC on May 11, 1984 and last amended on June 27, 2017 and came into effect on January 1, 2018, an environmental impact assessment shall be conducted on new construction, reconstruction and construction expansion projects or other installations on water which directly or indirectly discharge pollutants into the water. The water pollution prevention and treatment facilities of a construction project must be designed, constructed and put into operation simultaneously with the major construction works of the said construction project. The water pollution prevention and treatment facilities shall comply with the requirements of approved or filed EIA Documents.

According to the *Implementation Plan for the Permit System for Controlling Pollutants Emission* (《控制污染物排放許可制實施方案》) issued by the General Office of the State Council and came into effect on November 10, 2016, and the *Catalogue of Permitted Management of Pollution Discharge from Stationary Sources (2019 Edition)* (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the Ministry of Ecology and Environment and came into effect on December 20, 2019, the State implements focused, simplified and registered management of emission permits based on factors such as the amount of pollutants produced by enterprises and other production operators discharging pollutants, the amount of their emissions and the impact on the environment.

Laws and Regulations on Product Liability

Pursuant to the *Product Quality Law of the People's Republic of China* (《中華人民共和國產品質量法》) last amended by the Standing Committee of the NPC and came into effect on December 29, 2018, manufacturers and sellers shall establish a sound internal product quality control system and strictly implement the quality standards of their positions, quality responsibilities and the corresponding assessment methods. Manufacturers and sellers shall assume responsibility for product quality in accordance with the said law.

The product quality supervision department under the State Council is in charge of product quality supervision nationwide. The relevant departments under the State Council shall supervise product quality within their respective areas of responsibility. The quality of products shall be inspected and qualified, and sub-standard products shall not be passed off as qualified products. Industrial products that may endanger human health and safety of persons and property must comply with national and industry standards for the protection of human health and the safety of persons and property; if national or industry standards are not available, they must comply with the requirements for the protection of human health and the safety of persons and property. The production and sale of industrial products that do not meet the standards and requirements for the protection of human health and the safety of persons and property are prohibited. Manufacturers or sellers shall be liable for compensation for losses arising from their illegal acts (e.g. producing or selling defective, obsolete or invalid products, falsifying origin or quality marks, adulteration, adulteration, using fake products as genuine products, sub-standard products as good products, sub-standard products as qualified products). Penalties include confiscation of sales proceeds, revocation of business license and imposition of a fine. In serious cases, criminal liability shall be applied in accordance with the law. Manufacturers or sellers shall be responsible for any damage to persons or property caused by a defective product as a result of a breach of contract.

Pursuant to the *Civil Code of the People's Republic of China* (《中華人民共和國民法典》) promulgated by the National People's Congress on May 28, 2020 and came into effect on January 1, 2021,

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where a patient suffers damage due to defects in drugs, disinfection products, medical devices or transfusion of sub-standard blood, the patient may seek compensation from the drug marketing authorization holder, the manufacturer, the blood provider or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder, producer or the blood provider.

Laws and Regulations on Production Safety

Pursuant to the *Production Safety Law of the People's Republic of China* (《中華人民共和國安全生產法》) last amended by the Standing Committee of the NPC on June 10, 2021 and came into effect on September 1, 2021, the production and business operation entities shall (i) comply with this law and other laws and regulations on safety production, strengthen the management of safety production, establish a sound responsibility system for safety production for all employees and a system of rules and regulations on safety production; (ii) increase the investment and guarantee of safety production funds, materials, technologies, and personnel, improve safety production conditions, and boost safety production standardization and informatization; (iii) establish a dual prevention mechanism for safety risk classification and control, and for the investigation and treatment of hidden dangers, and improve the risk prevention and resolution mechanism to improve production safety standards and ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities.

The person-in-charge of an enterprise shall solely be responsible for the safety of production of the enterprise. An enterprise having more than 100 employees shall establish a safety production management agency or appoint a designated safety production management personnel. A personnel who is responsible for safety production management of an enterprise shall inspect the safety of production regularly based on the characteristics of production of the enterprise and shall deal with any safety issue identified during the inspection promptly. Any unsolved issue shall be reported to the person-in-charge in a timely manner who shall solve such issue immediately. The inspection and measures taken shall be duly documented. Enterprises and institutions shall provide their employees with trainings on production safety and shall truthfully inform their employees of any potential risks in relation to the workplace and their positions, preventive measures and emergency measures. In addition, an enterprise shall provide its employees with personal protective equipment that meet the national or industry standards, as well as supervise and train them to use such equipment.

Laws and Regulations on Intellectual Property Rights

Trademarks

Pursuant to the *Trademark Law of the People's Republic of China* (《中華人民共和國商標法》) promulgated by the Standing Committee of the NPC on August 23, 1982, last amended on April 23, 2019 and came into effect on November 1, 2019, and the *Implementation Rules of the Trademark Law of the People's Republic of China* (《中華人民共和國商標法實施條例》) passed by the State Council on August 3, 2002, last amended on April 29, 2014 and came into effect on May 1, 2014, registered trademarks in the PRC include goods marks, service marks, collective marks and certification marks. Registration of a trademark shall be made by the Trademark Office of the China National Intellectual Property Office and shall be valid for 10 years. Upon expiry, a trademark registration shall be valid for ten years for each renewal after completion of renewal procedures if it is necessary to be used continuously.

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Patents

Pursuant to the *Patent Law of the People's Republic of China* (《中華人民共和國專利法》) (the "**Patent Law**") promulgated by the Standing Committee of the NPC on March 12, 1984 and last amended on October 17, 2020 and came into effect on June 1, 2021 and the *Implementation Rules of The Patent Law of the People's Republic of China* (《中華人民共和國專利法實施細則》) amended by the State Council on January 9, 2010 and came into effect on February 1, 2010, patents in China are divided into invention patent, utility model patent or design patent. Invention patent refers to new technical solutions for a product, method or its improvement. Utility model patent refers to new technical solutions for the shape, structure or the combination of both shape and structure of a product, which is applicable for practical use. Design patent refers to new designs of the shape, pattern or the combination of shape and pattern, or the combination of the color, the shape and pattern of a product with aesthetic feeling and industrial application value. Invention patent shall be valid for 20 years, utility model patent shall be valid for 10 years and design patent shall be valid for 15 years, all commencing from the date of application. The patent right entitled to its owner shall be protected by the laws. Any person shall be licensed or properly authorized by the patent owner before he/she/it can use such patent. Otherwise, it shall constitute an infringement of the patent right.

According to the Patent Law, any entity or individual who exploits another person's patent shall enter into a license contract with the patent owner and pay a royalty for the use of the patent. The licensee is not entitled to allow any entity or individual other than those stipulated in the contract to exploit such patent.

According to the *Measures for the Filing of Patent Exploitation License Contracts* (《專利實施許可合同備案辦法》) promulgated by the CNIPA on June 27, 2011 and came into effect on August 1, 2011, the CNIPA is in charge of the filing of patent exploitation license contracts nationwide, and other parties shall complete the filing procedures within three months from the date the patent implementation license contract coming into effect.

Internet Domain Names

Pursuant to the requirements under the *Administrative Measures for Internet Domain Names* (《互聯網域名管理辦法》) promulgated by the Ministry of Industry and Information Technology of the People's Republic of China (the "**MIIT**") on August 24, 2017 and came into effect on November 1, 2017, the establishment of any domain name root server and institution for operating domain name root servers, managing the registration of domain name and providing registration services in relation to domain name within the territory of China shall be subject to the approval of the MIIT or a provincial, autonomous regional and municipal communication administration. The registration of domain name shall follow the principle of "first apply first register". The *Notice of the Ministry of Industry and Information Technology on Regulating the Use of Domain Names in Internet Information Services* (《工業和信息化部關於規範互聯網信息服務使用域名的通知》) promulgated by the MIIT on November 27, 2017 and came into effect on January 1, 2018 specifies the obligation of anti-terrorism and maintaining network security of internet information service providers.

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Laws and Regulations on Anti-Unfair Competition

According to the *Anti-Unfair Competition Law of the People’s Republic of China* (《中華人民共和國反不正當競爭法》) (the “**Anti-Unfair Competition Law**”) amended by the Standing Committee of the NPC and came into effect on April 23, 2019, unfair competition refers to the conduct of an operator who, in the course of production and operation activities, violates the Anti-Unfair Competition Law, disrupts the order of market competition and harms the lawful rights and interests of other operators or consumers. According to the Anti-Unfair Competition Law, operators shall follow the principles of voluntariness, equality, fairness, and honesty in market transactions, and abide by laws and business ethics. Operators who violate the Anti-Unfair Competition Law shall bear civil, administrative, or criminal liabilities based on specific situations.

According to the *Interim Provisions of the State Administration for Industry and Commerce on Banning Commercial Bribery* (《國家工商行政管理局關於禁止商業賄賂行為的暫行規定》) (the “**Provisions on Banning Commercial Bribery**”) promulgated by the State Administration for Industry and Commerce on November 15, 1996, commercial bribery refers to the use of money or other means by a business operator to bribe an entity or individual for the sale or purchase of goods. The term “other means” refers to the provision of any kind of domestic and overseas trips, study tours, and other means of benefit other than the payment of money. According to the Anti-Unfair Competition Law and the Provisions on Banning Commercial Bribery, the supervisory and inspection department may impose a fine according to the severity of the case and confiscate any illegal proceeds.

Laws and Regulations on Foreign Investment

Pursuant to the *Company Law of the People’s Republic of China* (《中華人民共和國公司法》) (the “**Company Law**”) promulgated by the Standing Committee of the NPC on December 29, 1993 and came into effect on July 1, 1994 and last amended and came into effect on October 26, 2018, a company established in the PRC may be in the form of a limited company with liability and joint stock limited companies. Both shall have the status of legal persons. The liability of shareholders of a limited company with liability and a joint stock limited company is limited to the amount of registered capital they have contributed or shares they have subscribed for. The Company Law shall also apply to foreign-invested companies. Where laws on foreign investment have other stipulations, such stipulations shall apply.

On March 15, 2019, the *Foreign Investment Law of the People’s Republic of China* (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) was promulgated by the NPC and came to effect on January 1, 2020, which superseded the *Sino-foreign Equity Joint Venture Enterprise Law of the People’s Republic of China* (《中華人民共和國中外合資經營企業法》), the *Sino-foreign Cooperative Joint Venture Enterprise Law of the People’s Republic of China* (《中華人民共和國中外合作經營企業法》) and the *Wholly Foreign-invested Enterprises Law of the People’s Republic of China* (《中華人民共和國外資企業法》) to become the legal foundation for foreign investment in the PRC. The Foreign Investment Law is formulated to further expand and open-up, proactively promote foreign investment and protect the legitimate rights and interests of foreign investors.

According to the Foreign Investment Law, foreign investments are entitled to pre-entry national treatment and are subject to negative list management system. The pre-entry national treatment means that the treatment given to foreign investors and their investments at the stage of investment access is not lower than that of domestic investors and their investments. The negative list management system means

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that the PRC implements special management measures for the access of foreign investment in specific fields. Foreign investors shall not invest in any prohibited areas stipulated in the negative list and shall meet the conditions stipulated in the negative list before investing in any restricted areas.

Foreign investors’ investment, earnings and other legitimate rights and interests in the PRC shall be protected in accordance with the law, and all national policies on supporting the development of enterprises shall equally apply to foreign-invested enterprises. The PRC guarantees that foreign-invested enterprises shall have equal chance to participate in the formulation of standards. The PRC guarantees that foreign-invested enterprises shall participate in government procurement activities through fair competition in accordance with the law. The PRC shall not levy on any foreign investment except under special circumstances. Under special circumstances, the PRC may levy or expropriate the investment of foreign investors in accordance with the law for public interest. The expropriation and requisition shall be conducted in accordance with legal procedures, and reasonable compensation shall be given in a timely manner. In carrying out business activities, foreign-invested enterprises shall comply with relevant provisions on labor protection, social insurance, tax, accounting, foreign exchange and other matters stipulated in the PRC laws and regulation.

On December 26, 2019, the *Regulations on Implementing the Foreign Investment Law of the People’s Republic of China* (《中華人民共和國外商投資法實施條例》) (the “**Implementation Regulations**”) was promulgated by the State Council and came into effect on January 1, 2020, which superseded the *Regulations of the People’s Republic of China on Implementing the Sino-Foreign Equity Joint Venture Enterprise Law* (《中華人民共和國中外合資經營企業法實施條例》), *Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture Enterprise Law* (《中外合資經營企業合營期限暫行規定》), the *Regulations of the People’s Republic of China on Implementing the Wholly Foreign-Owned Enterprise Law* (《中華人民共和國外資企業法實施細則》) and the *Regulations of the People’s Republic of China on Implementing the Sino-Foreign Cooperative Joint Venture Enterprise Law* (《中華人民共和國中外合作經營企業法實施細則》). The Implementation Regulations further clarifies that the PRC encourages and promotes foreign investment, protects the legitimate rights and interests of foreign investors, regulates the management of foreign investment, continues to optimize the foreign investment environment, and promotes a higher level of openness to the outside world.

The Catalogue of Industries for Encouraging Foreign Investment (2020 Version) (《鼓勵外商投資產業目錄(2020年版)》) (“**2020 Encouragement Catalogue**”) was promulgated by the National Development and Reform Commission of the People’s Republic of China (“**NDRC**”) and the Ministry of Commerce of the People’s Republic of China (“**MOFCOM**”) on December 27, 2020, and came into effect on January 27, 2021. The *Special Management Measures (Negative List) for the Access of Foreign Investment 2021* (《外商投資准入特別管理措施(負面清單)(2021年版)》) (the “**2021 Negative List**”) was promulgated by NDRC and MOFCOM on December 27, 2021, and came into effect on January 1, 2022. The 2020 Encouragement Catalogue and the 2021 Negative List set out the entry restrictions for foreign investment in different industries in the PRC. Industries for foreign investment are classified into “encouraged”, “restricted” and “prohibited”. Industries not listed in the 2020 Encouragement Catalogue and the 2021 Negative List are generally regarded as “permitted”, except for those restricted by other laws in the PRC.

The *Interim Administrative Measures on the Record-filing of the Incorporation and Changes of Foreign-invested Enterprises* (《外商投資企業設立及變更備案管理暫行辦法》) (the “**Interim Administrative Measures**”) promulgated by the MOFCOM on June 29, 2018 and came into effect on June 30, 2018 specifies the establishment and changes of procedures for foreign-invested enterprises

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which are not subject to the special management measures for the access of foreign investment implemented by the PRC. Foreign-invested enterprises or their investors shall provide true, accurate and complete information for filing purpose, complete the undertakings for filing and reporting purposes in accordance with these measures. No false statement, misleading representation or material omission is allowed.

On December 30, 2019, the *Measures for the Reporting of Foreign Investment Information* (《外商投資信息報告辦法》) was jointly promulgated by the MOFCOM and the SAMR, which came into effect on January 1, 2020 and superseded the *Interim Administrative Measures*. Since January 1, 2020, for carrying out investment activities directly or indirectly in the PRC, the foreign investors or shall submit investment information to a competent commerce authorities.

Laws and Regulations on Overseas Investment

The *Measures for the Administration of Overseas Investment* (《境外投資管理辦法》) was promulgated by the MOFCOM on March 16, 2009, last amended on September 6, 2014, and came into effect on October 6, 2014. As defined under the *Measures for the Administration of Overseas Investment*, overseas investment means that the enterprises legally incorporated in the PRC own the non-financial enterprises or obtain the ownership, control, operation and management rights and other rights of the existing non-financial enterprises in foreign countries through incorporation, merger and acquisition and other means. The MOFCOM and competent authorities of its provincial branches implement filing and approval management respectively according to the different overseas investment by enterprises. If the overseas investments involve sensitive countries and regions or sensitive industries, they shall be subject to the approval of competent authorities. For other overseas investments, they shall be subject to filing administration. Local enterprises shall conduct filing with a provincial commercial administration authority where they are located. Qualified enterprises will be documented by a competent provincial commercial administration authority and granted the Overseas Investment Certificate for Enterprise.

The *Measures for the Administration of Overseas Investment of Enterprises* (《企業境外投資管理辦法》) was promulgated by the NDRC on December 26, 2017, and came into effect on March 1, 2018. Pursuant to which, overseas investment refers to the investment activities of an enterprise in the PRC to acquire the ownership, control, operation and management rights, and other relevant interests outside the PRC, either directly or through a foreign enterprise under its control, by means of investing in assets, equity or providing financing and/or guarantees. Overseas investment shall be carried out in accordance with certain procedures, including approval, filing, reporting, and supervision and inspection of overseas investment projects. The *List of Sensitive Sectors for Outbound Investment (2018 Version)* (《境外投資敏感行業目錄(2018年版)》) promulgated by the NDRC on January 31, 2018 and came into effect on March 1, 2018 sets out the current sensitive industries.

Laws and Regulations on Employment and Social Security

The *Labor Law of People's Republic of China* (《中華人民共和國勞動法》) promulgated by the Standing Committee of the NPC on July 5, 1994 and last amended on December 29, 2018 provides that an employer shall develop and improve its rules and regulations to safeguard the rights of its workers. Labor safety and health facilities must comply with relevant national standards. Workers engaging in special industries shall receive specialized training and obtain the specific qualification for that industry.

The *Labor Contract Law of People's Republic of China* (《中華人民共和國勞動合同法》) promulgated by the Standing Committee of the NPC on June 29, 2007, last amended on December 28,

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2012, and came into effect on 1 July 2013, and the *Implementation Regulations on Labor Contract Law of the People's Republic of China* (《中華人民共和國勞動合同法實施條例》) promulgated by the State Council and came into effect on September 18, 2008 regulates the relationship between an employer and its employees, and contains specific provisions involving the terms of the labor contract.

According to the *Provisional Regulations on the Collection and Payment of Social Insurance Premium* (《社會保險費徵繳暫行條例》), the *Regulations on Work Injury Insurance* (《工傷保險條例》), the *Regulations on Unemployment Insurance* (《失業保險條例》) and the *Trial Measures on Employee Maternity Insurance of Enterprises* (《企業職工生育保險試行辦法》), an enterprise in the PRC must provide a benefit plan for their employees, which include basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance. An enterprise must provide social insurance by processing social insurance registration with local social insurance agencies, and must pay or withhold relevant social insurance premiums for or on behalf of its employees.

The *Social Insurance Law of the People's Republic of China* (《中華人民共和國社會保險法》) promulgated by the Standing Committee of the NPC on October 28, 2010, last amended and came into effect on December 29, 2018, regulates basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance, and has elaborated in detail the legal obligations and liabilities of an employer who does not comply with relevant laws and regulations on social insurance.

The *Regulations on the Administration of Housing Provident Fund* (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999, and last amended and came into effect on March 24, 2019 stipulates that an employer shall register with the Housing Provident Fund Management Centre for housing provident fund contributions and set up a housing provident fund account for its employees. The housing provident fund contributions paid by an individual employee and housing provident fund contributions paid by his/her employer shall vest to the individual employee.

Laws and Regulations on Taxation

Enterprise Income Tax

According to the *Enterprise Income Tax Law of the People's Republic of China* (《中華人民共和國企業所得稅法》) (the "EIT Law") promulgated by the Standing Committee of the NPC on March 16, 2007, last amended and came into effect on December 29, 2018, and the *Implementation Regulations on the EIT Law of the People's Republic of China* (《中華人民共和國企業所得稅法實施條例》) (the "EIT Regulations") promulgated by the State Council on December 6, 2007, last amended and came into effect on April 23, 2019, a uniform income tax rate of 25% will be applied to domestic enterprises, foreign-invested enterprises and foreign enterprises with institutions in the PRC. These enterprises are classified as either resident enterprises or non-resident enterprises. A resident enterprise refers to an enterprise that is established in the PRC in accordance with PRC laws, or that is established in accordance with the laws of foreign countries but whose actual control is administered within the PRC. A non-resident enterprise refers to an enterprise that is set up in accordance with the laws of foreign countries and whose actual administration is conducted outside the PRC, but who established institutions in the PRC, or who have established no institutions in the PRC but derive income from the PRC. Under the EIT Law and EIT Regulations, a uniform corporate income tax rate of 25% is applicable. For qualified small low-profit enterprises, a reduced EIT rate of 20% is applied. A high-tech enterprise which is supported by the PRC may entitle to a reduced EIT rate of 15%.

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According to the *Measures for the Administration of the Accreditation of High-Tech Enterprises* (《高新技術企業認定管理辦法》) (the “**Accreditation Measures**”) last amended and promulgated on January 29, 2016, a high-tech enterprise refers to a resident enterprise registered in the PRC (excluding Hong Kong, Macao and Taiwan) that is continuously engaged in research and development and the transformation of technological achievements under the High and New Technology Fields Supported by the PRC (《國家重點支持的高新技術領域》), forming its core independent intellectual property rights and conducting business activities on this basis. A high-tech enterprise accredited under the Accreditation Measures may apply for preferential taxation in accordance with the EIT Law and the EIT Regulations, *Tax Collection Administration Law of the People’s Republic of China* (《中華人民共和國稅收徵收管理法》) and the *Rules for the Implementation of the Law of the People’s Republic of China on the Administration of Tax Collection* (《中華人民共和國稅收徵收管理法實施細則》) and other relevant regulations. An enterprise certified as a high and new technology enterprise is subject to review by the relevant PRC authorities and shall submit the information about the relevant intellectual property, scientific and technical personnel, research and development expenses, operating revenue of previous year and other annual status on the required official website.

Value-added Tax

Pursuant to the *Interim Regulation of the People’s Republic of China on Value Added Tax* (《中華人民共和國增值稅暫行條例》) promulgated by the State Council on December 13, 1993 and last amended on November 19, 2017, and the *Detailed Rules for the Implementation of the Interim Regulation of the People’s Republic of China on Value Added Tax* (《中華人民共和國增值稅暫行條例實施細則》) last amended on October 28, 2011 and came into effect on November 1, 2011, all taxpayers selling goods or providing processing, repairing or replacement services, sales of services, intangible assets and immovable assets and importing goods in China shall pay a value-added tax. A tax rate of 17% shall be levied on general taxpayers selling goods and services, leasing of tangible movable assets or importing goods whereas the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated.

According to the *Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value added Tax Rates* (《財政部、國家稅務總局關於調整增值稅稅率的通知》) promulgated on April 4, 2018 and came into effective on May 1, 2018, the deduction rates of 17% and 11% originally applicable to the taxpayers who have VAT taxable sales activities or imported goods were adjusted to 16% and 10%, respectively. According to the *Notice of the Ministry of Finance, the State Administration of Taxation and the General Administration of Customs on Relevant Policies for Deepening Value Added Tax Reform* (《財政部、稅務總局、海關總署關於深化增值稅改革有關政策的公告》) promulgated on March 20, 2019 and came into effect on April 1, 2019, the value added tax rate was adjusted to 13% and 9%, respectively.

On November 16, 2011, the MOF and the STA promulgated the *Trial Scheme for the Conversion of Business Tax to Value-added Tax* (《營業稅改徵增值稅試點方案》), pursuant to the gradual taxation reforms launched by the government on January 1, 2012, value-added tax is imposed instead of business tax in pilot regions and industries with significant economic radiation, such as transportation and certain modern service industries on a trial basis.

According to the *Notice of the Ministry of Finance and the State Administration of Taxation on Overall Implementation of the Pilot Program of Replacing Business Tax with Value-added Tax* (《財政部、國家稅務總局關於全面推開營業稅改徵增值稅試點的通知》) promulgated by the MOF and the

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STA on March 23, 2016 and came into effective on May 1, 2016, and amended on July 11, 2017 and March 20, 2019, all business tax payers in the consumer service industry shall pay value-added tax instead of business tax from May 1, 2016. If the taxpayer of the pilot project has already entitled to tax incentives of business tax according to relevant policies and regulations before the application of the pilot collection of value-added tax instead of business tax, he/she may, in the remaining period of tax incentives, enjoy tax incentives of value-added tax in accordance with the relevant provisions.

Laws and Regulations on Foreign Exchange Control

According to the Regulations on the Control of Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) promulgated by the State Council on January 29, 1996 and last amended on August 5, 2008, foreign exchange receipts of domestic institutions or individuals may be transferred to China or deposited overseas. The SAFE shall specify the conditions for such transferring to China or depositing overseas in accordance with the international balance of payments and requirements of foreign exchange control. Foreign exchange receipts for current account transactions may be retained or sold to financial institutions engaged in the settlement or sale of foreign exchange. Domestic institutions or individuals that make direct investments overseas, are engaged in the distribution, sale of valuable securities or derivative products overseas should register according to SAFE regulations. Such institutions or individuals subject to prior approval or record-filing with relevant authorities shall complete the required approval or record-filing prior to foreign exchange registration. The exchange rate for RMB follows a managed floating exchange rate system based on market demand and supply.

According to *Circular of SAFE on Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies* (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) which came into effect on June 1, 2015, banks are required to review and directly carry out foreign exchange registration under offshore direct investment. The SAFE and its branches shall implement indirect supervision over foreign exchange registration of direct investment via the banks.

The *Circular of SAFE on Reforming the Management Approach regarding the Settlement of Foreign Capital of Foreign-invested Enterprise* (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the “**Circular 19**”) promulgated on March 30, 2015 and came into effect on June 1, 2015, allows foreign-invested enterprises to make equity investments by using RMB fund converted from foreign exchange capital. Pursuant to the Circular 19, the foreign exchange capital in the capital account of foreign-invested enterprises upon the confirmation of rights and interests of monetary contribution by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operation needs of the enterprise. The proportion of discretionary settlement of foreign exchange capital of foreign-invested enterprises is currently 100%. SAFE can adjust such proportion in due time based on the circumstances of the international balance of payments. However, Circular 19 and the *Circular of SAFE on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts* (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) came into effect on June 9, 2016 continue to prohibit foreign-invested enterprises from, among other things, using RMB fund converted from its foreign exchange capitals for expenditure beyond its business scope, investment and financing (except for security investment or guarantee products issued by banks), providing loans to non-affiliated enterprises or constructing or purchasing real estate not for self-use.

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On October 23, 2019, the SAFE released the Circular on Further Promoting Cross-border Trade and Investment Facilitation (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》) (the “**Circular 28**”) which was implemented on the same date. Pursuant to Circular 28, on the basis that a foreign-invested enterprise engaged in domestic equity investment business with its capital funds in accordance to laws and regulations, a non-investment foreign-invested enterprise is permitted to make domestic equity investments with its capital funds under the condition that the 2020 Negative List is not violated and the relevant domestic investment projects are true and compliant.

According to the *Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business* (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020 and came into effect on the same date, a qualified enterprise is allowed to make domestic payments by using its capital funds, foreign debts and the income from capital items including listing overseas, without the need to provide the banks with bona fide substantial materials in advance for each payment, provided that it shall ensure that its capital used is authentic and compliant and in line with the prevailing administrative measures in respect of the income from capital items. Such bank shall conduct spot checks in accordance with the relevant requirements.

The requirements on “Full Circulation” of H Shares

“Full circulation” means the listing and circulating on the Hong Kong Stock Exchange of domestic unlisted shares of an H-share company, including the unlisted domestic shares held by domestic shareholders prior to overseas listing, the unlisted domestic shares additionally issued after overseas listing, and the unlisted shares held by foreign shareholders. On November 14, 2019, CSRC announced the *Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies* (《H股公司境內未上市股份申請「全流通」業務指引》) (“**Guidelines for the “Full Circulation”**”).

According to the Guidelines for the “Full Circulation”, shareholders of domestic unlisted shares may determine by themselves through consulting the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the H-share company may be entrusted to file the said application for “Full Circulation”. To file an application for “Full Circulation”, an H-share company shall file the application with the CSRC according to the administrative licensing procedures necessary for the “examination and approval of public issuance and listing (including additional issuance) of shares overseas by a joint stock company”. An H-share company may apply for “Full Circulation” separately or when applying for refinancing abroad. An unlisted domestic joint stock company may apply for “Full Circulation” when applying for an overseas initial public offering. After the application for “Full Circulation” has been approved by the CSRC, an H-share company shall submit a report on the relevant situation to the CSRC within 15 days after the transfer registration with CSDC of the shares related to the application has been completed. Unlisted shares in the PRC once listed and circulated on the Hong Kong Stock Exchange may not be transferred back to the PRC.

On December 31, 2019, China Securities Depository and Clearing Co., Ltd. (“**CSDC**”) and Shenzhen Stock Exchange (“**SZSE**”) jointly announced the *Measures for Implementation of H-share “Full Circulation” Business* (《H股「全流通」業務實施細則》) (“**Measures for Implementation**”). The businesses involved in H-share “full circulation” business, including cross-border transfer registration, maintenance of depository and holding details, transaction entrustment and transmission of orders,

REGULATORY OVERVIEW

settlement, management of settlement participants, and services of nominal holders,, are subject to the Measures for Implementation. Where not provided for in the Measures for Implementation, reference shall be made to other business rules under CSDC, China Securities Depository and Clearing (Hong Kong) Company Limited (“**CSDC HK**”) and SZSE.

According to the Measures for Implementation, after having completed relevant information disclosure, the H-share listed companies with the approval of the CSRC to engage in the H-share “Full Circulation” business shall apply to the CSDC for the deregistration of part or all of the non-foreign listed shares, and shall re-register the fully circulated H-shares which are not pledged, frozen, restricted to transfer to the share register institutions in Hong Kong. Such shares shall become eligible for listing and circulation on the HKSE. Relevant securities are centrally deposited in CSDC for settlement. As the nominal holder of the above-mentioned securities, CSDC handles the depository and holding details maintenance, cross-border clearing and settlement and other businesses involved in the “Full Circulation” of H-shares, and provides nominal holder services for investors. The H-share listed company shall be authorized by “Full Circulation” shareholders to choose domestic securities companies that participate in the “full circulation” business of H-shares. “Full Circulation” shareholders submit trading orders of H-shares “Full Circulation” shares through domestic securities companies. Domestic securities companies shall select a securities firm in Hong Kong to submit trading orders of their “Full Circulation” shareholders to the HKSE for trading. After the transaction is concluded, CSDC and CSDC HK shall handle the cross-border clearing and settlement of relevant shares and funds. The settlement currency of H-share “Full Circulation” transaction business is HKD. Where an H-share listed company entrusts CSDC to distribute cash dividends, it shall file an application with CSDC. An H-share listed company distributing cash dividends may apply to the CSDC for the holding details of relevant “Full Circulation” shareholders on the securities registration date. The non-H-share “Full Circulation” securities listed on the HKSE obtained due to the distribution and conversion of H-share “Full Circulation” securities may be sold but shall not be purchased. Where the subscription right to subscribe for the shares listed on HKSE is obtained and the subscription right is listed on HKSE, it may be sold, but shall not be exercised.

In order to fully promote the reform of H-shares “Full Circulation”, specify the business arrangement and completion procedures for the relevant shares’ registration, custody, settlement and delivery, CSDC has promulgated the *Guide to the Program for “Full Circulation” of H-shares* (《H股「全流通」業務指南》) in February 2020, which clearly specified the matters including business preparation, account arrangement, cross-border share transfer registration, and Full Circulation.

Regulations on Share Incentive Scheme for Employees

Pursuant to the *Notice on Issues concerning the Foreign Exchange Administration of Domestic Individuals’ Participation in Share Incentive Scheme of Overseas Listed Companies* (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) promulgated by SAFE and came into effect on February 15, 2012, the employees, directors, supervisors and other senior management participating in any share incentive scheme of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, subject to a few exceptions, are required to register with SAFE or its local branches through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and has completed certain other procedures. In addition, the SAT has issued a circular on share incentive scheme for employees, whereby the employees working in the PRC will be subject to PRC individual income tax for exercising their incentive awards.

REGULATORY OVERVIEW

EU REGULATORY OVERVIEW

As of the Latest Practicable Date, medical devices in the EU were primarily subject to the following regulations:

- Regulation (EU)2017/745 of the European Parliament and of the Council of April 5, 2017 (Medical Devices Regulation, “**MDR**”) on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; and
- Regulation 2020/561 of the European Parliament and of the Council of April 23, 2020 amending Regulation (EU)2017/745 on medical devices which apply to medical device have been fully applicable since May 26, 2021, following the transition period.

In addition, there are some other regulations which providing the implementing measures for the MDR:

- Commission Implementing Regulation (EU)2021/2226 of December 14, 2021 laying down rules for the application of Regulation (EU)2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices;
- Commission Implementing Regulation (EU)2021/2078 of November 26, 2021 laying down rules for the application of Regulation (EU)2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices;
- Commission Implementing Regulation (EU)2020/1207 of August 19, 2020 laying down rules for the application of Regulation (EU)2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices;
- Commission Implementing Decision (EU)2019/1396 of September 10, 2019 laying down the rules for the application of Regulation (EU)2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices; and
- Commission Implementing Decision (EU)2019/939 of June 6, 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices.

The EU classifies medical device products applicable in the MDR according to their nature, function, and intended purpose. Medical devices are divided into four categories: I, IIa, IIb, and III. Broadly speaking, low-risk medical devices belong to Class I, medium-risk medical devices belong to Class IIa and IIb, and high-risk medical devices belong to Class III. The classification of these devices is a “risk-based” system, depending on the vulnerability of the human body and the potential risk associated with the device. According to Annex VIII of the MDR, in Europe, our Bladder Cryoablation System is classified as Class IIb, our Atrial Fibrillation Cryoablation System is classified as Class III, and our Endoscopic Clip for Anastomosis is classified as Class IIa. From time to time, a device may be classified differently by the respective regulatory authorities in different jurisdictions.

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Medical devices (except of Class I medical devices which can be commercialized in the European market by self-declaration) in the EU have to undergo a conformity assessment to demonstrate that they meet regulatory requirements to ensure they are safe and perform as intended. The conformity assessment usually involves an audit of the manufacturer's quality system and, depending on the type of device, a review of technical documentation from the manufacturer on the safety and performance of the device. According to the device complexity and potential risk to the patients, medical devices are divided into different risk classifications. And different devices classification should follow certain conformity assessment procedure or route. Confirmation of conformity with relevant MDR general safety and performance requirements under the normal conditions of the intended use of the device shall be provided by means of clinical evaluation, an evaluation procedure based on clinical data providing sufficient clinical evidence. Medical devices can be commercialized in the European market once they have passed the conformity assessment and obtained a CE Mark.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

INTRODUCTION

Overview

We are a medical device company in China with a main focus on the field of minimally-invasive interventional cryotherapy.

Our Company was established in the PRC on March 15, 2013. Our executive Director and the chairperson of our Board, Mr. LI Kejian, has led the overall operations and management of our Group since he joined our Group upon our Company’s establishment. For more details of the experience and qualifications of Mr. LI Kejian, see “Directors, Supervisors and Senior Management” in this document. Ms. Li and Mr. Lv, as the Concert Parties, had been our controlling shareholders throughout the Track Record Period. For more details of the concert party arrangement, see “— Concert Party Arrangement” in this section.

Business Milestones

The following table illustrates the key milestones of our business and corporate developments:

<u>Time</u>	<u>Milestone</u>
2013	Our Company was incorporated in the PRC with limited liability in March.
2015	We completed the pre-clinical product testing and pre-clinical animal study on dogs for our Bladder Cryoablation System in August.
2016	Our Bladder Cryoablation System’s cryoablation catheter was admitted into the Green Path for Innovative Medical Devices by the NMPA in June.
2017	Our Cryofocus Renal Denervation System (“ Cryo-RDN System ”) was admitted into the Green Path for Innovative Medical Devices by the NMPA in February. We initiated the multi-center clinical trial for our Bladder Cryoablation System in November.
2018	We completed the Series A Financing and raised RMB30 million through investment in our Company in March. We completed the Ningbo SensCure Series A Financing and raised RMB40 million through investment in Ningbo SensCure in May. We completed the pre-clinical animal study on dogs for our Atrial Fibrillation Cryoablation System (“ AF Cryoablation System ”) in December.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Time	Milestone
2019	<p>We completed the Series A+ Financing and raised RMB45 million through investment in our Company in February.</p> <p>We completed the pre-clinical product testing for our AF Cryoablation System in April.</p> <p>We completed the Ningbo SensCure Series A+ Financing and raised RMB22 million through investment in Ningbo SensCure in June.</p> <p>We completed the Series A++ Financing and raised RMB15 million through investment in our Company in June.</p> <p>Our AF Cryoablation System was admitted into the Green Path for Innovative Medical Devices by the NMPA in August.</p> <p>We completed the Ningbo SensCure Series A++ Financing and raised RMB20 million through investment in Ningbo SensCure in September.</p> <p>We completed the pre-clinical animal study on pigs for our Endoscopic Clip for Anastomosis in September.</p> <p>We initiated the multi-center clinical trial for our AF Cryoablation System in October.</p> <p>We completed the pre-clinical product testing for our Endoscopic Clip for Anastomosis in November.</p> <p>Our Endoscopic Clip for Anastomosis was admitted into the Green Path for Innovative Medical Devices by the Zhejiang MPA in November.</p>
2020	<p>We initiated the multi-center clinical trial for our Endoscopic Clip for Anastomosis in June.</p> <p>We completed the Equity Swap in December and Ningbo SensCure became our wholly-owned subsidiary under merger accounting.</p> <p>We completed all the subject enrollment for the clinical trial for our AF Cryoablation System in December.</p>
2021	<p>We completed the Series B Financing and raised RMB193.62 million through investment in our Company in March.</p>

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

<u>Time</u>	<u>Milestone</u>
	We completed the clinical trial for our Bladder Cryoablation System and submitted registration application to the NMPA in May.
	We completed the clinical trial for our Endoscopic Clip for Anastomosis and submitted registration application to the Zhejiang MPA in November.
2022	We completed the multi-center clinical trial for our AF Cryoablation System in May and submitted registration application to the NMPA in July.
	We received the NMPA approval for our Bladder Cryoablation System in June.
	We received the Zhejiang MPA approval for our Endoscopic Clip for Anastomosis in August.

OUR SUBSIDIARIES

As of the Latest Practicable Date, we had four wholly-owned subsidiaries and four non-wholly owned subsidiaries. The following sets forth details of our direct subsidiaries through which we conduct our businesses.

Ningbo SensCure

Ningbo SensCure was established in the PRC on September 28, 2011 with a registered capital of RMB19,814,323 as of the Latest Practicable Date, and is principally engaged in the R&D, manufacturing and sales of cryotherapy-related products applied in the field of minimally invasive intervention (via natural lumen) treatments and minimally invasive endoscopic surgery. On December 25, 2020, we completed the acquisition of 100% equity interests in Ningbo SensCure and it became our wholly-owned subsidiary under merger accounting. For details of Ningbo SensCure and the Equity Swap, see “—Reorganization” in this section.

Cryofocus America Inc.

Cryofocus America Inc. was established in Tustin, California, the U.S. on January 4, 2018 with a registered capital of USD1,000,000 as of the Latest Practicable Date and is principally engaged in the R&D of cryoablation medical devices and related technical consultation. It has been wholly owned by our Company since its establishment.

Beijifeng Biotechnology (Shanghai) Co., Ltd. (北極豐生物科技(上海)有限公司)

Beijifeng Biotechnology (Shanghai) Co., Ltd. (北極豐生物科技(上海)有限公司) was established in the PRC on April 9, 2021 with a registered capital of RMB41,764,700 as of the Latest Practicable Date, and is principally engaged in the R&D of technology based on nitrous oxide and carbon dioxide as the cryogenic source, and the manufacturing and sales of related products. Since its establishment, Beijifeng Biotechnology (Shanghai) Co., Ltd. has been owned as to 71.83% by our Company and 28.17% by Mr. DIAO Yuepeng (刁月鵬), our deputy vice president. When we established this subsidiary, we made the payments for the registered capital of this subsidiary in the form of cash contribution, while Mr. Diao made the payments by contributing to such subsidiary certain proprietary technologies he developed by himself. The amount of the registered capital, and the respective equity interests of Mr. Diao and us in this subsidiary, were determined based on, among other things, a valuation report issued by an independent asset valuer.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Huifeng Biotechnology (Shanghai) Co., Ltd. (輝豐生物科技(上海)有限公司)

Huifeng Biotechnology (Shanghai) Co., Ltd. (輝豐生物科技(上海)有限公司) was established in the PRC on April 9, 2021 with a registered capital of RMB79,207,900 as of the Latest Practicable Date, and is principally engaged in the R&D of pulsed electric field ablation technology applied on atrial fibrillation, and the manufacturing and sales of related products. Since its establishment, Huifeng Biotechnology (Shanghai) Co., Ltd. has been owned as to 50.50% by our Company and 49.50% by Mr. DIAO Yuepeng (刁月鵬), our deputy vice president. When we established this subsidiary, we made the payments for the registered capital of this subsidiary in the form of cash contribution, while Mr. Diao made the payments by contributing to such subsidiary certain proprietary technologies he developed by himself. The amount of the registered capital, and the respective equity interests of Mr. Diao and us in this subsidiary, were determined based on, among other things, a valuation report issued by an independent asset valuer.

CORPORATE DEVELOPMENT

Establishment of Our Company

Our Company was established in the PRC on March 15, 2013 with an initial registered capital of USD2,000,000. The shareholding structure of our Company upon establishment is set forth in the table below:

<u>Shareholder</u>	<u>Registered Capital (USD)</u>	<u>Equity Interest</u>
Shanghai Shidi Biotechnology Co., Ltd. (上海仕地生物科技有限公司) (“ Shidi Biotechnology ”) ⁽¹⁾	940,000	47.00%
Mr. ZENG Min Frank ⁽²⁾	440,000	22.00%
TD Engineering ⁽³⁾	400,000	20.00%
Shanghai Bochen Biotechnology Co., Ltd. (上海博晨生物科技有限公司) (“ Bochen Biotechnology ”) ⁽⁴⁾	220,000	11.00%
Total	2,000,000	100.00%

Notes:

- (1) Shidi Biotechnology is a limited company incorporated in the PRC and is a wholly-owned subsidiary of Ningbo Linfeng which is ultimately controlled by Ms. Li.
- (2) Mr. ZENG Min Frank is an Independent Third Party. He has not held any roles in our Group and has not participated in our Group’s R&D activities since our Company’s establishment.
- (3) TD Engineering is a limited company incorporated in the U.S. and is wholly owned by Mr. Thach Buu DUONG, our deputy general manager.
- (4) Bochen Biotechnology is a limited company incorporated in the PRC and is wholly owned by Mr. YE Xuli (葉旭禮), a nephew of Mr. Lv.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Ms. Li, through her spouse, Mr. WU Jianhui (鄔建輝) (“Mr. Wu”), became acquainted with Mr. Lv since 2006 when Mr. Wu was a director of LifeTech Scientific Corporation (先健科技公司), a company listed on the Stock Exchange (stock code: 1302) and Mr. Lv served as a vice general manager of Lifetech Scientific (Shenzhen) Co., Ltd., a wholly-owned subsidiary of LifeTech Scientific Corporation. Mr. Lv first became acquainted with Mr. ZENG Min Frank in 2000 when they both worked at MicroPort Medical (Shanghai) Co., Ltd. (微創醫療器械(上海)有限公司). Ms. Li became acquainted with Mr. ZENG Min Frank through her spouse, Mr. Wu who first became acquainted with Mr. ZENG Min Frank in September 2006 when they were both directors of LifeTech Scientific Corporation. Later, Ms. Li, Mr. Wu and Mr. Lv became acquainted with Mr. Thach Buu DUONG, our deputy general manager and one of the leaders of our research and development team, through Mr. ZENG Min Frank who was a colleague of Mr. Thach Buu DUONG. At that time, Mr. Thach Buu DUONG owned certain technology pertaining to liquid nitrogen cryotherapy and both Ms. Li and Mr. Lv were of the view that such technology could be applied to the biomedical field. As a result, our Company was established with a focus of medical products applying technology pertaining to liquid nitrogen cryotherapy. With the development of our Group, such technology has been applied to our Group’s vascular interventional cryotherapy products and product candidates and NOTES interventional cryotherapy products and product candidates, including our Bladder Cryoablation System and AF Cryoablation System.

Equity Transfers in 2014

On May 20, 2014, the following parties entered into equity transfer agreements, respectively, pursuant to which the following transfers of equity interest in our Company were conducted:

<u>Transferor</u>	<u>Transferee</u>	<u>Registered Capital Transferred (USD)</u>	<u>Corresponding Equity Interest in our Company</u>	<u>Consideration (USD)</u>
Shidi Biotechnology	Ningbo Linfeng	940,000	47.00%	940,000
Bochen Biotechnology	Mr. Lv	220,000	11.00%	220,000
Mr. ZENG Min Frank	Mr. Lv	100,000	5.00%	50,000 ⁽¹⁾
TD Engineering	Mr. Lv	200,035	10.00%	35 ⁽²⁾

Notes:

- (1) The consideration in the amount of USD50,000 represented the amount of the registered capital transferred which had been paid up at the time of the transfer.
- (2) The consideration in the amount of USD35 represented the amount of the registered capital transferred which had been paid up at the time of the transfer.

Ningbo Linfeng is a limited company established on November 8, 2011 in the PRC and serves as an investment platform of Ms. Li to cover potential investments in healthcare and technology industries together with other minority shareholders. As of the Latest Practicable Date, Ningbo Linfeng was held by Shanghai Shidi, Ms. WANG Tingxiang (王婷香), Mr. LI Yao (李堯), Mr. XIE Changqing (謝長慶), Mr. LOU Junjian (樓君建), Ms. XIE Youpei (謝優佩) and Mr. YUAN Jiang (元江) as to 65%, 20%, 5%, 2.5%, 2.5%, 2.5% and 2.5%, respectively. Other than Ms. WANG Tingxiang who is the mother of Mr. Wu and Mr. YUAN Jiang who is the chairman of the board of directors of Ningbo SensCure, each of the individual shareholders of Ningbo Linfeng is an Independent Third Party. Mr. Wu, the spouse of Ms. Li, has been the sole director of Ningbo Linfeng since December 14, 2020. For further details of Ningbo Linfeng, see “Relationship with our Controlling Shareholders — Non-competition Arrangement — Other Business Interests of Ms. Li, Shanghai Shidi, Ningbo Linfeng and Their Close Associates” in this document.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the abovementioned equity transfers on July 8, 2014, the shareholding structure of our Company was as follows:

Shareholder	Registered Capital (USD)	Equity Interest
Ningbo Linfeng	940,000	47.00%
Mr. Lv	520,035 ⁽¹⁾	26.00%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>1,460,035</i>	<i>73.00%</i>
Mr. ZENG Min Frank	340,000	17.00%
TD Engineering	199,965	10.00%
Total	2,000,000	100.00%

Note:

- (1) Among the registered capital of USD520,035, the registered capital of USD200,000 was unpaid at the time and was paid up on April 1, 2016 afterwards.

Re-denomination of our Registered Capital and Capital Increase in 2015

Pursuant to the Board resolutions dated August 1, 2015, we re-denominated our registered capital from U.S. dollars to Renminbi and the registered capital of our Company became RMB12,380,000. Further, pursuant to the same resolutions, the registered capital of our Company was increased from RMB12,380,000 to RMB18,600,000. Amongst the increased registered capital of RMB6,220,000, Shanghai Shidi subscribed for the increased registered capital of RMB3,732,000 at par value and Ningbo Dixiang Venture Capital Co., Ltd. (寧波迪翔創業投資有限公司) (formerly known as Ningbo Dixiang Medical Technology Co., Ltd. (寧波迪翔醫療科技有限公司)) (“**Ningbo Dixiang**”) subscribed for the increased registered capital of RMB2,488,000 at par value. Shanghai Shidi is a limited company established in the PRC and is wholly owned by Ms. Li. Ningbo Dixiang is a limited company established in the PRC and is owned as to 98% by Mr. Lv.

Upon completion of the abovementioned re-denomination of our registered capital and capital increase on November 9, 2015, the shareholding structure of our Company was as follows:

Shareholder	Registered Capital (RMB)	Equity Interest
Ningbo Linfeng	5,820,000	31.29%
Shanghai Shidi	3,732,000	20.06%
Mr. Lv	3,220,000	17.31%
Ningbo Dixiang	2,488,000	13.38%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>15,260,000</i>	<i>82.04%</i>
Mr. ZENG Min Frank	2,100,000	11.29%
TD Engineering	1,240,000	6.67%
Total	18,600,000	100.00%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Equity Transfers in 2017

Pursuant to respective equity transfer agreements dated March 22, 2017 entered into between (i) Ningbo Dixiang and Ningbo Maishang and (ii) Mr. ZENG Min Frank and Ningbo Maishang, Ningbo Maishang acquired the registered capital of our Company of RMB2,488,000 held by Ningbo Dixiang and that of RMB2,100,000 held by Mr. ZENG Min Frank, all at par value. Ningbo Maishang is one of our ESOP Platforms. For details relating to Ningbo Maishang, see “—Employee Incentive Platforms” in this section.

Upon completion of the abovementioned equity transfers on May 9, 2017, the shareholding structure of our Company was as follows:

Shareholder	Registered Capital (RMB)	Equity Interest
Ningbo Linfeng	5,820,000	31.29%
Ningbo Maishang	4,588,000	24.67%
Shanghai Shidi	3,732,000	20.06%
Mr. Lv	3,220,000	17.31%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>17,360,000</i>	<i>93.33%</i>
TD Engineering	1,240,000	6.67%
Total	18,600,000	100.00%

Series A Financing in 2018

Pursuant to an equity transfer agreement entered into between Ningbo Maishang and Suzhou Industrial Park New Phase 2 Venture Capital Enterprise (Limited Partnership) (蘇州工業園區新建元二期創業投資企業(有限合夥)) (“**Suzhou New Phase 2 VC**”) on December 5, 2017, Suzhou New Phase 2 VC acquired the registered capital of RMB1,240,000 held by Ningbo Maishang at a consideration of RMB10,000,000. The consideration for the equity transfer was determined after arm’s length negotiations between the relevant parties with reference to the then status of the business development of our Company and the then valuation of our Company, and taking into consideration the limited special rights attached to the existing registered capital purchased under the equity transfer, as compared to the special rights attached to the registered capital subscribed for as detailed below. For further details, see “—Pre-[REDACTED] Investments” in this section.

Further, concurrently with the abovementioned equity transfer and pursuant to the Board resolutions dated December 5, 2017, the registered capital of our Company was increased from RMB18,600,000 to RMB21,390,000. Suzhou New Phase 2 VC subscribed for the increased registered capital of RMB2,790,000 at a consideration of RMB30,000,000 (together with the abovementioned equity transfer, “**Series A Financing**”). The consideration for the increased registered capital was determined after arm’s length negotiations between our Company and Suzhou New Phase 2 VC with reference to the then status of the business development of our Company and the then valuation of our Company. For further details, see “—Pre-[REDACTED] Investments” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of Series A Financing on March 22, 2018, the shareholding structure of our Company was as follows:

Shareholder	Registered Capital (RMB)	Equity Interest
Ningbo Linfeng	5,820,000	27.21%
Shanghai Shidi	3,732,000	17.45%
Ningbo Maishang	3,348,000	15.65%
Mr. Lv	3,220,000	15.05%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>16,120,000</i>	<i>75.36%</i>
Suzhou New Phase 2 VC	4,030,000	18.84%
TD Engineering	1,240,000	5.80%
Total	21,390,000	100.00%

Series A+ Financing in 2019

Pursuant to the Board resolutions dated November 19, 2018, the registered capital of our Company was increased from RMB21,390,000 to RMB24,398,000. Amongst the increased registered capital of RMB3,008,000, (i) Hangzhou Proxima Innovative Investment L.P. (Limited Partnership) (杭州比鄰星創新投資合夥企業(有限合夥)) (“**Hangzhou Proxima**”) subscribed for the increased registered capital of RMB1,337,000 at a consideration of RMB20,000,000, (ii) Galaxy Yuanhui Investment Co., Ltd (銀河源匯投資有限公司) (“**Galaxy Yuanhui**”) subscribed for the increased registered capital of RMB1,003,000 at a consideration of RMB15,000,000 and (iii) Suzhou Shengshan Huiying Venture Capital Enterprise (Limited Partnership) (蘇州盛山滬贏創業投資企業(有限合夥)) (“**Shengshan Huiying**”) subscribed for the increased registered capital of RMB668,000 at a consideration of RMB10,000,000 (collectively, “**Series A+ Financing**”). The considerations for the increased registered capital were determined after arm’s length negotiations between our Company and relevant parties with reference to the then status of the business development of our Company and the then valuation of our Company. For further details, see “—Pre-[REDACTED] Investments” in this section.

Upon completion of Series A+ Financing on January 28, 2019, the shareholding structure of our Company was as follows:

Shareholder	Registered Capital (RMB)	Equity Interest
Ningbo Linfeng	5,820,000	23.85%
Shanghai Shidi	3,732,000	15.30%
Ningbo Maishang	3,348,000	13.72%
Mr. Lv	3,220,000	13.20%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>16,120,000</i>	<i>66.07%</i>
Suzhou New Phase 2 VC	4,030,000	16.52%
Hangzhou Proxima	1,337,000	5.48%
TD Engineering	1,240,000	5.08%
Galaxy Yuanhui	1,003,000	4.11%
Shengshan Huiying	668,000	2.74%
Total	24,398,000	100.00%

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Series A++ Financing in 2019

Pursuant to the Board resolutions dated May 7, 2019, the registered capital of our Company was increased from RMB24,398,000 to RMB25,401,000. Suzhou Jingtian Medical Investment Partnership (Limited Partnership) (蘇州景天醫療投資合夥企業(有限合夥)) (“**Suzhou Jingtian Medical**”) subscribed for the increased registered capital of RMB1,003,000 at a consideration of RMB15,000,000 (“**Series A++ Financing**”). The consideration for the increased registered capital was determined after arm’s length negotiations between our Company and Suzhou Jingtian Medical with reference to the then status of the business development of our Company and the then valuation of our Company. For further details, see “—Pre-[REDACTED] Investments” in this section.

Upon completion of Series A++ Financing on May 17, 2019, the shareholding structure of our Company was as follows:

Shareholder	Registered Capital (RMB)	Equity Interest
Ningbo Linfeng	5,820,000	22.91%
Shanghai Shidi	3,732,000	14.69%
Ningbo Maishang	3,348,000	13.18%
Mr. Lv	3,220,000	12.68%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>16,120,000</i>	<i>63.46%</i>
Suzhou New Phase 2 VC	4,030,000	15.87%
Hangzhou Proxima	1,337,000	5.26%
TD Engineering	1,240,000	4.88%
Galaxy Yuanhui	1,003,000	3.95%
Suzhou Jingtian Medical	1,003,000	3.95%
Shengshan Huiying	668,000	2.63%
Total	25,401,000	100.00%

Capital Increase pursuant to the Equity Swap and Subscription by Ningbo Hongyingkang

Pursuant to the Board resolutions dated December 1, 2020, the registered capital of our Company was increased from RMB25,401,000 to RMB54,044,681. Among the increased registered capital of RMB28,643,681, (i) Ningbo Linfeng, Mr. Lv, Suzhou New Phase 2 VC, Hangzhou Proxima, Ningbo Kangrui, Suzhou Proxima Venture Investment L.P. (Limited Partnership) (蘇州比鄰星創業投資合夥企業(有限合夥)) (“**Suzhou Proxima**”), Mr. LIU Ya (劉亞), Ms. SHEN Yao (申堯), Shanghai Shengshan Xingqian Venture Capital Center (Limited Partnership) (上海盛山興錢創業投資中心(有限合夥)) (“**Shengshan Xingqian**”), Ningbo Fuchuang Innovation and Venture Capital Center (Limited Partnership) (寧波複創創新創業投資中心(有限合夥)) (“**Ningbo Fuchuang**”), Mr. ZHU Jun (朱軍), Ms. YUAN Dan (袁丹) and Mr. XU Li (徐力) collectively subscribed for the increased registered capital of RMB25,401,000 (the abovementioned subscriptions by Suzhou New Phase 2 VC, Hangzhou Proxima, Suzhou Proxima, Mr. LIU Ya, Ms. SHEN Yao, Shengshan Xingqian, Ningbo Fuchuang and Mr. XU Li collectively referred to as “**Equity Swap Investments**”) in return for which each of Ningbo Linfeng, Mr. Lv, Suzhou New Phase 2 VC, Hangzhou Proxima, Ningbo Kangrui, Suzhou Proxima, Mr. LIU Ya, Ms. SHEN Yao, Shengshan Xingqian, Ningbo Fuchuang, Mr. ZHU Jun, Ms. YUAN Dan and Mr. XU Li transferred the equity interests they held in Ningbo SensCure to our Company pursuant to the Equity

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Swap, and (ii) Ningbo Hongyingkang subscribed for the increased registered capital of RMB3,242,681 at a consideration of RMB16,213,405. The consideration for the increased registered capital subscribed for by Ningbo Hongyingkang was determined after arm’s length negotiations between our Company and Ningbo Hongyingkang with reference to the amount of capital contribution payable by the participants of our employee incentive plan. The capital increase and subscriptions were completed on December 25, 2020. For more details of the Equity Swap, see “—Reorganization” in this section.

Below sets forth details of the subscriptions by Ningbo Linfeng, Mr. Lv, Suzhou New Phase 2 VC, Hangzhou Proxima, Ningbo Kangrui, Suzhou Proxima, Mr. LIU Ya, Ms. SHEN Yao, Shengshan Xingqian, Ningbo Fuchuang, Mr. ZHU Jun, Ms. YUAN Dan and Mr. XU Li.

Subscriber	Registered Capital subscribed for (RMB)
Ningbo Linfeng	10,798,649
Mr. Lv	4,114,585
Suzhou New Phase 2 VC	1,706,740
Hangzhou Proxima	765,090
Ningbo Kangrui	1,598,907
Suzhou Proxima	1,530,181
Mr. LIU Ya	1,322,723
Ms. SHEN Yao	938,708
Shengshan Xingqian	918,108
Ningbo Fuchuang	853,369
Mr. ZHU Jun	384,585
Ms. YUAN Dan	281,613
Mr. XU Li	187,742
Total	25,401,000

Ms. YUAN Dan is our former Supervisor. Each of Ms. SHEN Yao and Mr. XU Li is an Independent Third Party. Ningbo Hongyingkang and Ningbo Kangrui are two of our ESOP Platforms. For details of our ESOP Platforms, see “—Employee Incentive Platforms” in this section.

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Upon completion of the abovementioned capital increase on December 25, 2020, the shareholding structure of our Company was as follows:

Shareholder	Registered Capital (RMB)	Equity Interest
Ningbo Linfeng	16,618,649	30.75%
Mr. Lv	7,334,585	13.57%
Shanghai Shidi	3,732,000	6.91%
Ningbo Maishang	3,348,000	6.19%
Ningbo Hongyingkang	3,242,681	6.00%
Ningbo Kangrui	1,598,907	2.96%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>35,874,822</i>	<i>66.38%</i>
Suzhou New Phase 2 VC	5,736,740	10.61%
Hangzhou Proxima	2,102,090	3.89%
Suzhou Proxima	1,530,181	2.83%
Mr. LIU Ya	1,322,723	2.45%
TD Engineering	1,240,000	2.29%
Galaxy Yuanhui	1,003,000	1.86%
Suzhou Jingtian Medical	1,003,000	1.86%
Ms. SHEN Yao	938,708	1.74%
Shengshan Xingqian	918,108	1.70%
Ningbo Fuchuang	853,369	1.58%
Shengshan Huiying	668,000	1.24%
Mr. ZHU Jun	384,585	0.71%
Ms. YUAN Dan	281,613	0.52%
Mr. XU Li	187,742	0.35%
Total	54,044,681	100.00%

Series B Financing in 2021

On January 5, 2021, the following parties entered into equity transfer agreements, respectively, pursuant to which the following transfers of equity interest in our Company were conducted:

Transferor	Transferee	Registered Capital Transferred (RMB)	Corresponding Equity Interest in our Company	Consideration (RMB)
Suzhou New Phase 2 VC	Qingdao Marine Innovation Industry Investment Fund Co., Ltd. (青島海洋創新產 業投資基金有限公司) (“Qingdao Marine Innovation”)	317,113	0.59%	10,030,000

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<u>Transferor</u>	<u>Transferee</u>	<u>Registered Capital Transferred (RMB)</u>	<u>Corresponding Equity Interest in our Company</u>	<u>Consideration (RMB)</u>
Suzhou New Phase 2 VC	Shenzhen Furong No.1 Venture Capital Partnership (Limited Partnership) (深圳富鎔一號創業投資合夥企業(有限合夥)) (“ Shenzhen Furong ”)	126,845	0.23%	4,010,000
Suzhou New Phase 2 VC	Ningbo Tongshang Linfeng Equity Investment Partnership (Limited Partnership) (寧波通商麟豐股權投資合夥企業(有限合夥)) (“ Tongshang Linfeng ”)	632,102	1.17%	20,000,000
Suzhou New Phase 2 VC	FutureX Investment I Company Limited (“ FutureX ”)	887,918	1.64%	28,090,000
Suzhou New Phase 2 VC	Suzhou Proxima	190,268	0.35%	6,020,000
Suzhou New Phase 2 VC	Zhuhai Gao Ling Junheng Equity Investment L.P. (Limited Partnership) (珠海高瓴鈞恒股權投資合夥企業(有限合夥)) (“ Gao Ling Junheng ”)	374,160	0.69%	11,840,000
Ningbo Kangrui	Gao Ling Junheng	159,922	0.30%	5,060,000
Mr. Lv	Gao Ling Junheng	1,622,289	3.00%	51,330,000

The considerations for the equity transfers were determined after arm’s length negotiations between the relevant parties with reference to the then status of the business development of our Company and the then valuation of our Company, and taking into consideration the limited special rights attached to the existing registered capital purchased under the equity transfers, as compared to the special rights attached to the registered capital subscribed for as detailed below. For further details, see “—Pre-[REDACTED] Investments” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Further, concurrently with the abovementioned equity transfers and pursuant to the Shareholders’ resolutions dated January 5, 2021, the registered capital of our Company was increased from RMB54,044,681 to RMB59,551,834. Amongst the increased registered capital of RMB5,507,153, (i) Gao Ling Junheng subscribed for the increased registered capital of RMB2,894,843 at a consideration of RMB101,770,000, (ii) FutureX subscribed for the increased registered capital of RMB1,191,994 at a consideration of RMB41,910,000, (iii) Ningbo Tongshang Venture Capital Partnership (Limited Partnership) (寧波通商創業投資合夥企業(有限合夥)) (“**Tongshang VC**”) subscribed for the increased registered capital of RMB568,891 at a consideration of RMB20,000,000, (iv) Suzhou Proxima subscribed for the increased registered capital of RMB255,427 at a consideration of RMB8,980,000, (v) Shenzhen Furong subscribed for the increased registered capital of RMB170,285 at a consideration of RMB5,990,000 and (vi) Qingdao Marine Innovation subscribed for the increased registered capital of RMB425,713 at a consideration of RMB14,970,000 (together with the abovementioned equity transfers, “**Series B Financing**”). The considerations for the increased registered capital were determined after arm’s length negotiations between our Company and the relevant parties with reference to the then status of the business development of our Company and the then valuation of our Company. For further details, see “—Pre-[REDACTED] Investments” in this section.

Upon completion of Series B Financing on January 29, 2021, the shareholding structure of our Company was as follows:

Shareholder	Registered Capital (RMB)	Equity Interest
Ningbo Linfeng	16,618,649	27.91%
Mr. Lv	5,712,296	9.59%
Shanghai Shidi	3,732,000	6.27%
Ningbo Maishang	3,348,000	5.62%
Ningbo Hongyingkang	3,242,681	5.45%
Ningbo Kangrui	1,438,985	2.42%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>34,092,611</i>	<i>57.25%</i>
Gao Ling Junheng	5,051,214	8.48%
Suzhou New Phase 2 VC	3,208,334	5.39%
Hangzhou Proxima	2,102,090	3.53%
FutureX	2,079,912	3.49%
Suzhou Proxima	1,975,876	3.32%
Mr. LIU Ya	1,322,723	2.22%
TD Engineering	1,240,000	2.08%
Galaxy Yuanhui	1,003,000	1.68%
Suzhou Jingtian Medical	1,003,000	1.68%
Ms. SHEN Yao	938,708	1.58%
Shengshan Xingqian	918,108	1.54%
Ningbo Fuchuang	853,369	1.43%
Qingdao Marine Innovation	742,826	1.25%
Shengshan Huiying	668,000	1.12%
Tongshang Linfeng	632,102	1.06%
Tongshang VC	568,891	0.96%
Mr. ZHU Jun	384,585	0.65%
Shenzhen Furong	297,130	0.50%
Ms. YUAN Dan	281,613	0.47%
Mr. XU Li	187,742	0.32%
Total	59,551,834	100.00%

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Joint Stock Reform

Pursuant to the Shareholders’ resolutions dated June 15, 2021 and the Promoters’ agreement dated June 15, 2021, the then existing Shareholders of our Company agreed to convert our Company into a joint stock limited liability company with a registered capital of RMB228,000,000. According to the audit report of our Company upon joint stock reform prepared by Ernst & Young Hua Ming LLP, as of February 28, 2021, the net asset value of our Company amounted to RMB556,784,662.50, of which RMB228,000,000 has been converted into 228,000,000 Shares of a par value of RMB1.00 each and issued to the then Shareholders of our Company in proportion to their capital contribution to our Company, and the remaining amount of RMB328,784,662.50 was converted to capital reserve. Upon the completion of registration with the Shanghai Administration for Market Regulation (上海市市場監督管理局) on July 21, 2021, our Company was converted into a joint stock company with limited liability, and renamed as Cryofocus Medtech (Shanghai) Co., Ltd. (康禮生物科技(上海)股份有限公司).

Upon completion of the joint stock reform on July 21, 2021 and as of the Latest Practicable Date, the shareholding structure of our Company was as follows:

Shareholder	Number of Shares	Equity Interest
Ningbo Linfeng	63,626,136	27.91%
Mr. Lv	21,869,988	9.59%
Shanghai Shidi	14,288,532	6.27%
Ningbo Maishang	12,818,160	5.62%
Ningbo Hongyingkang	12,415,056	5.45%
Ningbo Kangrui	5,509,392	2.42%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>130,527,264</i>	<i>57.25%</i>
Gao Ling Junheng	19,338,960	8.48%
Suzhou New Phase 2 VC	12,283,500	5.39%
Hangzhou Proxima	8,047,944	3.53%
FutureX	7,963,128	3.49%
Suzhou Proxima	7,564,812	3.32%
Mr. LIU Ya	5,064,108	2.22%
TD Engineering	4,747,416	2.08%
Galaxy Yuanhui	3,839,976	1.68%
Suzhou Jingtian Medical	3,839,976	1.68%
Ms. SHEN Yao	3,593,964	1.58%
Shengshan Xingqian	3,515,076	1.54%
Ningbo Fuchuang	3,267,240	1.43%
Qingdao Marine Innovation	2,844,072	1.25%
Shengshan Huiying	2,557,476	1.12%
Tongshang Linfeng	2,419,992	1.06%
Tongshang VC	2,178,084	0.96%
Mr. ZHU Jun	1,472,424	0.65%
Shenzhen Furong	1,137,492	0.50%
Ms. YUAN Dan	1,078,212	0.47%
Mr. XU Li	718,884	0.32%
Total	228,000,000	100.00%

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REORGANIZATION

Incorporation of Ningbo SensCure and Early Shareholding Changes

Establishment of Ningbo SensCure

Ningbo SensCure was established in the PRC on September 28, 2011 with an initial registered capital of RMB100,000, and was wholly owned by Mr. YUAN Jiang (元江) (“**Mr. Yuan**”) (the chairman of the board of directors of Ningbo SensCure) upon its incorporation. Mr. Yuan is an entrepreneur based in Ningbo, the PRC. Mr. Yuan, Ms. Li and Mr. Lv are friends and they communicate from time to time on business management experience and potential investment opportunities. Upon preliminary communications of investment ideas among Mr. Yuan, Ms. Li and Mr. Lv, Ningbo SensCure was established as a shell company by Mr. Yuan using his personal fund at the time for the potential future business venture in the biomedical field without a concrete plan for any specific business segments or purposes at that time. At around similar time, Ms. Li also decided to establish an investment platform, Ningbo Linfeng, to cover potential investments in healthcare and technology industries with other minority shareholders, including Mr. Yuan who has been a founding minority shareholder of Ningbo Linfeng since November 2011.

Equity Transfer and Capital Increase in 2012

Shortly after the establishment of Ningbo SensCure, Ms. Li wanted to establish a subsidiary of Ningbo Linfeng to carry out the business activities later conducted by Ningbo SensCure. Upon discussing with Mr. Yuan on this business venture, both Ms. Li and Mr. Yuan agreed that (i) it would be quicker and more convenient for them to use Ningbo SensCure which at that time was still newly established with no actual business operation than establishing a new company, (ii) it suited Mr. Yuan’s investment strategy to hold indirect equity interests through Ningbo Linfeng instead of holding direct equity interests in Ningbo SensCure upon commencement of its business activities, and (iii) given Mr. Yuan’s business management experience, Mr. Yuan would remain as the chairman of the board of directors of Ningbo SensCure as a director appointed by Ningbo Linfeng to provide advice on overall business strategies and management of Ningbo SensCure. Under the applicable laws and regulations at the time, as compared to registration of an equity transfer, the establishment of a new company would take additional time as it required extra steps including: (1) applying for name verification and obtaining clearance for the proposed name; (2) opening bank account for capital verification and engaging professional third parties to verify capital and issue capital verification report; (3) providing address proof; and (4) undergoing other administrative steps such as obtaining a company seal and handling tax registration.

As a result, shortly after Ningbo SensCure had been established and pursuant to an equity transfer agreement entered into between Mr. Yuan and Ningbo Linfeng on January 5, 2012, Ningbo Linfeng acquired registered capital in Ningbo SensCure of RMB100,000 from Mr. Yuan at a consideration of RMB100,000. As advised by our PRC Legal Adviser, the historical arrangements, namely, the establishment of Ningbo SensCure by Mr. Yuan in September 2011 and the equity transfer of the entire registered capital in Ningbo SensCure from Mr. Yuan to Ningbo Linfeng, were in compliance with all applicable laws and regulations in the PRC. Further, concurrently with the abovementioned equity transfer and pursuant to the shareholder’s resolution of Ningbo SensCure dated January 5, 2012, the registered capital of Ningbo SensCure was increased from RMB100,000 to RMB5,000,000. Amongst the increased registered capital of RMB4,900,000, (i) Ningbo Linfeng subscribed for the increased registered capital of RMB2,575,000, (ii) Ms. SHEN Yao subscribed for the increased registered capital of

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RMB175,000, (iii) Ms. YUAN Dan subscribed for the increased registered capital of RMB75,000, (iv) Mr. YE Xuli (葉旭禮) subscribed for the increased registered capital of RMB1,425,000, (v) Mr. WANG Fengyong (王豐永) subscribed for the increased registered capital of RMB400,000 and (vi) Ms. LI Xizhen (李席珍) subscribed for the increased registered capital of RMB250,000, all at par value. Upon completion of the abovementioned equity transfer and capital increase on February 17, 2012, Ningbo SensCure was owned as to 53.50% by Ningbo Linfeng, 28.50% by Mr. YE Xuli, 8.00% by Mr. WANG Fengyong, 5.00% by Ms. LI Xizhen, 3.50% by Ms. SHEN Yao and 1.50% by Ms. YUAN Dan, respectively.

As of the Latest Practicable Date, Mr. Yuan held 2.5% equity interest in Ningbo Linfeng, and did not own (i) any interests in any member of our Group or (ii) any interests in any intellectual property used/owned by our Group.

Equity Transfer in 2013

Pursuant to an equity transfer agreement entered into between Mr. WANG Fengyong and Mr. YE Xuli on December 11, 2013, Mr. WANG Fengyong agreed to transfer registered capital in Ningbo SensCure of RMB400,000 to Mr. YE Xuli at a consideration of RMB400,000. Upon completion of such equity transfer on January 20, 2014, Ningbo SensCure was owned as to 53.50% by Ningbo Linfeng, 36.50% by Mr. YE Xuli, 5.00% by Ms. LI Xizhen, 3.50% by Ms. SHEN Yao and 1.50% by Ms. YUAN Dan, respectively.

Capital Increase and Equity Transfers in 2014

Pursuant to the shareholders' resolution of Ningbo SensCure dated June 3, 2014, the registered capital of Ningbo SensCure was increased from RMB5,000,000 to RMB10,000,000. Amongst the increased registered capital of RMB5,000,000, (i) Ningbo Linfeng subscribed for the increased registered capital of RMB2,675,000, (ii) Mr. YE Xuli subscribed for the increased registered capital of RMB1,825,000, (iii) Ms. LI Xizhen subscribed for the increased registered capital of RMB250,000, (iv) Ms. SHEN Yao subscribed for the increased registered capital of RMB175,000 and (v) Ms. YUAN Dan subscribed for the increased registered capital of RMB75,000, all at par value. Upon completion of the abovementioned capital increase on July 16, 2014, Ningbo SensCure was owned as to 53.50% by Ningbo Linfeng, 36.50% by Mr. YE Xuli, 5.00% by Ms. LI Xizhen, 3.50% by Ms. SHEN Yao and 1.50% by Ms. YUAN Dan, respectively.

On November 19, 2014, each of Ms. HE Tingting (何婷婷), Mr. ZHU Chunlin (朱春林) and Mr. HUANG Xilei (黃錫磊) entered into an equity transfer agreement with Ningbo Linfeng, pursuant to which Ningbo Linfeng agreed to transfer registered capital in Ningbo SensCure of (i) RMB100,000 to Ms. HE Tingting at a consideration of RMB100,000, (ii) RMB400,000 to Mr. ZHU Chunlin at a consideration of RMB400,000 and (iii) RMB100,000 to Mr. HUANG Xilei at a consideration of RMB100,000, respectively. On the same date, each of Mr. HUANG Xilei and Ningbo Dixiang entered into an equity transfer agreement with Mr. YE Xuli, pursuant to which Mr. YE Xuli agreed to transfer registered capital in Ningbo SensCure of (i) RMB100,000 to Mr. HUANG Xilei at a consideration of RMB100,000 and (ii) RMB3,550,000 to Ningbo Dixiang at a consideration of RMB3,550,000, respectively. Ningbo Dixiang is a limited company established in the PRC and is owned as to 98% by Mr. Lv. Upon completion of the abovementioned equity transfers on January 16, 2015, Ningbo SensCure was owned as to 47.50% by Ningbo Linfeng, 35.50% by Ningbo Dixiang, 5.00% by Ms. LI Xizhen, 4.00% by Mr. ZHU Chunlin, 3.50% by Ms. SHEN Yao, 2.00% by Mr. HUANG Xilei, 1.50% by Ms. YUAN Dan and 1.00% by Ms. HE Tingting, respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Equity Transfers and Capital Increase in 2015

On July 1, 2015, Mr. ZHU Chunlin entered into an equity transfer agreement with Ningbo Linfeng, pursuant to which Mr. ZHU Chunlin agreed to transfer registered capital in Ningbo SensCure of RMB300,000 to Ningbo Linfeng at a consideration of RMB300,000. On the same date, Mr. HUANG Xilei entered into an equity transfer agreement with Ningbo Dixiang, pursuant to which Mr. HUANG Xilei agreed to transfer registered capital in Ningbo SensCure of RMB200,000 to Ningbo Dixiang at a consideration of RMB200,000. Further, concurrently with the abovementioned equity transfers and pursuant to the shareholders’ resolution of Ningbo SensCure dated July 1, 2015, the registered capital of Ningbo SensCure was increased from RMB10,000,000 to RMB15,000,000. Amongst the increased registered capital of RMB5,000,000, (i) Ningbo Linfeng subscribed for the increased registered capital of RMB2,000,000, (ii) Ningbo Dixiang subscribed for the increased registered capital of RMB2,425,000, (iii) Ms. SHEN Yao subscribed for the increased registered capital of RMB400,000, (iv) Ms. YUAN Dan subscribed for the increased registered capital of RMB75,000, (v) Ms. HE Tingting subscribed for the increased registered capital of RMB50,000 and (vi) Mr. ZHU Chunlin subscribed for the increased registered capital of RMB50,000, all at par value. Upon completion of the abovementioned equity transfers and capital increase on August 4, 2015, Ningbo SensCure was owned as to 47.00% by Ningbo Linfeng, 41.17% by Ningbo Dixiang, 5.00% by Ms. SHEN Yao, 3.33% by Ms. LI Xizhen, 1.50% by Ms. YUAN Dan, 1.00% by Mr. ZHU Chunlin and 1.00% by Ms. HE Tingting, respectively.

Equity Transfers in 2017

On July 11, 2017, Ms. LI Xizhen entered into an equity transfer agreement with Ningbo Mukang Venture Capital L.P. (Limited Partnership) (寧波沐康創業投資合夥企業(有限合夥)) (formerly known as Ningbo Mukang Investment Management L.P. (Limited Partnership) (寧波沐康投資管理合夥企業(有限合夥))) (“**Ningbo Mukang**”), pursuant to which Ms. LI Xizhen agreed to transfer registered capital in Ningbo SensCure of RMB500,000 to Ningbo Mukang at a consideration of RMB500,000. On the same date, each of Ningbo Kangrui and Ningbo Mukang entered into an equity transfer agreement with Ningbo Dixiang, pursuant to which Ningbo Dixiang agreed to transfer registered capital in Ningbo SensCure of (i) RMB2,250,000 to Ningbo Kangrui at a consideration of RMB2,250,000 and (ii) RMB3,925,000 to Ningbo Mukang at a consideration of RMB3,925,000, respectively. Ningbo Mukang is a limited partnership established in the PRC and is indirectly controlled by Mr. Lv who controls the sole general partner of Ningbo Mukang. Upon completion of the abovementioned equity transfers on August 8, 2017, Ningbo SensCure was owned as to 47.00% by Ningbo Linfeng, 29.50% by Ningbo Mukang, 15.00% by Ningbo Kangrui, 5.00% by Ms. SHEN Yao, 1.50% by Ms. YUAN Dan, 1.00% by Mr. ZHU Chunlin and 1.00% by Ms. HE Tingting, respectively.

Ningbo SensCure Series Pre-A Financing in 2017

On December 6, 2017, each of Mr. ZHU Chunlin and Ningbo Mukang entered into an equity transfer agreement with Mr. LIU Ya (劉亞), pursuant to which Mr. ZHU Chunlin agreed to transfer registered capital in Ningbo SensCure of RMB150,000 to Mr. LIU Ya at a consideration of RMB2,340,000 and Ningbo Mukang agreed to transfer registered capital in Ningbo SensCure of RMB225,000 to Mr. LIU Ya at a consideration of RMB3,510,000 (collectively, “**Ningbo SensCure Series Pre-A Financing**”). The considerations for the equity transfers were determined after arm’s length negotiations between the relevant parties with reference to the then status of the business development of Ningbo SensCure and the then valuation of Ningbo SensCure, and taking into consideration the limited special rights attached to the existing registered capital purchased under the equity transfers, as compared

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to the special rights attached to the registered capital subscribed for in Ningbo SensCure Series A Financing as detailed below. For further details, see “—Pre-[REDACTED] Investments” in this section. Upon completion of the abovementioned equity transfers on January 16, 2018, Ningbo SensCure was owned as to 47.00% by Ningbo Linfeng, 28.00% by Ningbo Mukang, 15.00% by Ningbo Kangrui, 5.00% by Ms. SHEN Yao, 2.50% by Mr. LIU Ya, 1.50% by Ms. YUAN Dan and 1.00% by Ms. HE Tingting, respectively.

Ningbo SensCure Series A Financing in 2018

Pursuant to the shareholders’ resolution of Ningbo SensCure dated March 21, 2018, the registered capital of Ningbo SensCure was increased from RMB15,000,000 to RMB17,307,692. Amongst the increased registered capital of RMB2,307,692, (i) Suzhou New Phase 2 VC subscribed for the increased registered capital of RMB1,153,846 at a consideration of RMB20,000,000, (ii) Ningbo Fuchuang subscribed for the increased registered capital of RMB576,923 at a consideration of RMB10,000,000 and (iii) Mr. LIU Ya subscribed for the increased registered capital of RMB576,923 at a consideration of RMB10,000,000 (collectively, “**Ningbo SensCure Series A Financing**”). The considerations for the increased registered capital were determined after arm’s length negotiations between Ningbo SensCure and relevant parties with reference to the then status of the business development of Ningbo SensCure and the then valuation of Ningbo SensCure. For further details, see “—Pre-[REDACTED] Investments” in this section. Upon completion of the abovementioned capital increase on April 13, 2018, Ningbo SensCure was owned as to 40.73% by Ningbo Linfeng, 24.27% by Ningbo Mukang, 13.00% by Ningbo Kangrui, 6.67% by Suzhou New Phase 2 VC, 5.50% by Mr. LIU Ya, 4.33% by Ms. SHEN Yao, 3.33% by Ningbo Fuchuang, 1.30% by Ms. YUAN Dan and 0.87% by Ms. HE Tingting, respectively.

Equity Transfer in 2018

Pursuant to an equity transfer agreement entered into between Ms. HE Tingting and Mr. XU Li on July 2, 2018, Ms. HE Tingting agreed to transfer registered capital in Ningbo SensCure of RMB150,000 to Mr. XU Li at a consideration of RMB150,000. Mr. XU Li is the spouse of Ms. HE Tingting. Upon completion of such equity transfer on October 29, 2018, Ningbo SensCure was owned as to 40.73% by Ningbo Linfeng, 24.27% by Ningbo Mukang, 13.00% by Ningbo Kangrui, 6.67% by Suzhou New Phase 2 VC, 5.50% by Mr. LIU Ya, 4.33% by Ms. SHEN Yao, 3.33% by Ningbo Fuchuang, 1.30% by Ms. YUAN Dan and 0.87% by Mr. XU Li, respectively.

Equity Transfers in 2019

On April 19, 2019, the following parties entered into equity transfer agreements, respectively, pursuant to which the following transfers of equity interest in Ningbo SensCure were conducted:

<u>Transferor</u>	<u>Transferee</u>	<u>Registered Capital Transferred (RMB)</u>	<u>Consideration (RMB)</u>
Ningbo Linfeng	Suzhou New Phase 2 VC	166,864	0
Ningbo Mukang	Suzhou New Phase 2 VC	10,651	0
Ningbo Mukang	Ningbo Fuchuang	88,757	0
Ms. SHEN Yao	Mr. LIU Ya	17,751	0
Ningbo Kangrui	Mr. LIU Ya	53,255	0
Ms. YUAN Dan	Mr. LIU Ya	5,325	0
Mr. XU Li	Mr. LIU Ya	3,550	0

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The abovementioned equity transfers were conducted in accordance with the valuation adjustment provision contained in the shareholders’ agreement entered into by Ningbo SensCure and its then shareholders on February 23, 2018 following Ningbo SensCure Series A Financing. Upon completion of the abovementioned equity transfers on May 14, 2019, Ningbo SensCure was owned as to 39.77% by Ningbo Linfeng, 23.69% by Ningbo Mukang, 12.69% by Ningbo Kangrui, 7.69% by Suzhou New Phase 2 VC, 5.96% by Mr. LIU Ya, 4.23% by Ms. SHEN Yao, 3.85% by Ningbo Fuchuang, 1.27% by Ms. YUAN Dan and 0.85% by Mr. XU Li, respectively.

Ningbo SensCure Series A+ Financing in 2019

Pursuant to the shareholders’ resolution of Ningbo SensCure dated May 15, 2019, the registered capital of Ningbo SensCure was increased from RMB17,307,692 to RMB18,620,689. Amongst the increased registered capital of RMB1,312,997, (i) Hangzhou Proxima subscribed for the increased registered capital of RMB596,817 at a consideration of RMB10,000,000 and (ii) Shengshan Xingqian subscribed for the increased registered capital of RMB716,180 at a consideration of RMB12,000,000 (collectively, “**Ningbo SensCure Series A+ Financing**”). The considerations for the increased registered capital were determined after arm’s length negotiations between Ningbo SensCure and relevant parties with reference to the then status of the business development of Ningbo SensCure and the then valuation of Ningbo SensCure. For further details, see “—Pre-[REDACTED] Investments” in this section. Upon completion of the abovementioned capital increase on May 24, 2019, Ningbo SensCure was owned as to 36.97% by Ningbo Linfeng, 22.02% by Ningbo Mukang, 11.80% by Ningbo Kangrui, 7.15% by Suzhou New Phase 2 VC, 5.54% by Mr. LIU Ya, 3.93% by Ms. SHEN Yao, 3.85% by Shengshan Xingqian, 3.58% by Ningbo Fuchuang, 3.21% by Hangzhou Proxima, 1.18% by Ms. YUAN Dan and 0.79% by Mr. XU Li, respectively.

Ningbo SensCure Series A++ Financing in 2019

Pursuant to the shareholders’ resolution of Ningbo SensCure dated July 5, 2019, the registered capital of Ningbo SensCure was increased from RMB18,620,689 to RMB19,814,323. Suzhou Proxima subscribed for the increased registered capital of RMB1,193,634 at a consideration of RMB20,000,000 (“**Ningbo SensCure Series A++ Financing**”). The consideration for the increased registered capital was determined after arm’s length negotiations between Ningbo SensCure and Suzhou Proxima with reference to the then status of the business development of Ningbo SensCure and the then valuation of Ningbo SensCure. For further details, see “—Pre-[REDACTED] Investments” in this section. Upon completion of the abovementioned capital increase on September 2, 2019, Ningbo SensCure was owned as to 34.74% by Ningbo Linfeng, 20.70% by Ningbo Mukang, 11.09% by Ningbo Kangrui, 6.72% by Suzhou New Phase 2 VC, 6.02% by Suzhou Proxima, 5.21% by Mr. LIU Ya, 3.70% by Ms. SHEN Yao, 3.61% by Shengshan Xingqian, 3.36% by Ningbo Fuchuang, 3.01% by Hangzhou Proxima, 1.11% by Ms. YUAN Dan and 0.74% by Mr. XU Li, respectively.

Equity Transfers in 2020

Pursuant to an equity transfer agreement entered into between Ningbo Mukang and Ningbo Linfeng on September 2, 2020, Ningbo Mukang agreed to transfer registered capital in Ningbo SensCure of RMB990,716 to Ningbo Linfeng at a consideration of RMB990,716. Upon completion of such equity transfer on September 8, 2020, Ningbo SensCure was owned as to 39.74% by Ningbo Linfeng, 15.70% by Ningbo Mukang, 11.09% by Ningbo Kangrui, 6.72% by Suzhou New Phase 2 VC, 6.02% by Suzhou Proxima, 5.21% by Mr. LIU Ya, 3.70% by Ms. SHEN Yao, 3.61% by Shengshan Xingqian, 3.36% by Ningbo Fuchuang, 3.01% by Hangzhou Proxima, 1.11% by Ms. YUAN Dan and 0.74% by Mr. XU Li, respectively.

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On October 15, 2020, each of Ningbo Linfeng and Mr. ZHU Jun entered into an equity transfer agreement with Ningbo Kangrui, pursuant to which Ningbo Kangrui agreed to transfer registered capital in Ningbo SensCure of (i) RMB549,750 to Ningbo Linfeng at a consideration of RMB1,023,503 and (ii) RMB150,000 to Mr. ZHU Jun at a consideration of RMB279,255. On the same date, each of Mr. ZHU Jun and Mr. Lv entered into an equity transfer agreement with Ningbo Mukang, pursuant to which Ningbo Mukang agreed to transfer registered capital in Ningbo SensCure of (i) RMB150,000 to Mr. ZHU Jun at a consideration of RMB279,255 and (ii) RMB2,959,876 to Mr. Lv at a consideration of RMB5,510,610. Upon completion of the abovementioned equity transfers on November 23, 2020, Ningbo SensCure was owned as to 42.51% by Ningbo Linfeng, 14.94% by Mr. Lv, 7.56% by Ningbo Kangrui, 6.72% by Suzhou New Phase 2 VC, 6.02% by Suzhou Proxima, 5.21% by Mr. LIU Ya, 3.70% by Ms. SHEN Yao, 3.61% by Shengshan Xingqian, 3.36% by Ningbo Fuchuang, 3.01% by Hangzhou Proxima, 1.51% by Mr. ZHU Jun, 1.11% by Ms. YUAN Dan and 0.74% by Mr. XU Li, respectively.

Pursuant to an equity transfer agreement entered into between Ningbo Kangrui and Mr. Lv on November 24, 2020, Ningbo Kangrui agreed to transfer registered capital in Ningbo SensCure of RMB249,750 to Mr. Lv at a consideration of RMB465,415. Upon completion of such equity transfer on November 23, 2020, Ningbo SensCure was owned as to 42.51% by Ningbo Linfeng, 16.20% by Mr. Lv, 6.72% by Suzhou New Phase 2 VC, 6.29% by Ningbo Kangrui, 6.02% by Suzhou Proxima, 5.21% by Mr. LIU Ya, 3.70% by Ms. SHEN Yao, 3.61% by Shengshan Xingqian, 3.36% by Ningbo Fuchuang, 3.01% by Hangzhou Proxima, 1.51% by Mr. ZHU Jun, 1.11% by Ms. YUAN Dan and 0.74% by Mr. XU Li, respectively.

Shareholding Structure Immediately Prior to the Equity Swap

After the abovementioned increases in and subscription for registered capital and equity transfers, immediately prior to the Equity Swap, the shareholding structure of Ningbo SensCure was as follows:

Shareholder of Ningbo SensCure	Registered Capital of Ningbo SensCure (RMB)	Equity Interest in Ningbo SensCure
Ningbo Linfeng	8,423,602	42.51%
Mr. Lv	3,209,626	16.20%
Ningbo Kangrui	1,247,245	6.29%
<i>Subtotal of interests held/controlled by the Concert Parties</i>	<i>12,880,473</i>	<i>65.01%</i>
Suzhou New Phase 2 VC	1,331,361	6.72%
Suzhou Proxima	1,193,634	6.02%
Mr. LIU Ya	1,031,804	5.21%
Ms. SHEN Yao	732,249	3.70%
Shengshan Xingqian	716,180	3.61%
Ningbo Fuchuang	665,680	3.36%
Hangzhou Proxima	596,817	3.01%
Mr. ZHU Jun	300,000	1.51%
Ms. YUAN Dan	219,675	1.11%
Mr. XU Li	146,450	0.74%
Total	19,814,323	100.00%

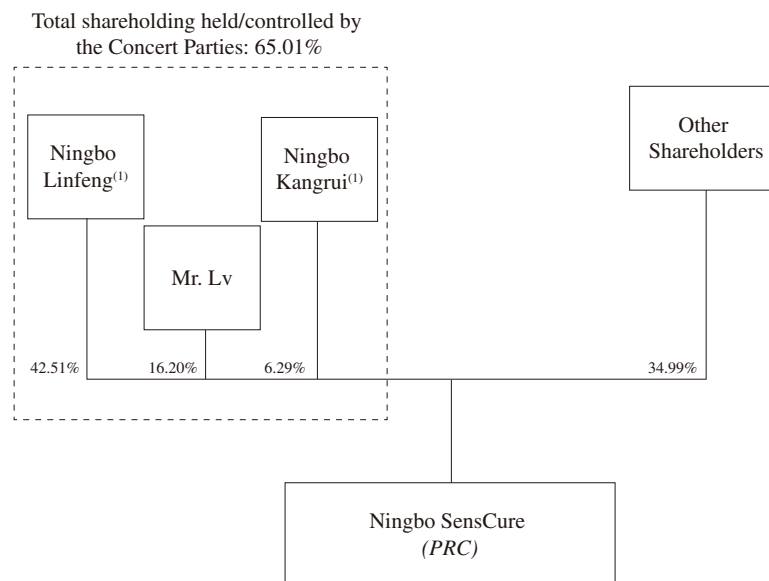
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Equity Swap

Throughout the Track Record Period, our Company was held as to more than 50% by the Concert Parties (through the interests held by Ningbo Linfeng, Mr. Lv, Shanghai Shidi, Ningbo Maishang, Ningbo Hongyingkang and/or Ningbo Kangrui). For details of the shareholding changes in our Company, see “—Corporate Development” in this section. On the other hand, at the beginning of the Track Record Period, Ningbo SensCure was held as to 66.52% by the Concert Parties (through the interests held by Ningbo Linfeng, Ningbo Mukang and Ningbo Kangrui). Throughout the period from the beginning of the Track Record Period to the date immediately prior to the Equity Swap, Ningbo SensCure was held as to more than 50% by the Concert Parties (through the interests held by Ningbo Linfeng, Ningbo Mukang, Ningbo Kangrui and/or Mr. Lv). For details of the shareholding changes in Ningbo SensCure, see “—Reorganization — Incorporation of Ningbo SensCure and Early Shareholding Changes” in this section.

For reasons stated in “Reasons for the Equity Swap” below, the equity interests in Ningbo SensCure (as detailed in “Shareholding Structure Immediately Prior to the Equity Swap” above) were acquired by our Company in return for subscription of equity interests in our Company by all the then existing shareholders of Ningbo SensCure in a proportion of approximately RMB1 registered capital of Ningbo SensCure to approximately RMB1.28 registered capital of our Company (the “**Equity Swap**”). The conversion ratio was determined after arm’s length negotiations with reference to (i) the registered capital of our Company and that of Ningbo SensCure immediately prior to the Equity Swap, and (ii) the valuation of our Company and that of Ningbo SensCure as reflected in the valuation reports issued by an independent valuer.

A simplified corporate structure of Ningbo SensCure immediately prior to the Equity Swap was as follows:

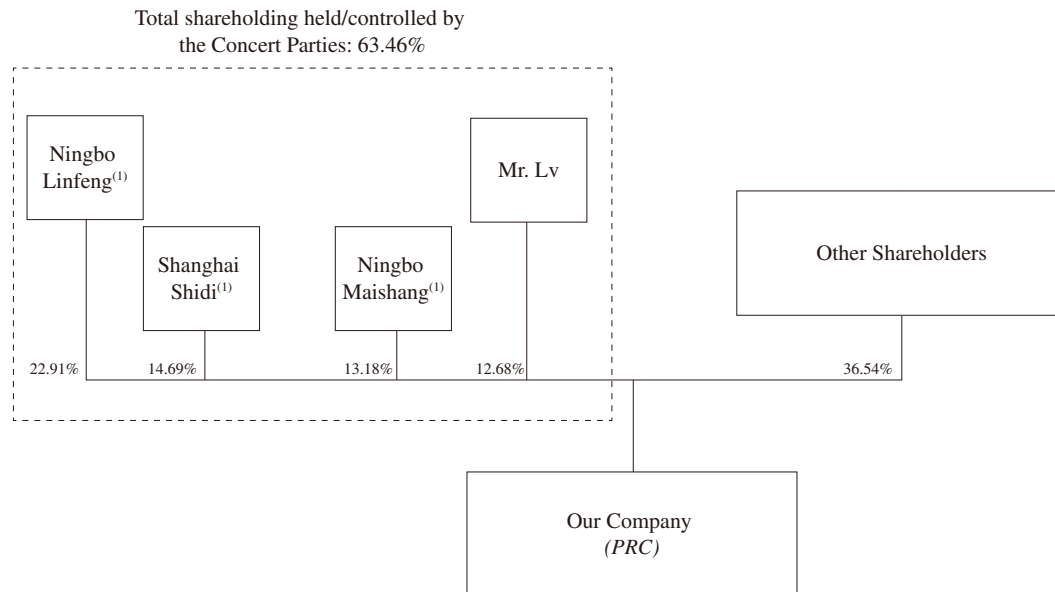


Note:

- (1) Ningbo Linfeng and Ningbo Kangrui are entities controlled by the Concert Parties. For further details of the concert party arrangement, see “—Concert Party Arrangement” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

A simplified corporate structure of our Company immediately prior to the Equity Swap was as follows:



Note:

- (1) Shanghai Shidi, Ningbo Linfeng and Ningbo Maishang are entities controlled by the Concert Parties. For further details of the concert party arrangement, see “—Concert Party Arrangement” in this section.

Capital Increase and Subscription in Our Company

Pursuant to the Board resolutions dated December 1, 2020, the registered capital of our Company was increased from RMB25,401,000 to RMB54,044,681. Among the increased registered capital of RMB28,643,681, all the then existing shareholders of Ningbo SensCure immediately prior to the Equity Swap, namely, Ningbo Linfeng, Mr. Lv, Suzhou New Phase 2 VC, Hangzhou Proxima, Ningbo Kangrui, Suzhou Proxima, Mr. LIU Ya, Ms. SHEN Yao, Shengshan Xingqian, Ningbo Fuchuang, Mr. ZHU Jun, Ms. YUAN Dan and Mr. XU Li (collectively, “**Equity Swap Shareholders**”), subscribed for the increased registered capital of RMB10,798,649, RMB4,114,585, RMB1,706,740, RMB765,090, RMB1,598,907, RMB1,530,181, RMB1,322,723, RMB938,708, RMB918,108, RMB853,369, RMB384,585, RMB281,613 and RMB187,742, respectively, with each in return having transferred their respective equity interests in Ningbo SensCure to our Company as described below. The capital increase and subscription was completed on December 25, 2020.

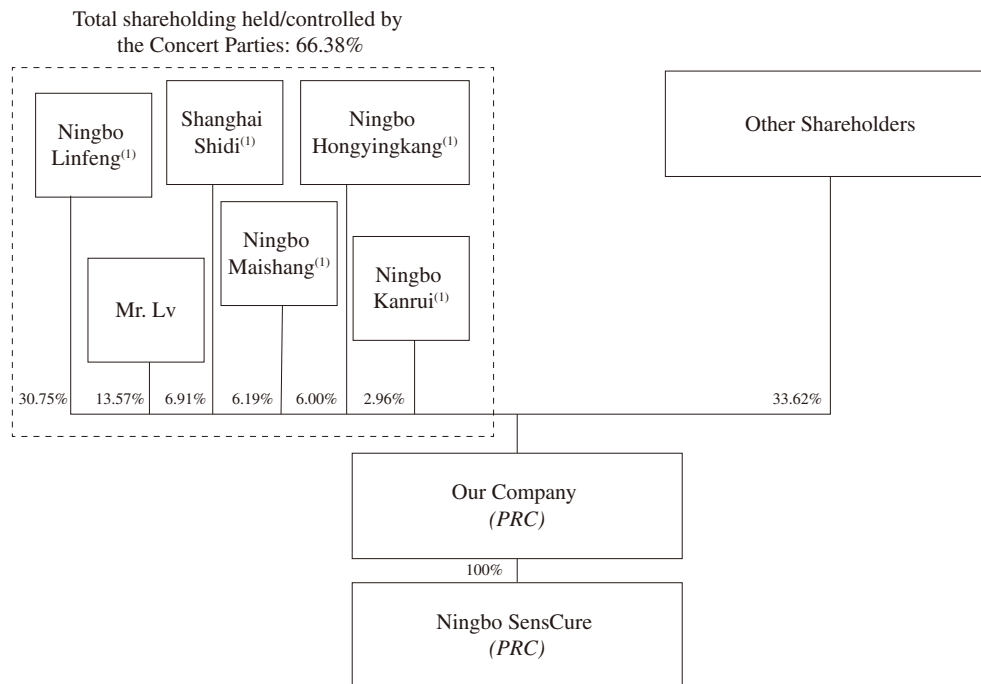
Equity Transfers at Ningbo SensCure

Pursuant to the respective equity transfer agreements dated November 30, 2020 entered into by our Company and each of the Equity Swap Shareholders, each of the Equity Swap Shareholders transferred the registered capital of Ningbo SensCure held by each of them which represented the entire equity interests in Ningbo SensCure held by them (as detailed in “Shareholding Structure Immediately Prior to the Equity Swap” above) to our Company, in return for their subscription of equity interests in our Company as described above.

Upon completion of the equity transfers on December 25, 2020, Ningbo SensCure became a wholly-owned subsidiary of our Company under merger accounting.

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Upon completion of the Equity Swap and the capital subscription by Ningbo Hongyingkang (as detailed in “Capital Increase Pursuant to Equity Swap and Subscription by Ningbo Hongyingkang” in this section), our simplified corporate structure was as follows:



Note:

- (1) Shanghai Shidi, Ningbo Linfeng, Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui are entities controlled by the Concert Parties. For further details of the concert party arrangement, see “—Concert Party Arrangement” in this section.

Reasons for the Equity Swap

Given that both our Company and Ningbo SensCure were held as to more than 30% by the Concert Parties and Ningbo SensCure had been consolidated into our Group by way of business combination under common control throughout the Track Record Period under merger accounting, the Equity Swap was conducted in order to (i) integrate the businesses of our Company and Ningbo SensCure which focuses on cryoablation minimally-invasive treatments; (ii) restructure the corporate structures of our Company and Ningbo SensCure for us to become an integrated medical device platform for cryoablation minimally-invasive treatment; and (iii) restructure the interests of the Concert Parties.

Upon and subsequent to the Equity Swap, the respective functions in the day-to-day management of both companies were consolidated. Our Directors are of the view that the integration was beneficial to the Group, given the cost and operational efficiencies generated from unified business processes, centralized procurement and manufacturing, and sharing of working relationships with physicians and hospitals within the Group. Accordingly, as a result of the Equity Swap, there was considerable integration of the day-to-day management of the businesses of our Company and Ningbo SensCure.

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We expect that the synergetic effects resulting from the restructuring of the businesses of our Company and Ningbo SensCure would help save costs and improve operational efficiency, mitigate significant uncertainties and risks involved in the development of innovative medical devices, and help us expand our product portfolio and expedite our product iteration. For further details, see “Business— Our Competitive Strengths” in this document.

Our PRC Legal Adviser has confirmed that the capital increase and equity transfers in respect of our Company and Ningbo SensCure, and the Equity Swap as described above have been properly and legally completed and all regulatory approvals have been obtained in accordance with PRC laws and regulations.

CONCERT PARTY ARRANGEMENT

Pursuant to a concert party agreement dated April 26, 2021 entered into by Ms. Li and Mr. Lv, the Concert Parties confirmed that they have been acting in concert in exercising Shareholders’ rights pertaining to our Group (including our Company and Ningbo SensCure) since January 1, 2014, and they have agreed to continue to act in concert and reach consensus on proposals related to the daily management and operation of our Group presented to general meetings of the Shareholders of our Company for voting. As of the Latest Practicable Date, the Concert Parties were entitled to exercise voting rights of approximately 57.25% voting rights in our Company. In particular, Ms. Li was able to exercise approximately 47.66% voting rights in our Company through (i) Ningbo Linfeng as to 27.91%, (ii) Shanghai Shidi as to 6.27%, (iii) Ningbo Maishang as to 5.62%, (iv) Ningbo Hongyingkang as to 5.45% and (v) Ningbo Kangrui as to 2.42%. As of the Latest Practicable Date, Ningbo Linfeng was owned as to 65% by Shanghai Shidi which was in turn wholly owned by Ms. Li. Further, as of the Latest Practicable Date, Ms. Li controlled the executive partner of each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui, namely, Shidi Biotechnology. Shidi Biotechnology is entitled to exercise the voting power held by each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui in our Company pursuant to their respective partnership agreements. As of the Latest Practicable Date, Mr. Lv was able to exercise approximately 9.59% voting rights in our Company through his personal capacity. For further details relating to Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui, see “—Employee Incentive Platforms” in this section.

EMPLOYEE INCENTIVE PLATFORMS

In recognition of the contributions of our employees and to incentivize them to further promote our development, Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui were established in the PRC as our employee incentive platforms.

Ningbo Maishang

Ningbo Maishang Investment L.P. (Limited Partnership) (寧波脈尚投資合夥企業(有限合夥)), which was established in the PRC on February 9, 2017, is managed by its executive partner, Shidi Biotechnology. Shidi Biotechnology is a wholly-owned subsidiary of Ningbo Linfeng which is a non-wholly owned subsidiary of Shanghai Shidi which is in turn wholly owned by Ms. Li. As of the Latest Practicable Date, Ningbo Maishang had 26 limited partners, including Mr. ZHU Jun (朱軍) (our executive Director), Mr. Lv (our non-executive Director), Ms. LI Cuiqin (李翠琴) (our Supervisor), Mr. QIU Junkang (邱軍康) (our Supervisor), Mr. DIAO Yuepeng (刁月鵬) (our senior management), Dr. ZHAO Kuiwen (趙奎文) (our senior management), Mr. LIU Yulong (劉玉龍) (our senior management), 18 employees of our Group and Ms. YUAN Dan (袁丹) (“**Ms. Yuan**”), and directly held approximately 5.62% equity interest in our Company. As of the Latest Practicable Date, Ms. Yuan beneficially held approximately 1.67% partnership interests in Ningbo Maishang.

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Ningbo Hongyingkang

Ningbo Hongyingkang Enterprise Management Partnership (Limited Partnership) (寧波弘盈康企業管理合夥企業(有限合夥)), which was established in the PRC on November 23, 2020, is managed by its executive partner, Shidi Biotechnology. Shidi Biotechnology is a wholly-owned subsidiary of Ningbo Linfeng which is a non-wholly owned subsidiary of Shanghai Shidi which is in turn wholly owned by Ms. Li. As of the Latest Practicable Date, Ningbo Hongyingkang had five limited partners, including Ms. Li, Mr. ZHU Jun (朱軍) (our executive Director), Mr. LIU Wei (劉偉) (our senior management) and two employees of our Group, and directly held approximately 5.45% equity interest in our Company.

Ningbo Kangrui

Ningbo Kangrui Investment Management Partnership (Limited Partnership) (寧波康銳投資管理合夥企業(有限合夥)), which was established in the PRC on July 5, 2017, is managed by its executive partner, Shidi Biotechnology. Shidi Biotechnology is a wholly-owned subsidiary of Ningbo Linfeng which is a non-wholly owned subsidiary of Shanghai Shidi which is in turn wholly owned by Ms. Li. As of the Latest Practicable Date, Ningbo Kangrui had 24 limited partners, including Mr. Lv (our non-executive Director), Mr. CHEN Zhimin (陳智敏) (our senior management), 21 employees of our Group and Mr. TANG Hao (唐皓) (“**Mr. Tang**”), and directly held approximately 2.42% equity interest in our Company. As of the Latest Practicable Date, Mr. Tang beneficially held approximately 6.67% partnership interests in Ningbo Kangrui.

In respect of the partnership interests held by Ms. Yuan in Ningbo Maishang and the partnership interests held by Mr. Tang in Ningbo Kangrui, Ms. Yuan was first acquainted with Mr. Lv in 2005 when they both worked at Lifetech Scientific (Shenzhen) Co., Ltd. (先健科技(深圳)有限公司) whereas Mr. Tang was first acquainted with Mr. Lv in 2014 when he worked at Ningbo Linfeng which was a shareholder of Jenscare Scientific Co., Ltd. (寧波健世科技股份有限公司) where Mr. Lv served as, among other roles, the general manager. Each of them has later provided Mr. Lv with valuable assistance and support in relation to administrative and financial matters for companies controlled by Mr. Lv at their respective early stage of development. To recognize and compensate for such assistance and support, Mr. Lv, upon separate mutual discussions with Ms. Yuan and Mr. Tang, agreed to transfer certain of his beneficially-owned partnership interests in Ningbo Maishang and Ningbo Kangrui to Ms. Yuan and Mr. Tang in July 2019 and February 2019, respectively, at nil consideration (collectively, the “**Transfers**”). As advised by the PRC Legal Adviser, (i) the Transfers are genuine, valid and effective, (ii) the Transfers complied with all applicable PRC laws and regulations and the respective partnership agreements governing Ningbo Maishang and Ningbo Kangrui, and (iii) there were no special arrangements including nominee shareholding arrangements in respect of the Transfers.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

PRE-[REDACTED] INVESTMENTS

The Pre-[REDACTED] Investments include: (i) Series A Financing; (ii) Ningbo SensCure Series Pre-A Financing; (iii) Ningbo SensCure Series A Financing; (iv) Series A+ Financing; (v) Ningbo SensCure Series A+ Financing; (vi) Series A++ Financing; (vii) Ningbo SensCure Series A++ Financing; and (viii) Series B Financing.

	Ningbo SensCure							
	Series A Financing	Ningbo SensCure Series Pre-A Financing	Ningbo SensCure Series A Financing	Series A+ Financing	Ningbo SensCure Series A+ Financing	Series A++ Financing	Ningbo SensCure Series A++ Financing	Series B Financing
Pre-[REDACTED] Investors	Suzhou New Phase 2 VC	Mr. LIUYa (劉亞)	Suzhou New Phase 2 VC, Ningbo Fuchuang and Mr. LIUYa	Hangzhou Proxima, Galaxy Yuanhui and Shengshan Huiying	Hangzhou Proxima and Shengshan Xingqian	Suzhou Jingtian Medical	Suzhou Proxima	Qingdao Marine Innovation, Shenzhen Furong, Tongshang Linfeng, FutureX, Suzhou Proxima, Gao Ling Junheng, and Tongshang VC
Date of agreement	December 5, 2017	December 6, 2017	February 23, 2018	November 19, 2018	April 22, 2019	May 7, 2019	June 28, 2019	January 5, 2021
Date of which investment was fully settled	January 15, 2018	March 16, 2018	May 28, 2018	February 15, 2019	June 18, 2019	June 3, 2019	September 12, 2019	March 11, 2021

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	Ningbo SensCure Series Pre-A Financing		Ningbo SensCure Series A Financing		Ningbo SensCure Series A+ Financing		Ningbo SensCure Series A++ Financing		Ningbo SensCure Series A++ Financing		Series B Financing			
Approximate cost per share paid	Series A Financing	RMB3.18 ⁽²⁾	Series A Financing	RMB3.53 ⁽²⁾	Series A+ Financing	RMB3.91 ⁽¹⁾	Series A+ Financing	RMB3.41 ⁽²⁾	Series A++ Financing	RMB3.91 ⁽¹⁾	Series A++ Financing	RMB3.41 ⁽²⁾	Series B Financing	(i) Equity transfers of existing registered capital: RMB8.26 ⁽¹⁾
		(i) Equity transfer of existing registered capital: RMB2.11 ⁽¹⁾												(ii) Subscriptions for new registered capital: RMB9.18 ⁽¹⁾
Discount to the [REDACTED] (in a approximation)⁽³⁾		[REDACTED]%		[REDACTED]%		[REDACTED]%		[REDACTED]%		[REDACTED]%		[REDACTED]%		(i) Equity transfers of existing registered capital: [REDACTED]%
		(ii) Subscription for new registered capital: [REDACTED]%												(ii) Subscriptions for new registered capital: [REDACTED]%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	Ningbo SensCure Series Pre-A Financing		Ningbo SensCure Series A Financing		Ningbo SensCure Series A+ Financing		Ningbo SensCure Series A++ Financing		Ningbo SensCure Series A++ Financing		Series B Financing	
Amount of registered capital subscribed for/purchased⁽⁴⁾	RMB4,030,000 (among which RMB1,240,000 were subscribed for by the relevant Pre-[REDACTED] Investors and RMB2,790,000 were purchased by the relevant Pre-[REDACTED] Investor from the then existing shareholder)	RMB375,000	RMB2,307,692	RMB3,008,000	RMB1,312,997	RMB1,003,000	RMB1,193,634	RMB9,817,770 (among which RMB5,507,153 were subscribed for by the relevant Pre-[REDACTED] Investors and RMB4,310,617 were purchased by the relevant Pre-[REDACTED] Investors from the then existing shareholders)				
Amount of consideration paid⁽⁴⁾	RMB40 million (among which RMB30 million has been invested in our Company as registered capital and capital reserve and RMB10 million was paid pursuant to the equity transfer agreement)	RMB5.85 million (all of which was paid pursuant to the equity transfer agreements)	RMB40 million (all of which has been invested in Ningbo SensCure as registered capital and capital reserve)	RMB45 million (all of which has been invested in our Company as registered capital and capital reserve)	RMB22 million (all of which has been invested in Ningbo SensCure as registered capital and capital reserve)	RMB15 million (all of which has been invested in our Company as registered capital and capital reserve)	RMB20 million (all of which has been invested in Ningbo SensCure as registered capital and capital reserve)	RMB330 million (among which RMB193.62 million has been invested in our Company as registered capital and capital reserve and RMB136.38 million was paid pursuant to the equity transfer agreements)				

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	Ningbo SensCure Series Pre-A Financing		Ningbo SensCure Series A Financing		Ningbo SensCure Series A+ Financing		Ningbo SensCure Series A++ Financing		Ningbo SensCure Series A++ Financing		Series B Financing	
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Post-money valuation of our Company or Ningbo SensCure (as the case may be)⁽⁵⁾

Approximately RMB230 million	Approximately RMB234 million	Approximately RMB300 million	Approximately RMB365 million	Approximately RMB312 million	Approximately RMB380 million	Approximately RMB332 million	Approximately RMB2,093 million
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Lock-up Period

Subject to a lock-up period of 12 months following the [REDACTED] pursuant to the PRC Company Law.

Use of proceeds from the Pre-[REDACTED] Investments

As of the Latest Practicable Date, all of the net proceeds from the Pre-[REDACTED] Investors were used to support the R&D activities of our Group, including the R&D activities conducted for our Core Products, as well as to support the working capital needs of our Group.

Strategic benefits of the Pre-[REDACTED] Investors brought to our Company

At the time of the Pre-[REDACTED] Investments, our Directors were of the view that our Company could benefit from the additional capital that would be provided by the Pre-[REDACTED] Investors' investments in our Company and the Pre-[REDACTED] Investors' knowledge and experience. Further, Mr. SUN Xiaolu (孫曉璐), our non-executive Director, represents certain of our Pre-[REDACTED] Investors and he complements our executive Directors to support good corporate governance.

Notes:

- (1) Calculated based on the amount of consideration paid divided by the number of Shares as adjusted after joint stock reform.
- (2) Calculated based on the total consideration paid by relevant parties for equity interests in Ningbo SensCure divided by the number of Shares converted from the equity interests in our Company exchanged for such equity interests in Ningbo SensCure pursuant to the Equity Swap, as adjusted after joint stock reform.
- (3) Calculated based on the currency translation of HK\$1 to RMB0.91304 and on the [REDACTED] of HK\$[REDACTED].
- (4) For details relating to the registered capital of our Company and/or Ningbo SensCure subscribed for by or transferred to each Pre-[REDACTED] Investor and the corresponding consideration paid by each Pre-[REDACTED] Investor for each round of the Pre-[REDACTED] Investments, see “— Corporate Development” and “— Reorganization” in this section.
- (5) As further detailed in “— Corporate Development” in this section with respect to the background of our Company's establishment, the technology pertaining to liquid nitrogen cryotherapy owned by Mr. Thach Buu DUONG has been applied to our Group's vascular interventional cryotherapy products and product candidates and NOTES interventional cryotherapy products and product candidates, including our Bladder Cryoablation System and AF Cryoablation System. Prior to Series A Financing in December 2017, our Company primarily focused on the application of such technology in the cardiovascular field, in particular, the R&D of our Cryo-RDN System. Our Company started the R&D of our Cryo-RDN System since our establishment in March 2013 and commenced a multi-center feasibility clinical trial in China in June 2015, which was completed in July 2018.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

The increase in valuation from Series A Financing to Series A+ Financing was mainly because we completed the feasibility clinical trial of our Cryo-RDN System in July 2018.

The increase in valuation from Ningbo SensCure Series Pre-A Financing to Ningbo SensCure Series A+ Financing was mainly because (i) we obtained the NMPA registration certificate for our Pulmonary Nodule Localization Needle in March 2019 and (ii) more than half of the total subjects had been enrolled for the multi-center clinical trial for our Bladder Cryoablation System by April 2019.

The increase in valuation from Series A++ Financing to Series B Financing was mainly because (i) we commenced a confirmatory clinical trial in China for our Cryo-RDN System in July 2019, (ii) our AF Cryoablation System was admitted into the Green Path for Innovative Medical Devices by the NMPA in August 2019, (iii) we completed all the subject enrollment for the clinical trial for our AF Cryoablation System in December 2020, and (iv) we completed the Equity Swap in December 2020 as a result of which Ningbo SensCure became a wholly-owned subsidiary of our Company under merger accounting and the business developments of Ningbo SensCure from Ningbo SensCure Series A++ Financing in June 2019 to Series B Financing in January 2021 were taken into consideration when the valuation of our Company for Series B Financing was determined. In particular, (a) the pre-clinical product testing for our Endoscopic Clip for Anastomosis was completed in November 2019, (b) our Endoscopic Clip for Anastomosis was admitted into the Green Path for Innovative Medical Devices by the Zhejiang MPA in November 2019, (c) the first patient was enrolled for the multi-center clinical trial for our Endoscopic Clip for Anastomosis in June 2020, (d) a single-center, open-label and single-arm feasibility clinical trial for our Gastric Cryoablation System was initiated in July 2020, (e) approvals from relevant ethical committees of relevant hospitals for our Asthma Cryoablation System and Malignant Stenosis Cryoablation System were obtained in August 2020 and November 2020, respectively, (f) more than half of the total subjects had been enrolled for the single-center feasibility clinical trial for our Gastric Cryoablation System by December 2020, (g) follow-up visits with all the enrolled subjects for the multi-center clinical trial of our Bladder Cryoablation System had been completed by December 2020, and (h) more than 30% of the total subjects had been enrolled for the multi-center clinical trial for our Anti-Gastroesophageal Reflux System by December 2020.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Reasons for the Increase in our Company’s Valuation from Series B Financing to the Proposed [REDACTED] Valuation

Calculated on the [REDACTED] of HK\$[REDACTED], the valuation of our Company upon [REDACTED] will be approximately HK\$[REDACTED] million (the “**Proposed [REDACTED] Valuation**”).

The increase in the Proposed [REDACTED] Valuation from Series B Financing is because our Company has achieved several major milestones in respect of our products since Series B Financing, including (i) submission of the registration application with the NMPA for our Bladder Cryoablation System in May 2021, (ii) completion of the clinical trial and submission of the registration application with the Zhejiang MPA for our Endoscopic Clip for Anastomosis in November 2021, (iii) completion of multi-center clinical trial for our AF Cryoablation System in May 2022, (iv) obtaining of the NMPA approval for commercialization of our Bladder Cryoablation System in June 2022, (v) submission of the registration application with the NMPA for our AF Cryoablation System in July 2022 and (vi) obtaining of the Zhejiang MPA approval for commercialization of our Endoscopic Clip for Anastomosis in August 2022.

These milestones, especially those achieved in relation to our Core Products, have significantly reduced the development risks in relation to our Core Products and other pipeline products and increased the probability of success (“**POS**”), which in turn boosts our Company’s valuation. POS reflects the likelihood of the products being approved and the attainability of future cash flow, and is an important parameter for risk-adjusted discounted cash flow valuation.

Rights of the Pre-[REDACTED] Investors

The Pre-[REDACTED] Investors were granted customary special rights, including but not limited to divestment right, right of first refusal and tag-along rights, veto right, director/supervisor appointment right and anti-dilution right. Pursuant to an agreement entered into between, among others, our Company and the Pre-[REDACTED] Investors dated September 28, 2021, the divestment right, veto right and anti-dilution right were automatically terminated, and all other special rights were automatically terminated on December 27, 2021.

Information About Our Pre-[REDACTED] Investors

Information of our Pre-[REDACTED] Investors are as set out below. To the best knowledge of our Directors, save as disclosed below, each of our Pre-[REDACTED] Investors and their respective general partner and limited partners (as applicable) is an Independent Third Party and none of these Pre-[REDACTED] Investors has any relationship with any other Pre-[REDACTED] Investors.

1. **Zhuhai Gao Ling:** Zhuhai Gao Ling Junheng Equity Investment L.P. (Limited Partnership) (珠海高瓴鈞恒股權投資合夥企業(有限合夥)) is a limited partnership established in the PRC, the general partner of which is Shenzhen Gao Ling Tiancheng III Investment Co., Ltd. (深圳高瓴天成三期投資有限公司), and the limited partner investors of which are private equity funds managed by Zhuhai Gao Ling Equity Investment Management Co., Ltd. (珠海高瓴股權投資管理有限公司) (“**Zhuhai Gao Ling**”), a limited liability company established in the PRC. Zhuhai Gao Ling is a sophisticated investor. As of the Latest Practicable Date, the assets under Zhuhai Gao Ling’s management exceeded HK\$1 billion. Shenzhen Gao Ling Tiancheng III Investment Co., Ltd. is jointly held by ZHANG Haiyan, MA Cuifang, CAO Wei, LI Liang and ZHU Jia. Zhuhai Gao Ling partners with exceptional entrepreneurs and management teams to create value with a focus on enacting innovation and technological transformation.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

2. **Suzhou New Phase 2 VC:** Suzhou Industrial Park New Phase 2 Venture Capital Enterprise (Limited Partnership) (蘇州工業園區新建元二期創業投資企業(有限合夥)) is a limited partnership established in the PRC and is managed by its general partner, Suzhou YuanBio Private Equity Fund Management Partnership Enterprise (Limited Partnership) (蘇州元生私募基金管理合夥企業(有限合夥)) (formerly known as Suzhou Industrial Park YuanFu Venture Capital Management Partnership Enterprise (Limited Partnership) (蘇州工業園區元福創業投資管理企業(有限合夥)) which is ultimately controlled by Mr. CHEN Jie (陳杰). As of the Latest Practicable Date, Suzhou New Phase 2 VC had 42 limited partners, with the two largest limited partners each holding approximately 14.71% partnership interests. Suzhou New Phase 2 VC is an investment fund established by YuanBio Venture Capital (元生創投) which focuses on early and growth stage life science and healthcare investments. YuanBio Venture Capital is a sophisticated investor. As of June 30, 2022, YuanBio Venture Capital had total assets under management of over RMB5 billion and its investment portfolio has included nearly 100 companies across biopharmaceuticals, medical technology, in vitro diagnostic medical device and health services sectors, including Suzhou Nanomicro Technology Company Limited (蘇州納微科技股份有限公司) (a company listed on the Shanghai Stock Exchange; stock code: 688690) and Shenzhen YHLO Biotech Co., Ltd. (深圳市亞輝龍生物科技股份有限公司) (a company listed on the Shanghai Stock Exchange; stock code: 688575).
3. **Proxima Ventures:** Each of Hangzhou Proxima Innovative Investment L.P. (Limited Partnership) (杭州比鄰星創新投資合夥企業(有限合夥)) and Suzhou Proxima Venture Investment L.P. (Limited Partnership) (蘇州比鄰星創業投資合夥企業(有限合夥)) is a limited partnership established in the PRC and is managed by its general partner, Hangzhou Proxima Innovative Investment Management L.P. (Limited Partnership) (杭州比鄰星創新投資管理合夥企業(有限合夥)) which is ultimately controlled by Mr. SUN Xiaolu (孫曉路), our non-executive Director. As of the Latest Practicable Date, Hangzhou Proxima had 25 limited partners, with the largest limited partner holding approximately 13.00% partnership interests whereas Suzhou Proxima had 28 limited partners, with the largest limited partner holding approximately 10.61% partnership interests. Hangzhou Proxima and Suzhou Proxima are investment arms of Proxima Ventures (比鄰星創投) which focuses on the healthcare industry to support outstanding enterprises with innovative technologies that have tremendous potential. Proxima Ventures is a sophisticated investor. As of June 30, 2022, Proxima Ventures had total assets under management of approximately RMB2.2 billion and its investment portfolio has included over 40 companies across medical device, diagnostics, biotechnology, pharmaceutical and healthcare services sectors, including Jiangsu B. H. Med Co., Ltd. (江蘇海萊新創醫療科技有限公司), AccuMedical Medical Device (Beijing) Ltd. (艾柯醫療器械(北京)有限公司), Hangzhou Matridx Biotechnology Co Ltd (杭州杰毅生物技術有限公司) and Beijing Biosis Healing Biological Technology Co., Ltd (北京博輝瑞進生物科技股份有限公司).
4. **FutureX:** FutureX Investment I Company Limited is a limited company incorporated in Hong Kong and is wholly owned by FutureX ICT Opportunity Fund II LP (the "Fund"). The general partner of the Fund is FutureX Innovation II Limited, a limited company incorporated in the Cayman Islands, which holds 100% partnership interests in the Fund and is in turn indirectly wholly owned by Ms. ZHANG Qian (張倩). The Fund has invested in other medical technology companies such as Jenscare Scientific Co., Ltd. (寧波健世科技股份有限公司).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

5. **Mr. LIU Ya (劉亞):** Mr. LIU Ya is an individual investor with investments in several healthcare companies, such as Guangzhou LBP Medicine Science & Technology Co., Ltd. (廣州安必平醫藥科技股份有限公司) and Shenzhen Raycome Health Technology Co., Ltd (深圳瑞光康泰科技有限公司). He became acquainted with Ms. Li through his relative.
6. **Galaxy Yuanhui:** Galaxy Yuanhui Investment Co., Ltd (銀河源匯投資有限公司) is a limited company incorporated in the PRC with registered capital of RMB3 billion, and is wholly owned by China Galaxy Securities Co., Ltd. (中國銀河證券股份有限公司) which is listed on the Hong Kong Stock Exchange (stock code: 6881) and the Shanghai Stock Exchange (stock code: 601881). As of June 30, 2022, Galaxy Yuanhui had total assets under management of approximately RMB3.6 billion. The main scope of its business includes equity investments by using internal funds or establishing direct investment funds. In respect of equity investments, its investment portfolio includes Trina Solar Co., Ltd. (天合光能股份有限公司) (a company listed on the Shanghai Stock Exchange; stock code: 688599) and Hangzhou Bioer Technology Co., Ltd (杭州博日科技股份有限公司).
7. **Suzhou Jingtian Medical:** Suzhou Jingtian Medical Investment Partnership (Limited Partnership) (蘇州景天醫療投資合夥企業(有限合夥)) is a limited partnership established in the PRC and is managed by its general partner, Suzhou Qiaojing Investment Management Consulting Co., Ltd. (蘇州喬景投資管理諮詢有限公司) which is ultimately controlled by Mr. JIN Dan (金澹). As of the Latest Practicable Date, Suzhou Jingtian Medical had 11 limited partners, with the largest limited partner holding approximately 24.35% partnership interests. Suzhou Jingtian Medical is an investment arm of Qiaojing Capital (喬景資本) which had total assets under management of approximately RMB800 million as of June 30, 2022, and has focused on investments in medical and consumer industries, including Allgens Medical Science & Technology Co., Ltd. (奧精醫療科技股份有限公司) (a company listed on the Shanghai Stock Exchange; stock code: 688613), Leto Laboratories Co., Ltd. (北京志道生物科技有限公司) and Xiamen Spacegen Co., Ltd. (廈門飛朔生物科技有限公司).
8. **Shengshan Xingqian and Shengshan Huiying:** Shanghai Shengshan Xingqian Venture Capital Center (Limited Partnership) (上海盛山興錢創業投資中心(有限合夥)) is a limited partnership established in the PRC and is managed by its general partner, Shengshan Asset Management (Shanghai) Co., Ltd. (盛山資產管理(上海)有限公司) which is owned as to 51% by Mr. GAN Shixiong (甘世雄). As of the Latest Practicable Date, Shengshan Xingqian had three limited partners, with the largest limited partner holding approximately 10.09% partnership interests. Suzhou Shengshan Huiying Venture Capital Enterprise (Limited Partnership) (蘇州盛山惠贏創業投資企業(有限合夥)) is a limited partnership established in the PRC and is managed by its general partner, Suzhou Shengshan Chuanghe Venture Capital Center (Limited Partnership) (蘇州盛山創禾創業投資中心(有限合夥)) whose general partner is Shengshan Asset Management (Shanghai) Co., Ltd. As of the Latest Practicable Date, Shengshan Huiying had 18 limited partners, with the largest limited partner holding approximately 15.46% partnership interests. Shengshan Asset Management (Shanghai) Co., Ltd. had total assets under management of over RMB1.2 billion as of June 30, 2022, and has focused on investments in biotechnology, medical technology and healthcare services industries in China, including Viva Biotech Holdings (a company listed on the Hong Kong Stock Exchange; stock code: 1873) and Obio Technology (Shanghai) Corp., Ltd. (和元生物技術(上海)股份有限公司) (a company listed on the Shanghai Stock Exchange; stock code: 688238).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

9. **Ningbo Fuchuang:** Ningbo Fuchuang Innovation and Venture Capital Center (Limited Partnership) (寧波復創創新創業投資中心(有限合夥)) is a limited partnership established in the PRC and is managed by its general partner, Ningbo Fudan Venture Capital Co., Ltd. (寧波復旦創業投資有限公司) (formerly known as Ningbo Fudan Innovation Center Co., Ltd. (寧波復旦創新中心有限公司)) which is owned as to 40%, 30% and 30% by Shanghai Funing Investment Co., Ltd. (上海復寧投資有限公司), Ningbo Hangzhou Bay New Area Emerging Industry Venture Capital Co., Ltd. (寧波杭州灣新區新興產業創業投資有限公司) and Ningbo Hangzhou Bay New Area Qingyun Enterprise Management Partnership (Limited Partnership) (寧波杭州灣新區卿雲企業管理合夥企業(有限合夥)), respectively. As of the Latest Practicable Date, Ningbo Haifan Technology Development Co., Ltd. (寧波海帆科技發展有限公司) held approximately 99.00% partnership interests in Ningbo Fuchuang as its sole limited partner. Ningbo Fudan Venture Capital Co., Ltd. (寧波復旦創業投資有限公司) has invested in technology companies, including Ningbo Shangcai Sanwei Technology Co., Ltd. (寧波尚材三維科技有限公司) and Ningbo Ruochuang Nanotechnology Co., Ltd. (寧波柔創納米科技有限公司).
10. **Qingdao Marine Innovation:** Qingdao Marine Innovation Industry Investment Fund Co., Ltd. (青島海洋創新產業投資基金有限公司) is a limited company incorporated in the PRC and is owned as to 52.50% by Qingdao Conson Financial Holdings Co., Ltd. (青島國信金融控股有限公司) which is ultimately controlled by State-Owned Assets Supervision & Administration Commission of Qingdao Municipal Government (青島市人民政府國有資產監督管理委員會).
11. **Tongshang Linfeng and Tongshang VC:** Ningbo Tongshang Linfeng Equity Investment Partnership (Limited Partnership) (寧波通商麟豐股權投資合夥企業(有限合夥)) is a limited partnership established in the PRC whose general partners are Ningbo Tongshang Fund Management Co., Ltd. (寧波通商基金管理有限公司) (“**Tongshang Fund Management**”) and Ningbo Ruifeng Enterprise Management Co., Ltd. (寧波瑞豐企業管理有限公司). As a general partner and the manager of Tongshang Linfeng, Tongshang Fund Management is responsible for the management and operation of Tongshang Linfeng. Ningbo Tongshang Venture Capital Partnership (Limited Partnership) (寧波通商創業投資合夥企業(有限合夥)) is a limited partnership established in the PRC and is managed by its general partner, Tongshang Fund Management. Tongshang Fund Management is ultimately controlled by State-Owned Assets Supervision & Administration Commission of Ningbo Municipal Government (寧波市人民政府國有資產監督管理委員會). Ningbo Ruifeng Enterprise Management Co., Ltd. is a wholly-owned subsidiary of Ningbo Linfeng, one of our Controlling Shareholders. As of the Latest Practicable Date, Tongshang Linfeng had two limited partners (including Ningbo Linfeng) each holding approximately 49.02% partnership interests whereas Tongshang VC had one limited partner holding approximately 99.90% partnership interests.
12. **Shenzhen Furong:** Shenzhen Furong No.1 Venture Capital Partnership (Limited Partnership) (深圳富鎔一號創業投資合夥企業(有限合夥)) is a limited partnership established in the PRC and is managed by its general partner, Qianhai Furong (Shenzhen) Investment Management Co., Ltd. (前海富鎔(深圳)投資管理有限公司) which is jointly owned by Ms. LI Liping (李麗萍), Mr. LIN Hongqiang (林宏強), Mr. YUAN Dan (袁丹), Ms. ZHAO Yanni (趙燕泥), Ms. LI Siying (李思穎), Mr. REN Zhigang (任志剛) and Ms. ZHANG Wei (張威), each holding less than 30% equity interests. As of the Latest Practicable Date, Shenzhen Furong had 11 limited partners with the largest limited partner holding approximately 26.80% partnership interests. As of June 30, 2022, Shenzhen Furong had total assets under management of approximately RMB400 million. Shenzhen Furong has invested in technology companies, including Elevoc Technology Company Limited (大象聲科(深圳)科技有限公司), Shenzhen Trustworthy Huacheng Communication Technology Co., Ltd. (深圳市可信華成通信科技有限公司) and Dongguan Xionglin New Material Technology Co., Ltd. (東莞市雄林新材料科技股份有限公司).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Compliance With Interim Guidance and Guidance Letters

The Joint Sponsors confirm that the investments by the Pre-[REDACTED] Investors are in compliance with the Guidance Letter HKEX-GL29-12 issued in January 2012 and updated in March 2017 by the Stock Exchange, the Guidance Letter HKEX-GL43-12 issued in October 2012 and updated in July 2013 and in March 2017 by the Stock Exchange and the Guidance Letter HKEX-GL44-12 issued in October 2012 and updated in March 2017 by the Stock Exchange.

[REDACTED]

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

[REDACTED]

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

[REDACTED]

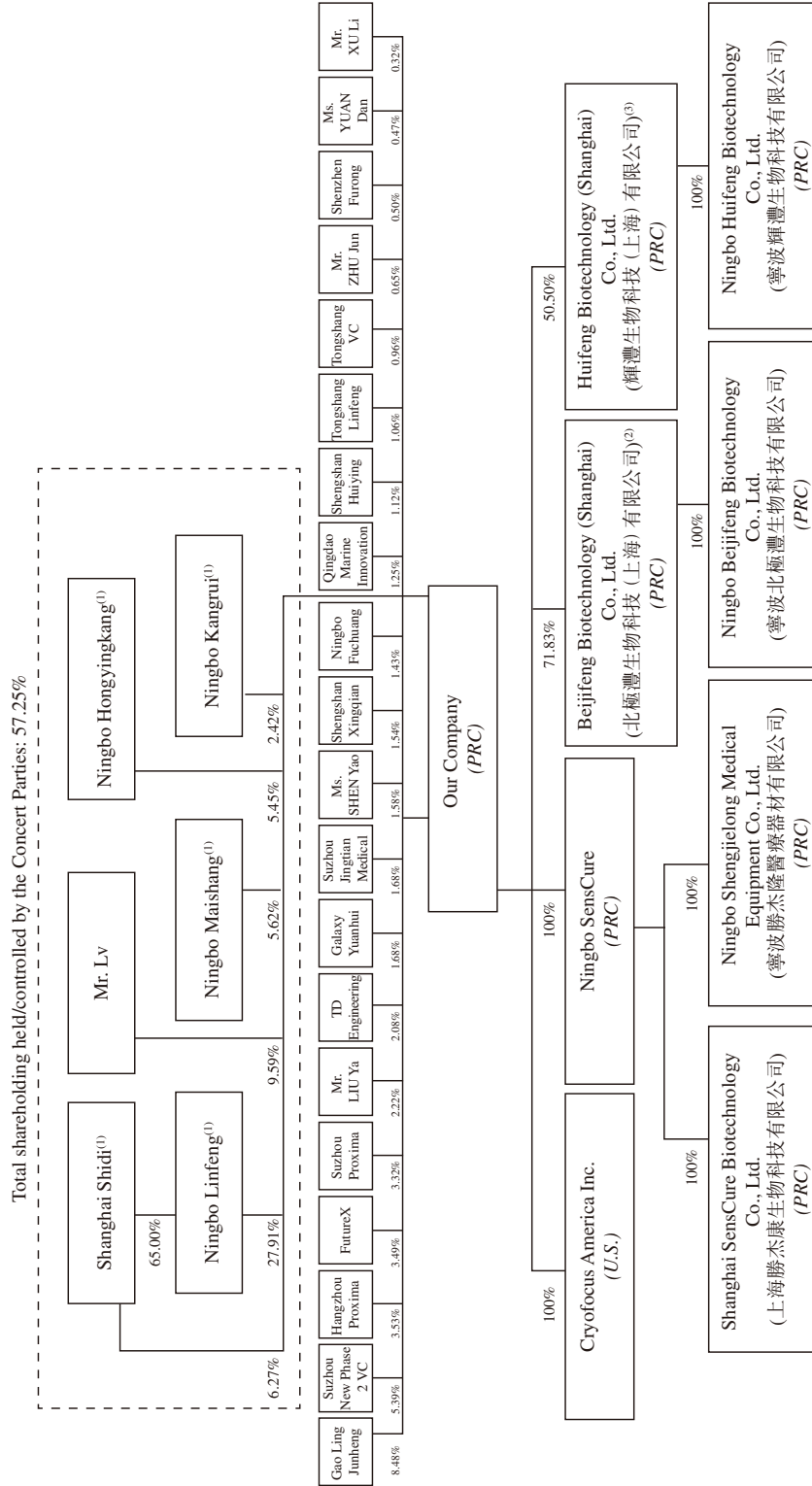
HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

[REDACTED]

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR STRUCTURE IMMEDIATELY PRIOR TO THE [REDACTED]

The following chart sets forth our Group’s corporate structure immediately prior to the completion of the [REDACTED].



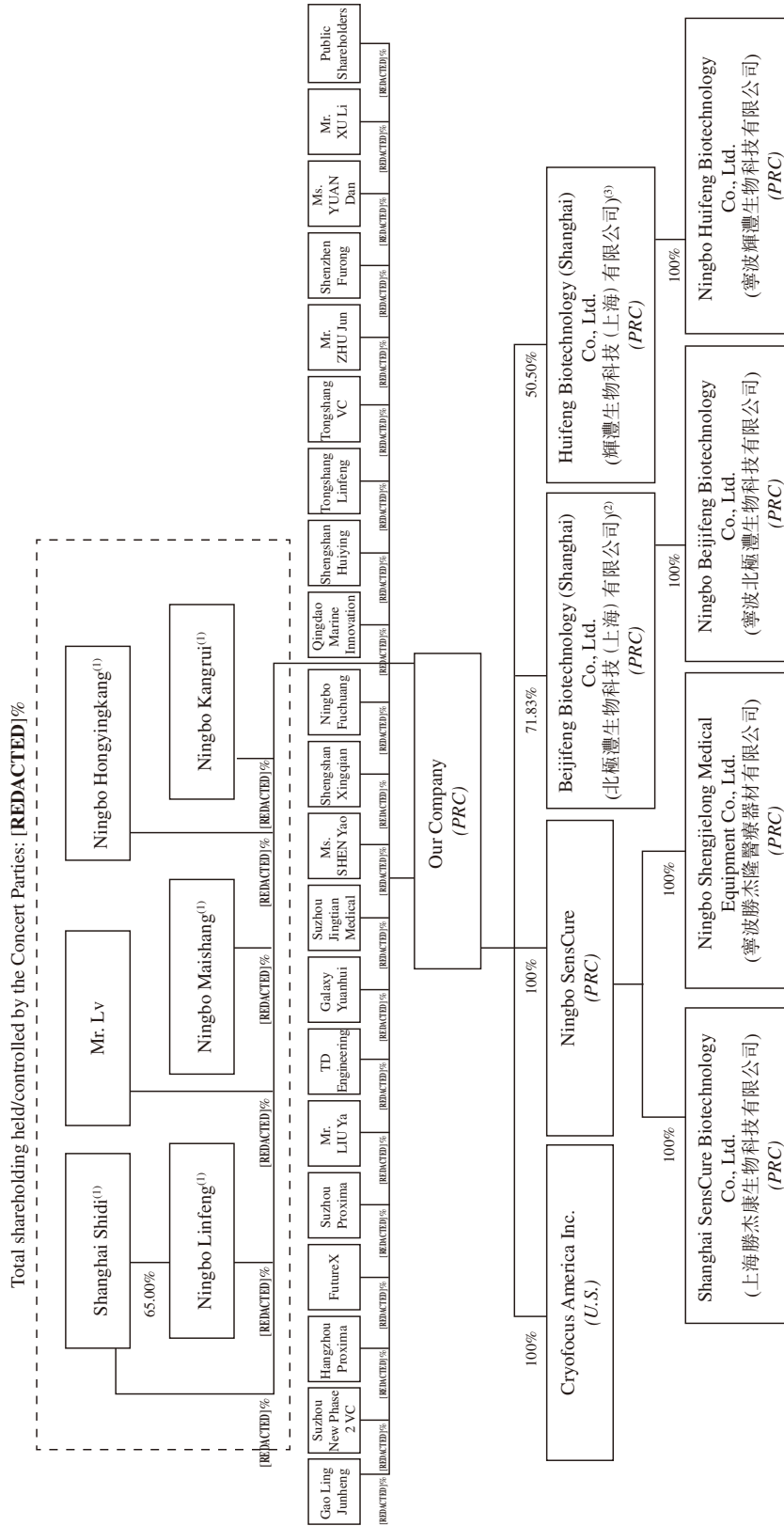
Notes:

- (1) Shanghai Shidi, Ningbo Linfeng, Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui are entities controlled by the Concert Parties. For further details of the concert party arrangement, see “—Concert Party Arrangement” in this section.
- (2) As of the Latest Practicable Date, Beijingfeng Biotechnology (Shanghai) Co., Ltd. (北極豐生物科技(上海)有限公司) was owned as to 71.83% by our Company and 28.17% by Mr. DIAO Yuepeng (刁月鹏), our senior management.
- (3) As of the Latest Practicable Date, Huifeng Biotechnology (Shanghai) Co., Ltd. (輝豐生物科技(上海)有限公司) was owned as to 50.50% by our Company and 49.50% by Mr. DIAO Yuepeng (刁月鹏), our senior management.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR STRUCTURE IMMEDIATELY FOLLOWING THE [REDACTED]

The following chart sets forth our Group’s corporate structure immediately after the [REDACTED].



Notes: See the notes to “Our Structure Immediately Prior to the [REDACTED]” in this section.

BUSINESS

OVERVIEW

Founded in 2013, we are a medical device company in China with a main focus on the field of minimally-invasive interventional cryotherapy. We have two Core Products, the Bladder Cryoablation System (膀胱冷凍消融系統) and the Endoscopic Clip for Anastomosis (內鏡吻合夾). The Bladder Cryoablation System is a cryotherapy device designed for the treatment of bladder cancer approved for commercialization in China. The Endoscopic Clip for Anastomosis is an anastomotic device for closure of soft tissue in digestive tract, which is one of over-the-scope clips (“**OTS Clips**”) approved for commercialization in China. Leveraging our liquid nitrogen cryoablation technology, we have developed a comprehensive product portfolio mainly focusing on two therapeutic areas: (i) natural orifice transluminal endoscopic surgery, or NOTES, for the treatment of urinary, respiratory, and digestive diseases (e.g., bladder cancer, chronic obstructive pulmonary disease, asthma, airway stenosis, gastric cancer, and esophageal cancer); and (ii) vascular interventional therapy for the treatment of atrial fibrillation, hypertension and other cardiovascular diseases. Our product pipeline includes a variety of cryotherapy systems and surgical consumables, and four of them, including two Core Products, the Atrial Fibrillation Cryoablation System (心臟冷凍消融系統) (“**AF Cryoablation System**”) that is in the process of registration application and the Cryofocus Renal Denervation System (Cryofocus 冷凍消融系統) (“**Cryo-RDN System**”) that is still in the clinical trial stage, were recognized as “innovative medical devices” by the NMPA or its provincial counterparts. Our Core Products, the Bladder Cryoablation System (膀胱冷凍消融系統) and the Endoscopic Clip for Anastomosis (內鏡吻合夾), have demonstrated good efficacy and safety profiles in their respective clinical trials. We believe our competitive advantages, technologies and product pipeline helped us establish high entry barriers difficult for our competitors to surpass.

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The following diagram summarizes the status of our products and product candidates as of the Latest Practicable Date:

Core Products	Product/Product Candidates	Indications/Clinical Applications	NMPA Classification	Development Stage			Expected/Actual Time of Completion of the Current Stage	Expected/Actual Time of Approval for Commercialization
				Pre-Clinical	Clinical	Registration and Approval		
NOTES Interventional Cryotherapy Product Non-Cryotherapy Product	Bladder Cryoablation System (膀胱冷凍消融系統) ¹⁾	Non-muscle-invasive bladder tumors	III			Jun-22	Jun-22	
	Endoscopic Clip for Anastomosis (內臟吻合夾) ²⁾	Closure treatment of soft tissues	II			Aug-22	Aug-22	
Other Products and Product Candidates								
NOTES Vascular Interventional Cryotherapy Products and Product Candidates Cancer Intervention NOTES Interventional Cryotherapy Products and Product Candidates	AF Cryoablation System (心臟冷凍消融系統) ³⁾	Paroxysmal atrial fibrillation	III			2Q23	2Q23	
	Cryo-RDN System (Cryofocus 冷凍消融系統)	Resistant hypertension	III			3Q24	2H25	
	Pulmonary Hypertension Cryoablation System (肺動脈高壓冷凍消融系統)	Pulmonary hypertension	III			2Q23	1H26	
	Gastric Cryoablation System (胃部冷凍消融系統)	Gastric tumors	III			2H25	2H26	
	Esophageal Cryospray System (食道冷凍噴霧治療系統)	Intermediate to advanced esophagus cancer	III			2H25	1H27	
	COPD Cryospray System (慢阻肺冷凍噴霧治療系統)	COPD with chronic bronchitis	III			2H25	2H26	
	Asthma Cryoablation System (哮喘冷凍消融系統)	Moderate and severe asthma	III			2H25	2H26	
	Malignant Stenosis Cryoablation System (惡性狹窄冷凍消融系統)	Malignant airway stenosis	III			3Q23	4Q24	
	Benign Stenosis Cryoablation System (良性狹窄冷凍消融系統)	Benign airway lesion	III			4Q24	1H26	
	Peri-Pulmonary Nodule Cryoablation System (肺周結節冷凍消融系統)	Peri-pulmonary nodules	III			2Q23	2H27	
NOTES Non-Cryotherapy Products and Product Candidates	Cough Cryospray System (咳嗽冷凍噴霧治療系統)	Chronic cough	III			1H25	2H26	
	Tuberculosis Cryospray System (結核冷凍噴霧治療系統)	Tracheobronchial tuberculosis	III			2H25	2H26	
	Cryoablation System (冷凍結核治療系統)	Biopsy, stenosis recanalization and foreign body retrieval	III			4Q22	1Q24	
	Atrial Fibrillation Pulsed Field Ablation System (房顫脈衝電場消融 (PFA) 系統)	Paroxysmal atrial fibrillation	III			2Q23	1H26	
	Avic Gastroesophageal Reflux System (胃食管反流系統)	Gastroesophageal reflux disease	III			1Q24	1H25	
	Pulmonary Nodule Localization Needle (肺結節定位針)	CT-guided localization of lung nodules	III			N/A	Mar-19 ⁴⁾	
	Laparoscopic Single Port Multi-Channel Access Platform (單孔多通道腹腔镜手術系統)	Laparoscopic surgery	II			N/A	Feb-17 ⁵⁾	
	Wound Retractor (開創保護器)	Small incision surgery and minimally invasive surgery	II			N/A	May-14 ⁶⁾	
	Ureteral Dilator Balloon Catheter (輸尿管擴張球囊導管)	Ureteral Stenosis	II			N/A	Dec-18 ⁷⁾	
	Laparoscopic Biopsy Bag (腹腔镜用活检袋)	Biopsy	II			N/A	May-14	
Laparoscopic Surgical Instrument (腹腔镜手術器械)	Laparoscopy	II			N/A	Oct-18		



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Notes:

- (1) refers to the time of approval for commercialization in China. In addition to receiving approval in China, these four products obtained CE Marking in January 2019.
- (2) We plan to apply for CE Mark registration for the AF Cryoablation System in around 2027 and to expand its indication from paroxysmal atrial fibrillation to persistent atrial fibrillation. For further information, see the paragraphs headed “—Our Products and Product Candidates—Other Products and Product Candidates—Vascular Interventional Cryotherapy Products—1. AF Cryoablation System—Further Development Plan” in this section.
- (3) We plan to apply for CE Mark registration for the Bladder Cryoablation System in around 2027 and to expand its indication from non-muscle-invasive bladder cancer to muscle invasive bladder cancer. For further information, see the paragraphs headed “—Our Products and Product Candidates—Our Core Products—1. Bladder Cryoablation System—Further Development Plan” in this section.
- (4) We plan to apply for CE Mark registration for the Endoscopic Clip for Anastomosis in 2025. For further information, see the paragraphs headed “—Our Products and Product Candidates—Our Core Products—2. Endoscopic Clip for Anastomosis—Further Development Plan” in this section.

BUSINESS

Cryotherapy is a treatment method that freezes and destroys abnormal cells or diseased tissue through extreme cold. Interventional cryotherapy includes cryoablation that employs extremely low temperature to freeze tissue for destruction, as well as cryoadhesion that freezes tissue for adhesion. Many recent studies have demonstrated that interventional cryotherapy can effectively destroy diseased tissues and stop the growth or spread of cancerous cells in a minimally invasive manner. As compared to traditional treatment solutions such as open surgeries, interventional cryotherapy is potentially cheaper, safer, associated with fewer side effects and lower chances of post-operative complications, and allows patients a quicker recovery with less scars, although additional risks of bleeding may be posed due to friction between the tissue and instruments used in interventional cryotherapy. The Bladder Cryoablation System is not the only cryoablation medical device that uses liquid nitrogen as its cryogen in China and in the world. For details of other cryoablation medical devices that use liquid nitrogen as cryogen for the treatment of solid tumors, see “Industry Overview—The Bladder Cancer Interventional Cryotherapy Market—Competitive Landscape of Interventional Cryotherapy Devices for Solid Tumor” in this document.

We use liquid nitrogen as the main cryogenic source for cryotherapy systems by leveraging our liquid nitrogen cryoablation technology and advanced flexible catheter technology. Compared to other cryogenic sources like nitrous oxide and carbon dioxide, liquid nitrogen is obtainable and affordable with relatively rapid cooling rate. However, despite its advantages, the clinical application of liquid nitrogen had been limited, primarily because it tends to vaporize and undergo substantial volume expansion when delivering energy to the lesions, causing the catheter to become clogged with gas and unable to deliver liquid nitrogen continuously, and it also has a risk of destroying healthy cells surrounding the tumors. Our liquid nitrogen cryoablation technology platform can resolve the excessive volume change associated with vaporization to lower the device’s working pressure and increase operational safety, while keeping the advantages of ablation efficiency and controllability of liquid nitrogen. In addition, we continue to explore various underlying and supporting technologies based on our core technologies, such as precise temperature gradient control technology and real-time vacuum technology, to improve the efficacy and safety of our products and facilitate the clinical application of our cryotherapy systems.

Driven by the accelerated population aging and patient pool expansion, technological innovations and favorable policy support, as well as the advantages associated with the cryotherapy devices, the cryotherapy device market in China has experienced rapid growth. According to Frost & Sullivan, the market size of interventional cryotherapy devices in China has increased from RMB98.0 million in 2016 to RMB390.8 million in 2020 at a CAGR of 41.3%, and is expected to further climb to RMB11,233.9 million in 2030.

We have a comprehensive product portfolio that includes two Core Products as well as other products and product candidates mainly targeting two markets, namely NOTES and vascular intervention:

- In the area of NOTES, we have developed a series of cryotherapy systems and surgical consumables. Our Core Products, the Bladder Cryoablation System and the Endoscopic Clips for Anastomosis, belong to this category. According to Frost & Sullivan, patients with bladder cancer generally have a high risk of recurrence after undergoing the transurethral resection of bladder tumor (“TURBT”) surgeries, and the overall recurrence rate of non-muscle-invasive bladder cancer (“NMIBC”) post TURBT can reach 60%. There is a growing demand for an effective treatment to lower the incidence of postoperative tumor residuals. Similar to BCG perfusion or chemotherapy, our self-developed Bladder Cryoablation System is indicated for use in conjunction with TURBT to reduce tumor residuals for patients suffering from NMIBC. The Endoscopic Clip for Anastomosis, is an anastomotic device for closure of soft tissues in digestive tract, treating bleeding, perforation, and tissue defects. This product is one of the OTS Clips approved for commercialization in China. Our other product candidates in this area focus on respiratory and digestive diseases, such as chronic obstructive pulmonary disease, asthma, airway stenosis, gastric cancer and esophageal cancer.

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- In the area of vascular intervention, we have developed product candidates for the treatment of atrial fibrillation, hypertension and other cardiovascular disease. Our AF Cryoablation System is a minimally-invasive interventional device that treats atrial fibrillation by freezing and damaging abnormal heart tissues that cause irregular heartbeats. This product features stable energy supply, fast cooling rate and low system pressure, which potentially enhance the safety and ease of the intervention procedure. Our Cryo-RDN System is a cryoablation device for the treatment of hypertension.

We have built an in-house R&D team, which is led by industry experts with vast industry experience. We have also developed relationships with industry leaders, including scientists, physicians and industry practitioners, giving us a thorough understanding of the clinical needs and demands of patients and physicians. We held 110 registered patents and 44 pending patent applications in China and overseas.

Our two manufacturing facilities located in Shanghai and Ningbo can support the production and commercialization of our various cryotherapy devices and medical consumables. Our manufacturing facilities meet the applicable GMP requirements, and we follow rigorous manufacturing and quality control standards to ensure a high level of product quality and safety. As our pipeline products are gradually commercialized in the near future, we will continue to upgrade our production facilities.

During the Track Record Period, we have launched six minimally-invasive surgical consumables. We have established an extensive distributorship network, and had entered into distribution agreements with 57 distributors in China for the sales of our commercialized products as of August 31, 2022. In 2020, 2021 and the eight months ended August 31, 2022, our revenue amounted to RMB9.1 million, RMB22.4 million and RMB16.4 million, respectively. In October 2022, we also commercialized one of our Core Products, the Endoscopic Clip for Anastomosis. Given that we have only commercialized a small portion of our full product portfolio for now, our commercialization efforts are still in the early stages. However, we believe that our experience in commercializing our existing products, our established working relationships with physicians and hospitals, our reputation in the medical device industry in China, and our expanding sales and marketing team and distribution network will benefit our future commercialization of our cryotherapy systems and other product candidates upon their approval.

OUR COMPETITIVE STRENGTHS

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

A cryotherapy technology platform company with extensive presence in two fast-growing areas, namely NOTES and vascular intervention

Cryotherapy is a treatment method that freezes and destroys abnormal cells or diseased tissue through extreme cold. Interventional cryotherapy includes cryoablation that employs extremely low temperature to freeze tissue for destruction, as well as cryoadhesion that freezes tissue for adhesion. Many recent studies have demonstrated that interventional cryotherapy can effectively destroy diseased tissues and stop the growth or spread of cancerous cells in a minimally invasive manner. As compared to traditional treatment solutions such as open surgeries, interventional cryotherapy is potentially cheaper, safer, associated with fewer side effects and lower chances of post-operative complications, and allows patients a recovery with less scars. In addition, interventional cryotherapy procedures are easy to learn, easy to conduct by physicians, and typically require a short operation time.

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We are a major industry player in the field of minimally-invasive interventional cryotherapy globally, according to Frost & Sullivan. We have developed a number of cryotherapy systems and non-cryotherapy products for use in various treatment scenarios, by leveraging our technologies and understanding of industry pain points. Our Bladder Cryoablation System is a cryotherapy device designed for the treatment of bladder cancer approved for commercialization in China, and several of our self-developed product candidates, such as our AF Cryoablation System, are expected to be among the first batches of products in their respective product types to receive approval for commercialization in China or in the world.

We use liquid nitrogen as the main cryogenic source for cryotherapy systems by leveraging our liquid nitrogen cryoablation technology and advanced flexible catheter technology. Cryoablation works by creating persistent lesions to treat diseases, and the cooling rate, the end temperature, the hold time and the thawing rate of the cryogenic source are critical to the treatment result. Traditional cryoablation products typically use nitrous oxide as the cryogenic source, and their clinical application is generally limited by the difficulty of obtaining nitrous oxide and the associated regulatory constraints. In comparison, liquid nitrogen is relatively safe, environmentally friendly and readily available. As a cryogenic source, it also enables rapid cooling and adjustable energy supply. Despite its features, the clinical application of liquid nitrogen is restricted by its tendency to vaporize and undergo substantial volume expansion during the energy delivery to the lesions. Our liquid nitrogen cryoablation technology platform can resolve the excessive volume change associated with vaporization while maintaining the benefits of liquid nitrogen, thus substantially lowering the devices' working pressure and increasing operational safety. Our cryoablation system typically comprises an active device, namely cryoablation equipment, and ancillary consumables such as catheters. We have developed proprietary active devices for cryoablation based on our liquid nitrogen cryoablation technology platform, and concurrently developed various ancillary consumables utilizing our flexible catheter technology, which can safely pass through blood vessels and natural orifices and effectively deliver energy to the target tissue.

We currently concentrate our efforts on two Core Products and other products and product candidates in two minimally-invasive surgical areas, namely NOTES and vascular intervention:

- **NOTES:** Our Core Products belong to this category. Similar to BCG perfusion or chemotherapy, the Bladder Cryoablation System is indicated for use in conjunction with TURBT to reduce tumor residuals for patients suffering from NMIBC. The other Core Product, the Endoscopic Clip for Anastomosis, is an anastomotic device for closure of soft tissues in digestive tract, treating bleeding, perforation, and tissue defects. In the area of NOTES, we have been exploring the application of cryotherapy technology in a variety of natural orifice interventional areas, such as respiratory, urological and gastrointestinal intervention. In addition, we have developed several non-cryotherapy products to create a comprehensive surgical product solution for NOTES.
- **Vascular intervention:** We are one of the first medical device companies in developing cryotherapy treatment solutions for atrial fibrillation and hypertension, and have developed innovative cryoablation systems for the treatment of atrial fibrillation and hypertension based on our technologies. The cryoablation systems employ our fluid control system, which allows for faster cooling rate without excessive tissue damage, thereby considerably improving the efficacy and safety of the procedures.

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Comprehensive surgical product portfolio catering to the natural orifice transluminal endoscopic surgery with a focus on cryotherapy

Natural orifice transluminal endoscopic surgery, or NOTES, has obvious advantages over conventional laparoscopic surgery, including a reduced need for anesthesia, decreasing surgical incision complications, such as incisional hernias, adhesions, intestinal obstruction, scars, and wound infection, as well as better aesthetics, implying a broad market prospect, according to Frost & Sullivan. Our Core Products, the Bladder Cryoablation System and the Endoscopic Clip for Anastomosis, are medical devices targeting NOTES. In the field of NOTES, cryoablation technology enjoys clinical benefits compared to the traditional thermal ablation, such as low occurrence of complications, higher safety, less formation of scar stenosis, and retaining immunogenicity of tumor cells to activate tumor immunity, according to Frost & Sullivan.

Based on our cryoablation technology platform, we have developed cryogen-based active devices indicated for use in various NOTES surgical scenarios, and designed ancillary consumables tailored to different clinical needs and surgeries. For example, our balloon catheter for asthma treatment has a unique narrow balloon design that better fits the structure of lumen in the human body. Currently, our research and development has covered several therapeutic areas with great market potential such as respiratory intervention, urinary tract intervention and gastrointestinal intervention.

Product candidates for urological interventional therapy

According to Frost & Sullivan, the incidence of bladder cancer in China was 85.7 thousand in 2020 which is expected to grow to 117.6 thousand in 2030. Non-muscle-invasive bladder cancer, or NMIBC, accounts for 75% of newly diagnosed bladder cancer, and more than 80% of NMIBC patients were treated with traditional transurethral resection of bladder tumor, namely TURBT, in 2020, according to Frost & Sullivan. However, NMIBC patients may experience *in situ* tumor recurrence following the TURBT, and they are in need of treatment that effectively reduces postoperative tumor residuals.

Similar to BCG perfusion or chemotherapy, our self-developed Bladder Cryoablation System is indicated for use in conjunction with TURBT to reduce tumor residuals for patients suffering from NMIBC. The cryoablation catheter of the Bladder Cryoablation System was recognized as an "innovative medical device" by the NMPA, and we submitted the registration application for our Bladder Cryoablation System with the NMPA in May 2021. We received the NMPA approval for this product candidate in June 2022.

Product candidates for respiratory interventional therapy

As of the Latest Practicable Date, we had conducted research and development for the following indications:

- **COPD:** According to Frost & Sullivan, the number of patients suffering from COPD in China was 105.3 million in 2020, and will grow to 109.6 million and 113.3 million in 2025 and 2030, respectively. Of these patients with COPD, 27% are in severe or extremely severe stages (i.e. GOLD stage III and IV), with a five-year survival rate of only 46%. The entire COPD-affected population is in need of effective treatment solutions for different stages of COPD, and effective treatment for COPD in early stage is essential for prolonging the survival of patients. We have designed and developed a cryoablation spray catheter tailored

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to the surgical features of COPD surgery for the treatment of COPD in early stage. Our COPD Cryospray System (慢阻肺冷凍噴霧治療系統) allows for shallow freezing over a large area, which significantly reduces the incidence of complications while ensuring the surgical efficacy. As of the Latest Practicable Date, we were conducting a feasibility clinical trial for this product candidate, with the confirmatory clinical trial expected to begin in 2023.

- *Airway stenosis:* According to Frost & Sullivan, the number of patients with airway stenosis in China was 1.2 million in 2020 and will increase to 1.4 million and 1.6 million in 2025 and 2030, respectively. Our airway cryotherapy products can reach extremely low temperature and increase the tissue contact area with our unique balloon structure, thereby enhancing ablation efficiency. We are in the process of conducting a confirmatory clinical trial in China for the Malignant Stenosis Cryoablation System (惡性狹窄冷凍消融系統) and plan to submit registration application for it with the NMPA in 2023. We have also combined airway dilation and cryoablation to develop a system for the surgical treatment of benign airway stenosis. We are currently conducting a feasibility clinical trial for our Benign Stenosis Cryoablation System (良性狹窄冷凍消融系統), with a confirmatory clinical trial scheduled to commence in 2023.
- *Asthma:* According to Frost & Sullivan, the number of patients with asthma in China was 65.0 million in 2020 and is expected to grow to 72.2 million and 78.5 million in 2025 and 2030, respectively. Our Asthma Cryoablation System (哮喘冷凍消融系統) can perform efficient cryoablation to treat moderate and severe asthma while keeping high safety and ease of operation. We are currently conducting a feasibility clinical trial for our Asthma Cryoablation System in China and intend to begin a confirmatory clinical trial in 2023.
- *Others:* We are carrying out feasibility clinical trials for our Cough Cryospray System (咳嗽冷凍噴霧治療系統), and Tuberculosis Cryospray System (結核冷凍噴霧治療系統).

Product candidates for gastrointestinal interventional therapy

According to Frost & Sullivan, the number of new gastric cancer cases in China was 469.6 thousand in 2020 and is predicted to reach 622.4 thousand in 2030. Currently, approximately 80% of gastric cancer patients in China are already at an advanced stage when they are diagnosed, according to Frost & Sullivan. There are limited treatment options available and the first-line therapy is still systemic chemotherapy. The absence of effective local surgical treatment (局部手術治療) for primary lesions (原發病灶) is one of the pain points in the surgical treatment of gastric cancer. Our self-developed cryoablation catheter can facilitate the operation performed on gastric primary lesions under endoscopy. As of the Latest Practicable Date, we had completed the subject enrolment and follow-up visits in our feasibility clinical trial for the Gastric Cryoablation System (胃部冷凍消融系統). In addition, we developed our Esophageal Cryospray System (食道冷凍噴霧治療系統) for treating patients with intermediate to advanced esophagus cancer, and are currently conducting a feasibility clinical trial for this product candidate in China.

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Other products and product candidates

We have successfully developed and commercialized multiple minimally-invasive surgical consumables to provide physicians with comprehensive surgical consumable solutions. During the Track Record Period, we had launched our Laparoscopic Single Port Multi-Channel Access Platform, Pulmonary Nodule Localization Needle and other medical consumables. We also received the Zhejiang MPA approval for our Endoscopic Clip for Anastomosis in August 2022 and commercialized it in October 2022. Additionally, we are developing surgical device for treating gastroesophageal reflux disease. We are conducting a confirmatory clinical trial for the Anti-Gastroesophageal Reflux System and expect to complete the clinical trial in the second quarter of 2023.

Product portfolio based on advanced cryoablation technologies in the vascular interventional therapeutic area, with R&D progress in China

According to Frost & Sullivan, traditional thermal ablation generally requires a lengthy procedure, and has limited ablation efficiency and high risk of serious discomfort and complications. In comparison, cryoablation features high ablation efficiency, ease of operation and low risk of complications, and is expected to become a mainstream treatment for vascular interventional procedures.

In the vascular interventional therapeutic area, we have developed a robust portfolio of cryoablation systems with unique technical features and have built our footprints in other active devices for the treatment of atrial fibrillation, resistant hypertension and pulmonary hypertension, with R&D progress in China.

Product candidates for the treatment of atrial fibrillation

According to Frost & Sullivan, the number of patients with atrial fibrillation in China was 11.6 million in 2020, and is expected to rise to 16.6 million in 2030 at a CAGR of 3.7% from 2020 to 2030. In China, the market of atrial fibrillation cryoablation devices is still in its early stage of development, with significant growth potential. With the technology advancement and the increasing recommendation of cryoablation, the number of cryoablation procedures for atrial fibrillation in China increased from 2.3 thousand in 2016 to 9.8 thousand in 2020 at a CAGR of 44.0%, and is expected to rise further to 224.9 thousand in 2030, according to Frost & Sullivan. The market size of atrial fibrillation cryoablation catheters in China increased from RMB48.4 million in 2016 to RMB255.0 million in 2020 at a CAGR of 51.5%, which is expected to reach RMB5,103.0 million in 2030, according to Frost & Sullivan. As of the Latest Practicable Date, there was only one cryoablation device for the treatment of atrial fibrillation approved for commercialization in China, indicating the unmet medical needs in the atrial fibrillation cryoablation market.

Our self-developed AF Cryoablation System has many advanced features, such as stable energy supply, fast cooling rate and low system pressure, which improves the safety and ease of surgery. This product candidate was recognized as an “innovative medical device” by the NMPA. We submitted the registration application for the AF Cryoablation System with NMPA in July 2022, and currently expect to receive the NMPA approval for this product candidate in or around the second quarter of 2023.

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Product candidates for the treatment of hypertension

According to Frost & Sullivan, the number of patients with hypertension in China was 325.9 million in 2020 and is anticipated to increase to 390.1 million in 2030. In 2020, only 22.5% of hypertension patients in China have controlled their blood pressure, with the remainder suffering from uncontrolled hypertension or resistant hypertension. It is difficult to treat resistant hypertension with pharmacotherapy alone. Although antihypertensive medications are effective in treating uncontrolled hypertension, patients’ adherence to pharmacotherapy has been poor. In recent years, many clinical trials suggest that RDN provides general safety and clear efficacy in the treatment of resistant hypertension. However, according to Frost & Sullivan, there was no commercialized RDN product in China as of the Latest Practicable Date, and as a result, there are unmet medical needs for patients with uncontrolled and resistant hypertension.

Most RDN studies use a radiofrequency current or ultrasound as the energy sources for ablating the renal sympathetic nerves, which requires a relatively complicated and lengthy surgical procedure, according to Frost & Sullivan. According to Frost & Sullivan, theoretically cryoablation can significantly improve the surgical efficiency by expanding the ablated area to maximize the destruction of the target renal sympathetic nerves. Our self-developed Cryo-RDN System increases the ablated area through circumferential ablation, resulting in more complete ablation, less endothelial damage, and faster repair of renal vessels and surrounding tissues, hence improving the overall safety and efficacy of the RDN procedure. This product candidate was recognized as an “innovative medical device” by the NMPA. We currently expect to make the product registration submission for this product candidate with the NMPA in the third quarter of 2024, and to obtain the NMPA approval for it in the second half of 2025. We aim to make our Cryo-RDN System the world’s first cryoablation device for the treatment of hypertension approved for commercialization.

Other vascular interventional therapeutic areas and technology expansion: all-around development of active device-related technologies

Our position in the industry reflects our strong R&D capabilities and our in-depth understanding of cardiovascular disease treatment. Based on our experience in the development of cryogen-based active devices, we have continued to explore novel application of our cryogen-based active devices in different scenarios of vascular interventional therapy. At the same time, we have designed a roadmap to develop other types of active devices and have taken the lead in applying such in the field of vascular interventional therapy that we are familiar with. For example, we have a pulse field ablation (PFA) product candidate for the treatment of atrial fibrillation, which is currently in the pre-clinical study stage and is expected to start clinical trials in China in 2023. Furthermore, we have a cryotherapy product candidate for the treatment of pulmonary hypertension in the pre-clinical study stage.

Strong R&D capabilities and strategically designed IP portfolio empowering rapid innovation of products

We have a track record of in-house research and development leveraging our liquid nitrogen-based cryotherapy technology platform. The proprietary technologies we hold in hand through our in-house development pose high technical barriers difficult for our competitors to surpass. As of the Latest Practicable Date, we had 110 patents and 44 patent applications in China and overseas. In particular, our core liquid nitrogen cryoablation technology, flexible catheter technology and other key technologies are all self-developed and protected by our patent portfolio.

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The application of our liquid nitrogen cryoablation technology in several minimally-invasive treatment fields proves our ability to develop active devices for cryotherapy. Leveraging our in-depth understanding of active devices, we have started to actively and extensively develop other active devices, such as PFA devices.

We have built a strong in-house R&D team consisting of 83 members and a dedicated clinical operation team of 37 members as of the Latest Practicable Date (including certain management members undertaking product development functions). Our product development team is jointly led by Mr. DIAO Yuepeng, Mr. LIU Yulong, Mr. Thach Buu DUONG, Dr. ZHAO Kuiwen and Mr. CHEN Zhimin, industry experts with vast industry experience, enabling us to stay at the forefront of technology development.

Our staff responsible for clinical trials and registration affairs have in-depth knowledge of laws and regulations related medical devices in China and overseas. We have successfully launched several minimally-invasive medical devices in the past. In the process of development and commercialization of these products, we have gained significant experience in management and clinical trials, which help us optimize the clinical protocol design while adhering to scientific regulatory requirements.

Benefiting from our past R&D experience and technical performance of our products, we have maintained good working relationships with various medical institutions in the industry. As of the Latest Practicable Date, we conducted clinical trials in reputable Class III-A hospitals in China and collaborated with well-known principal investigators. Meanwhile, we have academic research collaboration with research institutions. We believe that our close cooperation with these renowned principal investigators, hospitals, as well as researchers and industry practitioners, deepens our understanding of clinical pain points and cutting-edge R&D trends, allowing us to identify opportunities in fields with high growth potential and translate innovative concepts into real-world products.

Growing commercialization capabilities and efficient manufacturing system that enable end-to-end integration

We expect to cultivate the stickiness of physicians and end-customers after the launch of our cryotherapy systems, including active devices and ancillary specialized consumables with unique and advanced features, and to achieve recurring revenue through sales of specialized consumables used in conjunction with our active devices.

We have not launched or commercialized any cryotherapy products and have no experience with commercialization of cryotherapy devices. However, we have launched a number of innovative minimally-invasive medical consumables, including the Laparoscopic Single Port Multi-Channel Access Platform and the Pulmonary Nodule Localization Needle. Through the development and commercialization of these products, we have an efficient GMP manufacturing system, mature commercialization capabilities and an extensive commercialization network to enable end-to-end connectivity from the clinical trial stage to commercial production, thereby laying a solid foundation for the upcoming commercialization of our pipeline products.

The manufacturing process and techniques of cryotherapy devices are complex and involve energy source treatment (能量源處理), multidisciplinary crossover (多學科交叉) and other difficulties. We have independently developed core manufacturing technologies such as liquid nitrogen treatment technology (液氮處理技術), design and manufacturing technology of balloon catheters and spray catheters, flexible catheter preparation technology (柔性導管製備技術). Almost all of our key manufacturing steps are performed in-house to achieve quality control and ensure product performance, while controlling manufacturing costs and keeping the pricing advantage of our products upon commercialization.

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Our in-house sales and marketing team has extensive expertise and clinical resources, and is led by industry experts with many years of commercialization experience in internationally recognized medical device companies. We are committed to gradually expanding our sales and marketing team so as to support the sales coverage of our products upon their commercialization.

We actively participate in academic promotion to enhance the awareness of our cryoablation products. We have maintained close and long-term relationships with many top hospitals and PIs in China. Our sales and marketing team keeps regular and active communications with physicians for product demonstrations and training, as well as organizing industry-related academic meetings for industry participants and sponsoring major industry conferences. We believe that through these close academic communications with industry participants, we can increase physician acceptance and market awareness of our products.

We have built an extensive commercialization network. As of August 31, 2022, we had launched six minimally-invasive surgical consumables and had entered into distributorship agreements with 57 distributors in China for the sale of our commercialized products. We believe that our experience in commercializing existing products, our strong working relationships with physicians and hospitals and our expanding sales and marketing team and distribution network will greatly benefit the future commercialization of our cryoablation systems and other product candidates upon their approval.

Visionary management team with rich industry experience and profound expertise, backed by strong support from renowned shareholders

We are led by a core management team of seasoned industry executives with extraordinary insight and working experience in well-known medical device companies. Our General Manager and CEO, Mr. ZHU Jun, has more than 19 years of experience in the medical industry. He previously held key positions in international medical device companies such as Erbe China Ltd. (愛爾博(上海)醫療器械有限公司) and served as a front-line clinician at the Affiliated Hospital of Nantong University (南通大學附屬醫院).

In addition to our management team, we benefit tremendously from the strong support of our shareholders. Our investors, such as Zhuhai Gao Ling (珠海高瓴), Proxima Ventures (比鄰星創投), YuanBio Venture Capital (元生創投), FutureX Capital (天際資本), have considerable experience in investing in and managing the medical device companies, and have given us invaluable advice on the development and commercialization of our products.

OUR STRATEGIES

Our mission is to become a global medical device platform in the field of minimally-invasive interventional cryotherapy, bringing benefits to patients and physicians worldwide with our cryotherapy technology. We plan to implement the following strategies to achieve our goal:

Rapidly advance the clinical development and commercialization of our product candidates

As of the Latest Practicable Date, we have built a broad product portfolio consisting of two Core Products, 15 other product candidates in various stages of development, and six additional commercialized products. We intend to facilitate the clinical development and commercialization of our pipeline products, particularly our Core Products and other cryotherapy products such as the AF Cryoablation System.

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By leveraging the benefits of cryotherapy such as high efficiency, ease of operation and low incidence of complications, as well as the strengths of our liquid nitrogen cryoablation technology and flexible catheter technology, we plan to promote the commercialization of our products through the following measures:

- We intend to further deepen our collaboration with top hospitals and research institutions on the target fields, and continue to actively participate in academic promotion and training of more physicians. With these measures, we expect to raise the awareness among hospitals, physicians and patients about the advantages of cryotherapy technology and enhance the penetration of interventional cryotherapy in China, as well as establishing our brand image as the minimally-invasive cryoablation technology platform.
- Moreover, we plan to expand our sales and marketing team by recruiting experienced sales managers and regional sales personnel, and to develop specialized and devoted sales and marketing teams for various products and clinical departments. We will have our sales headquarters in Shanghai to oversee and manage the entire marketing and sales of the Group, as well as localized staff in each region to offer professional services and timely responses to the requests of physicians and distributors.
- In addition, we will extend our distribution network for future commercialized products on the basis of our established commercialization network and related experience. We seek to cooperate with additional distributors who have impressive sales records and abundant marketing resources in China. We will also coordinate our sales and marketing team to support and train these distributors to improve our local sales network throughout China.
- As our sales and marketing team gradually expands and our sales network improves, we believe the recognition of interventional cryotherapy and our cryotherapy technologies among physicians will be enhanced. In addition to cooperating with top hospitals, we will actively respond to the national policy of graded diagnosis and treatment to sink medical resources to grassroots hospitals, and promote the minimally-invasive interventional cryotherapy vigorously in grassroots hospitals to benefit more physicians and patients.

Further expand our product portfolio leveraging technology platforms and continue to focus on minimally-invasive interventional cryotherapy

We will continue to explore the clinical application of our liquid nitrogen cryoablation technology platform. Our liquid nitrogen cryoablation technology resolves the issue of excessive volume change during the conversion of liquid nitrogen to gas, which improves surgical safety by reducing device working pressure and ensures effective energy supply for clinical treatment while keeping the advantages of liquid nitrogen being safe, environmentally friendly and easily accessible. Leveraging our liquid nitrogen cryoablation technology and our expertise in clinical trials and registration, we will continue to concentrate on the two major therapeutic areas and develop products targeting the atrial fibrillation, hypertension, respiratory, urinary and gastrointestinal disease treatment markets with unmet medical needs.

We plan to work closely with clinical experts in cardiovascular, respiratory, urology and gastroenterology departments as well as research institutions to further explore unmet clinical needs, address industry pain points and develop innovative minimally-invasive cryotherapy medical devices.

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In addition, we expect to further develop other types of technology platforms based on cryogenics besides liquid nitrogen. Different indications and surgical operating environments require varying energy sources and freezing depth in cryotherapy. We will continue to seek innovative applications of our liquid nitrogen cryoablation technology platform in areas with huge clinical needs and surgical difficulties. Meanwhile, we also intend to expand our presence into other types of cryotherapy technologies for use in outpatient and minor surgery, as well as develop mobile and portable medical devices, further expanding our products' applicable therapeutic areas to meet more clinical needs.

Continue to research and develop various underlying and supporting technologies

We have developed various underlying technologies based on our liquid nitrogen cryoablation technology platform, such as our volume control technology for physical phase change (輸運相態躍變體積變化控制技術), precise temperature gradient control technology (精準溫度場控制技術), and real-time vacuum technology (實時真空技術). In particular, the volume control technology for physical phase change can address the issue of excessive volume change during the phase change of liquid nitrogen, ensuring continuous and effective energy supply and improving the operational safety by lowering the device working pressure. The temperature field control technology allows us to accurately control the temperature through the fluid monitoring and measuring system (流體相控監測調控系统), which helps achieve faster cooling rate and avoid excessive damage, improving the safety and efficacy of products. We will continue to refine and iterate these underlying technologies to optimize our products.

We plan to continue our research and development on the basis of existing core technologies, with an emphasis on the advancement of our balloon structure design technology (球囊結構設計技術) and precision device manufacturing technology (精密器械製造技術), as well as the flexible catheter technology (柔性導管技術) and structure design technology for specific balloon and nozzle (特異性球囊和噴頭結構設計技術).

We have extended our footprint to certain new-type ablation fields. For example, we have a PFA product for atrial fibrillation in the pre-clinical study stage. In the future, we will pay close attention to, and possibly further tap into, other ablation technology areas with growth potential. We believe we are well positioned to capture market opportunities and explore novel applications of minimally-invasive ablation in additional therapeutic areas, utilizing our experience in developing energy-based technology platforms and deep understanding of the relevant fields. Moreover, we will investigate the use of our existing liquid nitrogen cryoablation technology in combination with other new ablation technologies such as PFA, and strive for continuous product innovation.

Selectively expand our worldwide footprint

As of the Latest Practicable Date, we owned 110 registered and 44 pending patent applications in China and overseas. We have built a complete IP portfolio to protect the technologies of our products. In particular, our core liquid nitrogen cryoablation technology and flexible catheter technology are self-developed and protected by our patent portfolio. Going forward, we will continue to protect the intellectual property rights for our new products and technologies through patent registration globally.

Based on our well-established IP portfolio and our liquid nitrogen cryoablation technology platform, we plan to advance the clinical development and commercialization of some products in overseas markets, which may be accomplished through co-development, licensing of commercial rights to third parties, collaboration with distributors, strategic acquisitions or other approaches. As of the

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Latest Practicable Date, we had not entered into any letters of intent or agreements with respect to acquisitions and had not identified any definite acquisition targets.

We have formed a mature R&D system. In the future, we plan to further enhance our R&D capabilities and to leverage our overseas resources and expertise to facilitate the R&D of our cryotherapy technologies and products.

OUR PRODUCTS AND PRODUCT CANDIDATES

We are a medical device company in China, with a focus on the research, development and commercialization of cryotherapy devices. As of the Latest Practicable Date, we had built a comprehensive product portfolio comprising two Core Products, 15 other product candidates in various development stages as well as six additional commercialized medical consumables. All of our product candidates are self-developed by us.

Our Core Products comprise the Bladder Cryoablation System and the Endoscopic Clip for Anastomosis. We received the NMPA approval for the Bladder Cryoablation System in June 2022, and obtained the Zhejiang MPA approval for the Endoscopic Clip for Anastomosis in August 2022, and we commercialized the Endoscopic Clip for Anastomosis in October 2022. For details, see “—Our Core Products” in this section. We believe that our Core Products and other product candidates can create synergetic effects. For instance, cryotherapy products can benefit from the R&D of the Bladder Cryoablation System as they share certain underlying technologies; the distribution network and marketing channels for the Endoscopic Clip for Anastomosis would bring synergy to the Gastric Cryoablation System and the Esophageal Cryospray System in the future, since they are used in the same specialty or department.

Our product and product candidates mainly target two therapeutic areas: (i) natural orifice transluminal endoscopic surgery, or NOTES, to treat urinary, respiratory, and digestive diseases (e.g., bladder cancer, COPD, asthma, airway stenosis, gastric cancer, esophageal cancer, etc.), and (ii) vascular interventional therapy to treat cardiovascular diseases (e.g., atrial fibrillation, hypertension, etc.). Our Core Products fall into the area of NOTES.

Our product candidates are subject to approval by relevant authorities, such as the NMPA and/or its local counterparts, before commercialization in the relevant jurisdictions. For details, see “Regulatory Overview” in this document. As of the Latest Practicable Date, we had not received any material comments or concerns raised by the relevant regulatory authorities with respect to our product candidates, and we believe we are on track to apply for the approval to commercialize our product candidates.

Our Core Products

1. *Bladder Cryoablation System*

Our Bladder Cryoablation System (膀胱冷凍消融系統) is a self-developed cryoablation system for the treatment of bladder tumors. This product candidate employs liquid nitrogen to perform efficient cryoballoon ablation on target tissue, and similar to BCG perfusion or chemotherapy, this product candidate is indicated for use in conjunction with TURBT to reduce tumor residuals for patients suffering from NMIBC. For details of its competitive landscape, see “Industry Overview—The NOTES Interventional Cryotherapy Device Market—The Bladder Cancer Interventional Cryotherapy Device Market” in this document.

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Our Bladder Cryoablation System is a Class III medical device under the classification criteria of the NMPA. We initiated a multi-center, randomized, parallel and controlled clinical trial for the Bladder Cryoablation System on 218 human subjects in November 2017, and the final clinical trial report for the trial was issued in May 2021. We submitted the registration application for our Bladder Cryoablation System with the NMPA in May 2021, and received the NMPA approval for the Bladder Cryoablation System in June 2022. We plan to commercialize our Bladder Cryoablation System in China in December 2022.

Product Structure and Features

The Bladder Cryoablation System consists of a cryoablation equipment (冷凍消融設備) and a single-use cryoablation catheter (一次性使用冷凍消融導管). Each component is described below.

Cryoablation Equipment (冷凍消融設備)

The cryoablation equipment comprises a freezing unit (冷凍裝置), a vacuum system (真空系統), a cryogen delivery circuit (低溫工質輸送回路), and a control system (控制系統). We use low-temperature liquid nitrogen as the cryogen in our Bladder Cryoablation System. This cryoablation equipment delivers the cryogen quickly, continuously and smoothly to the catheter to achieve stable and efficient ablation. It employs an excellent real-time vacuum insulation system (實時真空隔熱系統), enabling real-time monitoring to reduce the loss of energy. The cryoablation system also has a user interface, allowing physicians to easily monitor and manage the equipment. Its various monitoring and reminder functions ensure the safe and effective operation of the system.

Single-use Cryoablation Catheter (一次性使用冷凍消融導管)

The single-use cryoablation catheter, also known as the cryoablation catheter for intracavitary tumors (腔內腫瘤使用冷凍消融導管), mainly includes a balloon (球囊), a catheter shaft (導管主體), and a handle (手柄). This cryoablation catheter enables stable supply of low-temperature liquid nitrogen and achieves excellent vacuum heat insulation in real time. It uses the balloon as the cryotip, which expands during use, resulting in a large ablation area and deep ablation depth by covering the bladder wall and freezing and destroying tumor tissue deeply in the bladder wall. The balloon is designed to be concave at the distal end, which allows for effective freezing at both the lateral side and the distal end of the balloon. The liquid nitrogen is circulated inside the balloon, and multiple monitoring measures are in place for safe and stable use. The catheter is semi-flexible to reduce the difficulty of fitting the balloon to the lesion surface.

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Diagram 1 below illustrates the cryoablation equipment, and diagram 2 below illustrates the single-use cryoablation catheter:



Diagram 1

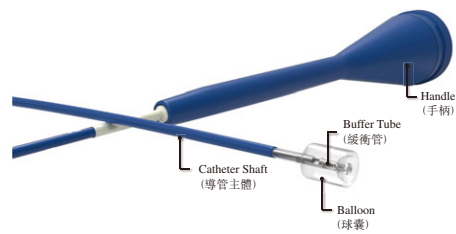


Diagram 2

Key features and competitive advantages of the Bladder Cryoablation System are summarized below:

- Similar to BCG perfusion or chemotherapy, this product can reduce tumor residuals after TURBT. As of the Latest Practicable Date, the Bladder Cryoablation System was the only interventional cryotherapy device which had completed a pivotal clinical trial for the treatment of bladder cancer.
- The cryogen of this product, liquid nitrogen, is obtainable and is circulated inside the balloon to ensure safety.
- The operation procedures for this product are simple to learn, easy to conduct by physicians, and typically require a short operation time. In particular, the cryoablation catheter can use the access established in the TURBT procedure to reach target tissue and freeze tumor residual immediately following TURBT, without the need for additional access. The catheter adheres to the tissue at low temperatures, making it less likely to displace and easier to operate.
- Cryotherapy with this product is less likely to cause side effects and damages to the adjacent tissue in bladder, such as bladder perforation and obturator nerve reflex.

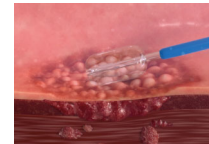
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Operation Procedure

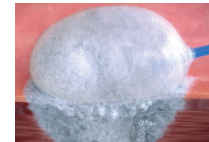
During the procedure, the physician first performs TURBT to resect the tumor, followed by cryoablation with our Bladder Cryoablation System to remove tumor residue at the site of the resection. After TURBT, the physician connects the single-use cryoablation catheter to the cryoablation equipment, and the catheter with pre-folded balloon is inserted into the bladder through the established channel. The balloon is gradually exposed to the field of view as the catheter is pushed in and is properly placed so that the balloon wall fits the lesion surface. After setting device pressure and freezing time, the physician can start the freezing cycle. The cryoablation equipment delivers liquid nitrogen to the balloon at the front of the catheter, which is then filled with liquid nitrogen. The phase change of liquid nitrogen absorbs heat and rapidly cools down the target tissue, and thus destroys the target cells. When reaching the set freezing time, the freezing process is stopped and the rewarming cycle is started. The cryoablation equipment delivers room temperature nitrogen gas to the balloon to raise the temperature of the target tissue, which process further destroys the target cells. Finally, following the cryoablation treatment, the physician turns on the venting function and withdraws the catheter.

The pictures below illustrate the key steps of the operation procedure:

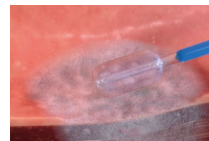
- (1) The cryoablation catheter is inserted into the bladder:



- (2) The balloon is inflated and fits the post-TURBT wound surface, and the freezing is initiated:



- (3) After the freezing process, rewarming starts:



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Key R&D and Registrational Activities

We sponsored all the clinical trials for the Bladder Cryoablation System in China through our subsidiary, Ningbo SensCure. For details of our roles and responsibilities in the R&D and the conduct of clinical trials, see “—Research and Development—Product Development” and “—Research and Development—Clinical Trials” in this section. The following table illustrates the key R&D and registrational activities related to the Bladder Cryoablation System:

R&D activities	Nature	Initiation Date	Completion Date
Type testing	Pre-clinical product testing	May 2015	August 2015
An animal study on dogs	Pre-clinical animal study	May 2015	August 2015
A multi-center, randomized, parallel controlled clinical trial	Human clinical trial	November 2017 ⁽¹⁾	May 2021 ⁽²⁾

Registrational activities	Relevant Authority	Submission Date	Actual Approval Date
“Green Path” application ⁽³⁾	NMPA	April 2016	June 2016
Registration application	NMPA	May 2021	June 2022

Notes:

- (1) The initiation date of this clinical trial refers to the date on which the first patient was enrolled according to the clinical trial protocol.
- (2) The completion date of this clinical trial refers to the date on which the final clinical trial report was issued.
- (3) Refers to an application for the designation of “innovative medical device” and admittance to the relevant expedited approval process.

Pre-clinical Animal Study

We started the animal study of the Bladder Cryoablation System in May 2015 and finished it in August 2015. Fifteen Beagle dogs participated in the trial and underwent cryoablation on their bladder wall with the Bladder Cryoablation System. Follow-up evaluations were performed up to 3 months after cryoablation.

All cryoablation procedures were completed successfully without any deaths or complications, and no complications such as infections occurred during the follow-up period. Furthermore, the study has shown that a 2-minute cryoablation can cause necrosis within a diameter of about 2 cm, penetrating deep into the muscle layer and gradually replacing the necrotic area with collagen fibers after the procedure. Therefore, the animal study validated the safety and feasibility of the Bladder Cryoablation System.

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Clinical Trial

We initiated a multi-center, randomized, parallel controlled clinical trial in China for the Bladder Cryoablation System in November 2017, which is designed to evaluate the safety and efficacy of cryoablation as an adjuvant therapy with transurethral resection to treat bladder tumors. Based on the final clinical trial report issued in May 2021, our Bladder Cryoablation System demonstrated good safety and efficacy results.

A total of 218 eligible subjects were enrolled in the clinical trial at six hospitals, led by Huashan Hospital, Fudan University (復旦大學附屬華山醫院). Among the 218 enrolled subjects, 205 completed treatment and all follow-ups in the clinical trial, out of which, 182 subjects had bladder cancer at clinical stage T1, 14 subjects had bladder cancer at clinical stage T2, and 9 subjects were initially confirmed at stage T1 or T2 based on CT scan but were eventually diagnosed with benign tumors or at other stages based on pathological sections obtained during surgery. The subjects were randomized in a 1:1 ratio to a study group, where the subjects received the cryoablation treatment immediately after TURBT, and a control group, where the subjects underwent immediate perfusion chemotherapy after TURBT (within 24 hours after TURBT). The subjects further underwent Re-TURBT or cystoscopy with biopsy to detect residual tumors at four to six weeks following initial TURBT, for evaluating and comparing the clinical success rate and the occurrence of adverse events between the two groups.

We completed the clinical procedures, and conducted follow-up visits (i) before the discharge within seven days following TURBT, (ii) 4–6 weeks before Re-TURBT, and (iii) before the discharge within seven days following Re-TURBT. Among the 109 enrolled subjects in the study group, 101 subjects were included in the FAS, 82 subjects were included in the PPS and 101 subjects were included in the safety set. Among the 109 enrolled subjects in the control group, 104 subjects were included in FAS, 81 subjects were included in the PPS, and 104 subjects were included in the safety set. The primary endpoint of the clinical trial was the clinical success rate, which was defined as the number of subjects without tumor residue observed during the Re-TURBT or cystoscopy with biopsy at four to six weeks after initial TURBT as a percentage of the total subjects who completed the trial in each group. Secondary endpoints of the clinical trial included the duration of indwelling catheterization after the initial TURBT, tumor progression and adverse events.

All of the subjects for the clinical trial met the following conditions:

- The subject is clinically diagnosed as a patient with bladder tumor at clinical stage T1 or T2;
- The subject has no more than three bladder tumors, the longest diameter of which is not greater than 3 centimeters;
- The subject is aged between 18 and 85 years old; and
- The subject voluntarily participates in this clinical trial and provides signed informed consent.

Safety Indicators

The safety of the Bladder Cryoablation System was primarily measured by comparing the adverse events among the subjects in the study group with the control group during the relevant follow-up periods. There was no occurrence of device-related serious adverse event, death or treatment emergent adverse events leading to withdrawal from the trial in either the study group or the control group. The adverse events included, among others, urinary tract infection, urethral stricture and urinary frequency. The safety analysis was performed on the safety set. According to the trial results, there was no significant statistical difference in adverse events between the study group and the control group during the relevant follow-up periods, which demonstrated the safety profile of the Bladder Cryoablation System.

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The table below illustrates the number and percentage of the adverse events among the subjects during the follow-up periods after the procedures.

	Study Group (N=101)	Control Group (N=104)	P-value⁽¹⁾
Treatment emergent adverse events	50 (49.5%)	42 (40.4%)	0.189
Medical device-related treatment emergent adverse events	7 (6.9%) ⁽²⁾	0 (0.0%)	N/A
Surgical operation-related treatment emergent adverse events	20 (19.8%)	15 (14.4%)	0.306
Serious adverse events	3 (3.0%)	4 (3.8%)	>0.999
Medical device-related serious adverse events	0 (0.0%)	0 (0.0%)	N/A
Surgical operation-related serious adverse events	0 (0.0%)	2 (1.9%)	0.498

Notes:

- (1) P-value indicates the level of statistical significance. A p-value less than 0.05 is statistically significant while a p-value higher than 0.05 is not statistically significant.
- (2) All of these device-related adverse events were mild or moderate, five of which were also related to surgical operations.

Efficacy Indicators

The efficacy of the Bladder Cryoablation System was primarily evaluated by comparing the clinical success rate in the study group with the control group at the relevant follow-up time after the procedures. Secondary efficacy indicators included the duration of indwelling catheterization after the initial TURBT and tumor progression. The primary efficacy indicator was assessed on both the FAS and PPS, and the secondary efficacy indicators were assessed on the FAS. According to the trial results, our Bladder Cryoablation System demonstrated non-inferiority to perfusion chemotherapy in terms of the primary efficacy indicator, namely the clinical success rate, and no statistically significant difference in both secondary efficacy indicators.

The chart below summarizes the efficacy indicators observed through follow-ups:

	Study Group	Control Group	P-value⁽⁴⁾
Primary efficacy indicator			
Clinical success rate ⁽¹⁾	91.5%	76.5%	0.009
	(N=82 for PPS)	(N=81 for PPS)	
	85.1%	61.5%	<0.001
	(N=101 for FAS)	(N=104 for FAS)	
Secondary efficacy indicators			
Duration of indwelling catheterization ⁽²⁾ (days)	5.1±2.30 (N=81)	5.2±2.83 (N=76)	0.763
Tumor progression ⁽³⁾	1.1% (N=93)	7.2% (N=83)	0.053

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Notes:

- (1) refers to the proportion of subjects without tumor residue observed through Re-TURBT or cystoscopy with biopsy at four to six weeks after the initial TURBT surgery in the total subjects.
- (2) refers to the duration of indwelling catheterization after the initial TURBT.
- (3) refers to the proportion of subjects with tumor progression.
- (4) P-value indicates the level of statistical significance. A p-value less than 0.05 is statistically significant while a p-value higher than 0.05 is not statistically significant.

Market Opportunity and Competition

According to Frost & Sullivan, the incidence of bladder cancer in China increased from 77.1 thousand in 2016 to 85.7 thousand in 2020 at a CAGR of 2.5%, and is expected to further grow to 117.6 thousand in 2030. As NMIBC accounts for approximately 75% of all bladder cancer incidences, the number of people with NMIBC in China is about 64.4 thousand in 2020, and is expected to reach 88.6 thousand by 2030. According to Frost & Sullivan, TURBT is the first-line treatment for NMIBC, and the number of NMIBC patients treated with TURBT in China was approximately 55.1 thousand in 2020, and is expected to increase to 82.9 thousand by 2030. On top of the above, the 5-year recurrence rate after initial TURBT is about 60%. Such patients are in need of new treatment modalities that can address the high recurrence rate.

The market of bladder cryotherapy devices in China is still in its early stage of development, with growth potentials. Cryoablation, as an adjuvant therapy with TURBT for bladder tumors, has various potential benefits. Synthesizing expert interviews, Frost & Sullivan predicts that by 2030, the number of patients expected to receive cryotherapy after TURBT will be about 37.4 thousand in 2030, and the volume of relevant cryotherapy procedures in 2030 will be about 44.9 thousand. Based on the above, Frost & Sullivan further predicts that the market size of interventional cryotherapy catheters for the treatment of bladder cancer in China will grow significantly to reach RMB355.7 million in 2030, with a CAGR of 42.3% from 2025 to 2030.

For a detailed description of market opportunities and competitive landscape of our Bladder Cryoablation System, including the basis for the estimated market growth, see “Industry Overview—The NOTES Interventional Cryotherapy Device Market—The Bladder Cancer Interventional Cryotherapy Device Market” in this document.

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Material Communication With Competent Authorities

In June 2016, the cryoablation catheter of the Bladder Cryoablation System was recognized as an “innovative medical device” by the NMPA, making it eligible for an expedited approval process in accordance with the *Special Procedures for Examination and Approval of Innovative Medical Devices* (創新醫療器械特別審查程序) in China. For details, see “Regulatory Overview—Laws and Regulations Relating to Administration of Medical Devices—Special Examination Procedures for Innovative Medical Devices (“**Green Path**”)” in this document. We believe that the cryoablation catheter of the Bladder Cryoablation System was recognized as “innovative medical device” by the NMPA primarily due to its innovation and novelty as well as significant clinical value. In particular, the cryoablation catheter of the Bladder Cryoablation System was one of the world’s first intracavitary cryoablation catheters dedicated to the treatment of bladder cancer, according to Frost & Sullivan. Its innovative structures, such as the concave balloon and buffer tube at the distal end of the catheter, allows for effective ablation in a large area with enhanced safety. For details of the product features of the Bladder Cryoablation System, see “—Product Structure and Features” in this section. In light of the concurrent review of the cryoablation catheter and cryoablation equipment, we believe that the Bladder Cryoablation System as a whole can benefit from the review advantages under the “Green Path” designation.

We completed the record filings (備案) for the multi-center, randomized, parallel and controlled clinical trial for the Bladder Cryoablation System in August 2017 (for three clinical trial centers), October 2017 (for two clinical trial centers), September 2018 (for one clinical trial center), and November 2018 (for one clinical trial center), respectively, with the Zhejiang MPA pursuant to *Article 26 of the Regulations on Supervision and Administration of Medical Devices* (《醫療器械監督管理條例》), and initiated such clinical trial in November 2017. We have followed the clinical trial protocol filed with the Zhejiang MPA throughout the whole clinical trial process.

After completing the clinical trial, we submitted the registration application for our Bladder Cryoablation System with the NMPA in May 2021. In June 2021, the NMPA formally accepted our application, and issued a *Notice of Acceptance* (受理通知書) to us. In September 2021, the Center for Medical Device Evaluation of the NMPA (國家藥品監督管理局醫療器械技術審評中心) (the “**CMDE**”) issued a *Notice of Requests for Supplemental Application Materials* (醫療器械補正資料通知) to us, requiring us to provide certain supplemental application materials that include, among others, (i) more detailed description of the product’s design and mechanism of action, (ii) details of the product’s technical requirements such as the strength of connection between components, balloon volume and scientific basis for key indicators selection, and (iii) more detailed analyses of clinical trial data, such as benefits of this products observed during follow-ups, information on subjects who did not receive treatment after randomization and the basis for setting relevant parameters. In November 2021, we submitted all the supplemental application materials as requested in such notice in one go. Our PRC Legal Adviser is of the view that such request for supplemental application materials will not hinder the NMPA’s review process for registration approval. On December 29, 2021, we conducted a face-to-face interview (the “**December 29 NMPA Interview**”) with an official of the NMPA (the “**NMPA Official**”), with representatives from the Joint Sponsors, our PRC Legal Adviser and the Joint Sponsors’ PRC legal adviser present. During the December 29 NMPA Interview, the NMPA Official confirmed, among other things, that (i) the Bladder Cryoablation System is a Class III medical device under the classification criteria of the NMPA; (ii) the clinical trial for the Bladder Cryoablation System had been successfully completed; (iii) we were required to conduct such clinical trial prior to filing the registration application for the Bladder Cryoablation System, and such clinical trial forms a key part of the application required by the NMPA; (iv) to his knowledge, the reviewing process for the Bladder Cryoablation System has been

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carried out smoothly, and there is no substantive legal or administrative impediment for us to obtain the registration certificate for such medical device and to commence sales for it thereafter; and (v) the NMPA has no objection for us to proceed to further clinical trials for the Bladder Cryoablation System (including but not limited to post-launch clinical trials). Our PRC Legal Adviser is of the view that the NMPA is a competent authority and the NMPA Official being interviewed is competent, to provide the aforementioned confirmations. We had received the NMPA approval for the Bladder Cryoablation System in June 2022. As of the Latest Practicable Date, other than the above, we had not had any material regulatory communication with the NMPA or its local counterparts regarding the Bladder Cryoablation System, and there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approval for the Bladder Cryoablation System.

Commercialization Strategies

We expect to make the following efforts to enhance market promotion for the Bladder Cryoablation System: (i) selecting suitable target departments and markets. Specifically, we will initially introduce our Bladder Cryoablation System to top Class III hospitals in provincial capitals or tier-one cities such as Beijing and Shanghai, and use this as a foundation for setting up benchmark hospitals and physician training centers in various locations. We will then introduce the Bladder Cryoablation System to the eligible hospitals in lower tier cities in China through providing training programs to physicians and organizing academic conferences; (ii) participating in or holding academic conferences and salons (e.g., China Bladder Cancer Forum (中國膀胱癌高峰論壇) and National Urological Academic Conference (全國泌尿科學術年會)), carrying out physician training in various locations (in particular, offering multiple training sessions per year in Beijing, Shanghai, Wuhan and other cities to provide hands-on training in animals and clinical surgery) and publishing additional research paper comprising of real-world clinical data based on further R&D activities to enhance the market acceptance and penetration; (iii) determining appropriate ex-factory prices and end-user prices with reference to a number of factors, such as prices of other products utilized by the same departments, costs and market demands, and industry practice. We will set the price that we believe can help to quickly capture the market while ensuring profitability, which will be generally in line with the prices of medical devices for similar therapeutic effects for use in the urology department, so that patients will still be able to afford the cost of this treatment. As of the Latest Practicable Date, the Bladder Cryoablation System was not covered by any government reimbursement program or private health insurance, as this product is quite innovative and has not yet been commercialized. After the Bladder Cryoablation System is commercialized, along with an increase in market acceptance, product sales, and more clinical data to support its efficacy, we will apply for inclusion in the government medical insurance reimbursement list or private insurance reimbursement list; and (iv) adopting a distributorship model, and expanding sales network through our own sales and marketing team and our distributors. We expect annual marketing promotion costs for the Bladder Cryoablation System to be around RMB6 million in 2023, rising to around RMB13 million in 2025 as sales volume increases and sales network expands.

We will continue to adopt a distributorship model, and will sell the Bladder Cryoablation System to hospitals primarily through distributors. When introducing the Bladder Cryoablation System to hospitals, the cryoablation equipment will first be sold in bundled with the cryoablation catheter. In the future we expect to generate recurring revenue through sales of cryoablation catheters used in conjunction with the cryoablation equipment.

For pricing strategies, see the paragraphs headed “— Sales and Marketing — Pricing” in this section.

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Further Development Plan

Since the clinical trial for the Bladder Cryoablation System did not include long-term follow-up visits, there are currently no long-term follow-up clinical data to demonstrate whether this product significantly reduces tumor recurrence at a later stage. As such, we plan to initiate post-launch clinical studies and conduct three- to five-year follow-ups for a sizable pool of patients who use the Bladder Cryoablation System to monitor the real-world clinical data and further evaluate its safety and efficacy. In particular, we intend to design and finalize the clinical trial protocol, as well as engage the CRO, in 2023, to enroll patients from 2024 to 2027, and to conduct follow-up visits from 2025 to 2028. The post-launch studies will focus on assessing the long-term efficacy of the Bladder Cryoablation System on a large number of patients, and it is expected to involve approximately 30 clinical trial institutions, with 600 to 800 patients enrolled covering approximately 20 cities.

We also plan to sponsor and initiate the clinical trial required for the registration of the Bladder Cryoablation System in Europe. In particular, we expect to update the product design in accordance with applicable European standards and conduct design verification from 2022 to 2023, to complete the relevant clinical trial from 2024 to 2026, to submit the CE Mark registration application and obtain the approval from 2027 to 2028, and to commercialize the product in Europe shortly after receiving the approval in 2028. Since the R&D and registration activities overseas were still at an early stage, as of the Latest Practicable Date, we had no material communication with the competent authorities overseas. If we have any consultations with the competent authorities overseas in the future, we will conduct our overseas R&D activities and registration activities in accordance with such consultations.

We intend to expand the indication of the Bladder Cryoablation System from NMIBC to muscle invasive bladder cancer, to remove tumor residue for more serious and advanced stage of bladder cancer with cryotherapy and achieve bladder preservation following TUBRT. For the indication expansion, we expect to discuss the clinical trial protocol with principal investigators, select the CRO, SMO and clinical trial institutions and finalize the clinical trial protocol from 2023 to 2025. Afterwards, we will initiate related clinical trial preparations, such as preparing ethical committee applications. The clinical trial is expected to enroll approximately 200 patients, involving multiple clinical trial institutions, with a follow-up period for about one year. We plan to enroll the first patient for this clinical trial in 2026, and expect to complete patient enrollment and follow-up visits by 2029. Subsequently, we will conduct statistical analysis, issue a final clinical trial report and prepare registration application. We expect to obtain the approval for commercialization in China around 2030. We may consider conducting R&D and registration activities for expanding the indications overseas after receiving CE Mark for the product with the present indication.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR BLADDER CRYOABLATION SYSTEM SUCCESSFULLY.

2. *Endoscopic Clip for Anastomosis*

Our Endoscopic Clip for Anastomosis (內鏡吻合夾) is a self-developed anastomotic device for closure (閉合治療) of soft tissue in digestive tract. It is indicated for the closure treatment of bleeding, perforation, and tissue defects in digestive tract, and in particular, is suitable for treating perforation in gastrointestinal endoscopic surgery and endoscopic full-thickness closure (全層內鏡閉合) after NOTES. Its addressable patients primarily include the patients with acute gastrointestinal bleeding, ulcerative or medically induced perforations, or those undergoing endoscopic tissue removal procedures. This product

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candidate offers various benefits, such as its large clamping scope and strong clamping force, and it is detachable to facilitate the clip removal and avoid secondary damage to the tissue. This product is one of the OTS Clips approved for commercialization in China. For details of its competitive landscape, see “Industry Overview—The Endoscopic Clip Market” in this document.

Our Endoscopic Clip for Anastomosis is a Class II medical device under the classification criteria of the NMPA. We initiated a prospective, multi-center, and single-arm target value clinical trial for the Endoscopic Clip for Anastomosis on 99 human subjects in June 2020, and this clinical trial was completed in November 2021. We submitted the registration application for our Endoscopic Clip for Anastomosis with the Zhejiang MPA in November 2021, and received the Zhejiang MPA approval for this product candidate in August 2022. We commercialized this product in October 2022.

Product Structure and Features

The Endoscopic Clip for Anastomosis is composed of a releaser (釋放器), a clamping cap (施夾帽), an anastomotic clamp (吻合夾), and wire hooks (線鉤). The core component is the detachable anastomotic clamp (吻合夾) located inside the clamping cap, which consists of two engagement parts (咬合件) made of nickel-titanium alloys and bound by medical stainless steel wires. The clamping cap can be placed at the distal end of the gastrointestinal endoscope, where the anastomotic clamp can be activated at the target location in the digestive tract to instantly close the target tissue, and can be quickly disassembled and removed after the tissue is healed.

Diagram 1 below illustrates each components of the Endoscopic Clip for Anastomosis, and diagram 2 below illustrates the use of the Endoscopic Clip for Anastomosis together with a gastrointestinal endoscope:

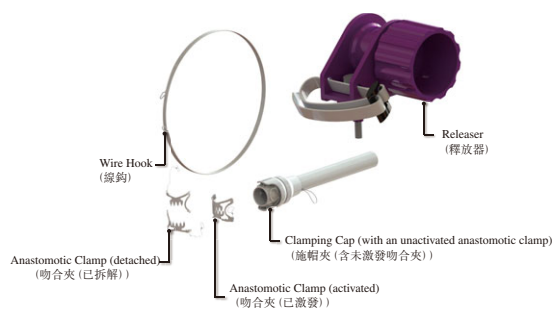


Diagram 1

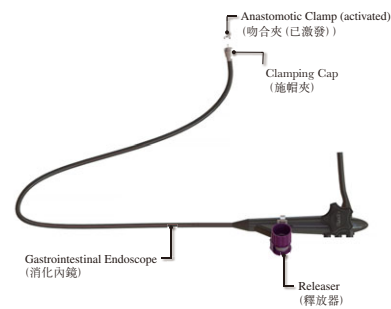


Diagram 2

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Key features and competitive advantages of the Endoscopic Clip for Anastomosis are summarized below:

- This product is made of nickel-titanium alloy material and medical stainless steel, with good elasticity and biocompatibility as well as strong clamping force. It is easy to operate for physicians and typically requires a short operation time;
- It can clamp the full thickness of the digestive tract and grasp a large range of tissues. In particular, compared to through-the-scope clips (“**TTS Clips**”), the Endoscopic Clip for Anastomosis has a wider clamping range and can achieve full endoscopic closure (內鏡下全層閉合), with results comparable to surgical sutures; and
- Its anastomotic clamp has a separable structure that allows for disassembly within the body before removal from the body, thus significantly reducing the difficulty of removing the anastomotic clamp. Specifically, the Endoscopic Clip for Anastomosis can be easily disassembled and removed when the tissue has healed or when the clamping position is not ideal, without interfering with the operation or remaining in the patient’s body for a long time. In addition, the space between engagement parts (咬合件) of its anastomotic clamp (吻合夾) can prevent tissue necrosis.

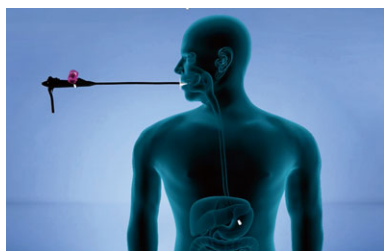
Risks associated with this product primarily include the risks related to the release of the anastomotic clamp at the wrong site and incomplete haemostasis or closure due to misuse by physicians, and the risks related to the endoscopic procedure.

Operation Procedure and Mechanism of Action

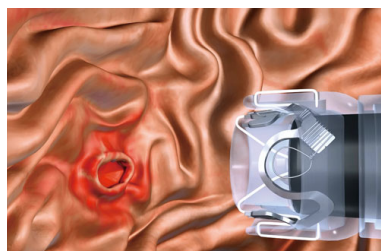
During the procedure, the anastomotic clamp is installed in an open state inside the clamping cap. The clamping cap is placed at the apex of the endoscope to enter the patient’s digestive tract, as shown in figures (1) and (2) below. The tissue to be closed is grabbed into the cavity of the clamping cap with the aid of negative pressure suction or other instruments, as shown in figure (3) below. The physician then pulls the pulling wires to release the anastomotic clamp, as shown in figure (4) below. At the releasing moment, the anastomotic clamp returns to the occluded state to close the tissue. The anastomotic clamp comprises two nickel-titanium alloy engagement parts (咬合件) that are bound by medical stainless steel wires. The clamping force is generated by the elastic deformation of the nickel-titanium alloy engagement parts, and the stainless steel wires connect the two engagement parts into a single unit by means of binding connection. In the occluded state of the anastomotic clamp, the engagement parts are the bundled, the wires serve to hold the engagement parts in place and transmit the clamping force. After the target tissue is healed, the anastomotic clamp can be removed either through natural dislodgment and excretion or through removal procedure performed by the physician. During the removal procedure, the physician unfastens the binding wires through a channel of the endoscope, as shown in figures (5) and (6) below. When the binding wires are dismantled, engagement parts are separated and the wires pull the engagement parts and facilitate the detach of the anastomotic clamp. As a result, the anastomotic clamp will be detached into two parts and removed separately.

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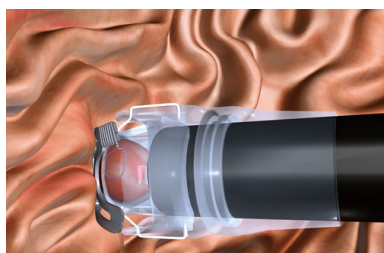
The figures below illustrate the key steps of the operation procedure:



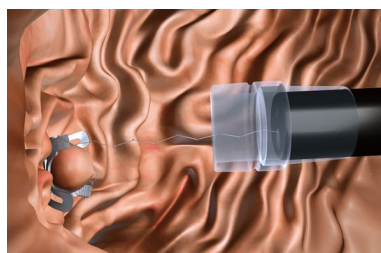
(1)



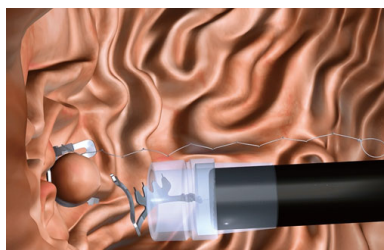
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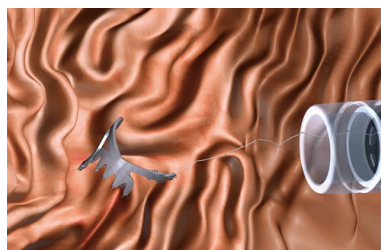
(3)



(4)



(5)



(6)

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Key R&D and Registrational Activities

We sponsored all the clinical trials for the Endoscopic Clip for Anastomosis in China through our subsidiary, Ningbo SensCure. For details of our roles and responsibilities in the R&D and the conduct of clinical trials, see “—Research and Development—Product Development” and “—Research and Development—Clinical Trials” in this section. The following table illustrates the key R&D and registrational activities related to the Endoscopic Clip for Anastomosis:

R&D activities	Nature	Initiation Date	Completion Date
Type testing	Pre-clinical product testing	June 2019	November 2019
An animal study on pigs	Pre-clinical animal study	July 2019	September 2019
A prospective, multi-center, and single-arm target value clinical trial	Human clinical trial	June 2020 ⁽¹⁾	November 2021 ⁽²⁾

Registrational activities	Relevant Authority	Submission Date	Approval Date
“Green Path” application ⁽³⁾	Zhejiang MPA	October 2019	November 2019
Registration application	Zhejiang MPA	November 2021	August 2022

Notes:

- (1) The initiation date of this clinical trial refers to the date on which the first patient was enrolled according to the clinical trial protocol.
- (2) The completion date of this clinical trial refers to the date on which the final clinical trial report was issued.
- (3) Refers to an application for the designation of “innovative medical device” and admittance to the relevant expedited approval process.

Pre-clinical Animal Study

We started the animal study of the Endoscopic Clip for Anastomosis in July 2019 and finished it in September 2019. Six pigs participated in the trial. We first created gastric perforations in the pigs and then used the Endoscopic Clip for Anastomosis to treat the perforations. At 30 days following the closure treatment, all of the pigs underwent removal procedure to withdraw the implanted clips. Follow-up evaluations were conducted up to 30 days after the removal procedure.

A total of 12 Endoscopic Clips for Anastomosis were implanted in six pigs, with a 100% immediate surgical success rate. In the removal procedure, all the implanted clips were withdrawn successfully. No laceration or ulceration of the wound tissue has been observed in the follow-up evaluations, and pathology showed good healing of the whole layer. Therefore, the animal study showed that the Endoscopic Clip for Anastomosis meets the requirements of tissue closure and haemostasis, and validated the safety and efficacy of the Endoscopic Clip for Anastomosis.

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Clinical Trial

We initiated a prospective, multi-center, and single-arm target value clinical trial for the Endoscopic Clip for Anastomosis in June 2020 to evaluate its safety and efficacy for endoscopic soft tissue closure. This clinical trial was completed in November 2021. Based on the final clinical trial report issued in November 2021, our Endoscopic Clip for Anastomosis demonstrated good safety and efficacy results.

A total of 99 eligible subjects were enrolled in the clinical trial at four hospitals, led by Zhongshan Hospital, Fudan University (復旦大學附屬中山醫院). The enrolled subjects received the closure with our Endoscopic Clip for Anastomosis for their upper gastrointestinal perforation or bleeding. The primary endpoint of the clinical trial was the clinical success rate of the closure. After the closure, the enrolled subjects were followed up (i) before discharge from the hospital (within 7 days after the closure), (ii) at the removal of anastomotic clamp (within 30 days after the closure), (iii) 30 days (± 7 days) after the closure, and (iv) 60 days (± 7 days) after the closure.

Among the 99 enrolled subjects, 93 subjects were included in the FAS, 92 subjects were included in the PPS, and 99 subjects were included in the safety set. The efficacy indicators were assessed on both the FAS and PPS, while the safety analysis was performed on the safety set. All of the subjects for the clinical trial met the following conditions:

- the subject is aged between 18 and 70 years old;
- the subject or his or her guardian understands the purpose of the trial, voluntarily participates in this trial and provides signed informed consent;
- the subject has at least one of the following clinical conditions for which endoscopic soft tissue closure is proposed:
 - (i) defects or perforations created during endoscopic excisional treatment of tumors or other lesions of the upper gastrointestinal tract that require closure of the wound with a metal clip; or
 - (ii) acute perforation, non-variceal bleeding or anastomotic leak of the upper gastrointestinal tract resulting from various causes, which is planned to be treated by endoscopic closure.

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Safety Indicators

The safety of the Endoscopic Clip for Anastomosis was evaluated by the incidence of device-/ procedure-related adverse events (器械/手術相關不良事件發生率), the incidence of serious adverse events (嚴重不良事件發生率) and the all-cause mortality rate (全因死亡率). The incidence of device-/procedure-related adverse events refers to the number of subjects who experience device- or procedure-related adverse events during the study as a proportion in all the subjects. The incidence of serious adverse events refers to the number of subjects who have serious adverse events during the study as a percentage in all the subjects. According to the trial results, the incidence of device- or procedure-related adverse events and the incidence of serious adverse events were relatively low and the all-cause mortality rate was nil, showing that our Endoscopic Clip for Anastomosis had a good safety profile. The table below set out details of safety indicators:

	Safety Set (N=99)
Treatment emergent adverse events ⁽¹⁾	54 (54.5%)
Device- or procedure-related adverse events ⁽²⁾	40 (40.4%)
Serious adverse events ⁽³⁾	5 (5.1%)
All-cause mortality	0 (0.0%)

Notes:

- (1) Refers to the adverse events that occurred or were exacerbated during the trial. The majority of the treatment emergent adverse events in this clinical trial were mild, primarily fever and constipation.
- (2) Refers to the treatment emergent adverse events related to the device or procedure. In this clinical trial, one subject had an adverse event possibly related to the device but not related to the procedure, which was a mild adverse event of esophageal bleeding; 38 subjects had adverse events definitely or possibly (as the case may be) related to the procedure but not related to the device; and one subject had an adverse event possibly related to the procedure and possibly related to the device, which was a serious adverse event further elaborated in note (3) below.
- (3) In this clinical trial, five subjects experienced a total of five serious adverse events. Three serious adverse events were definitely unrelated to the device and the procedure, including increased dyspepsia, gallbladder stones with acute attacks of chronic cholecystitis and oozing fluid from stomach antrum; one serious adverse event was likely unrelated to the device and possibly related to the procedure, which was gastrojejunal ulcer with bleeding and perforation; and one serious adverse event was possibly related to the procedure and possibly related to the device. For this subject, a portion of the anastomotic clamp was hidden by excessive tissue growth and thus could not be withdrawn during the removal procedure. Additional removal procedures were conducted and the remaining portion of the anastomotic clap had been successfully removed.

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Efficacy Indicators

The primary endpoint of the clinical trial was the clinical success rate of the closure (閉合治療臨床成功率). The secondary efficacy indicators of the clinical trial included the technical success rate of the closure (閉合治療技術成功率), the re-perforation/re-hemorrhage rate at the target lesion (靶病變再次出現穿孔/出血比例), the success removal rate of anastomotic clip (吻合夾取出成功率) and the target lesion reintervention rate (靶病變再次干預率). The table below set out details of efficacy indicators:

	FAS	PPS
Primary endpoint		
Clinical success rate of the closure ⁽¹⁾	91 (97.8%; N=93)	91 (98.9%; N=92)
Secondary efficacy indicators		
Technical success rate of the closure ⁽²⁾	93 (100.0%; N=93)	92 (100.0%; N=92)
Re-perforation/re-hemorrhage rate at the target lesion ⁽³⁾	1 (1.1%; N=93)	1 (1.1%; N=92)
Success removal rate of anastomotic clip ⁽⁴⁾	81 (98.8%; N=82)	81 (98.8%; N=82)
Target lesion reintervention rate ⁽⁵⁾	1 (1.1%; N=93)	1 (1.1%; N=92)

Notes:

- (1) refers to the proportion of subjects with technical success of the closure (閉合治療技術成功) who experience good lesion healing after 30 days of postoperative clinical assessment and no further endoscopic or surgical intervention on the target lesion, as well as no device- or procedure-related serious adverse events. For this indicator, the 95% CI for FAS was 92.4% to 99.7%, and the 95% CI for PPS was 94.1% to 100.0%, higher than the target value of 85%.
- (2) refers to the proportion of subjects who experience successful delivery and release of the Endoscopic Clip for Anastomosis at the target site, with immediate postoperative examination demonstrating complete closure of the wound without significant blood leakage and normal morphology and structure of the Endoscopic Clip for Anastomosis.
- (3) refers to the proportion of subjects with re-perforation/re-hemorrhage at the target lesion during the study.
- (4) refers to the proportion of subjects in whom the Endoscopic Clip for Anastomosis is successfully withdrawn safely from the body and there is no serious adverse event related to the operation or device, provided that the Endoscopic Clip for Anastomosis could be removed in the discretion of the investigator. Out of the 91 trial subjects with technical success of the closure, only 82 subjects' clinical data were collected and analyzed for this indicator, because nine subjects had their Endoscopic Clips for Anastomosis dislodged and naturally excreted and thus did not undergo the removal procedure.
- (5) refers to the number of subjects who have a successful closure procedure (閉合手術成功) but require reintervention for treatment under endoscopic or surgical procedures during the study as a percentage in all the subjects.

The trial results indicated a high clinical success rate for endoscopic soft tissue closure and a high technical success rate with few surgical complications and easy removal of the device, demonstrating the reliable efficacy of our Endoscopic Clip for Anastomosis.

Market Opportunity and Competition

According to Frost & Sullivan, the market size of endoscopic clips in China increased rapidly from RMB98.7 million in 2016 to RMB292.5 million in 2020, representing a CAGR of 31.2%; the market size of endoscopic clips in China is predicted to increase to RMB571.1 million in 2025 at a CAGR of 14.3% from 2020 to 2025 and further reach RMB1,124.4 million in 2030 at a CAGR of 14.5% from 2025 to 2030, as endoscopic clips are anticipated to become common in gastrointestinal surgery due to their benefits such as allowing for faster recovery than traditional drug hemostasis, and OTS Clips, which are priced higher than TTS Clips, are expected to increase its market share.

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As of the Latest Practicable Date, there were 32 endoscopic clips commercialized in China, out of which, three products were OTS Clips and the other 29 products were all TTS Clips, according to Frost & Sullivan. Our Endoscopic Clip for Anastomosis is one of the OTS Clips approved for commercialization in China.

For a detailed description of the addressable patient population, disease landscape and treatment paradigm, as well as market opportunities and competitive landscape of our Endoscopic Clip for Anastomosis, see “Industry Overview—The Endoscopic Clip Market” in this document.

Material Communication With Competent Authorities

In November 2019, the Endoscopic Clip for Anastomosis was recognized as an “innovative medical device” by the Zhejiang MPA, making it eligible for an expedited approval process in accordance with the Special Procedures for Examination and Approval of Innovative Medical Devices (創新醫療器械特別審查程序) in China. For details, see “Regulatory Overview—Laws and Regulations Relating to Administration of Medical Devices—Special Examination Procedures for Innovative Medical Devices (“Green Path”)” in this document. We believe that the Endoscopic Clip for Anastomosis was admitted into the Green Path for Innovative Medical Devices by the Zhejiang MPA mainly due to its innovation and novelty as well as significant clinical value. Specifically, the Endoscopic Clip for Anastomosis has a separable structure which allows for easier clip removal. Compared to non-detachable endoscopic clips, this product candidate can lower clinical risks caused by inaccurate release of anastomotic clips or inability to remove clips after healing, which brings significant benefits to patients. For details of the product features of the Endoscopic Clip for Anastomosis, see “—Product Structure and Features” in this section.

We completed the record filings (備案) for the prospective, multi-center, and single-arm target value clinical trial for the Endoscopic Clip for Anastomosis in March 2020 (for one clinical trial center), May 2020 (for one clinical trial center), July 2020 (for one clinical trial center), and August 2020 (for one clinical trial center), respectively, with the Zhejiang MPA, and initiated such clinical trial in June 2020. We have followed the clinical trial protocol filed with the Zhejiang MPA throughout the whole clinical trial process.

After completing the clinical trial, we submitted the registration application for our Endoscopic Clip for Anastomosis with the Zhejiang MPA in November 2021. The Zhejiang MPA formally accepted the application, and issued a Notice of Acceptance (受理通知書) to us in the same month. On December 29, 2021, we conducted a face-to-face interview, namely the December 29 NMPA Interview, with the NMPA Official, with representatives from the Joint Sponsors, our PRC Legal Adviser and the Joint Sponsors’ PRC legal adviser present. During the December 29 NMPA Interview, the NMPA Official confirmed, among other things, that (i) the Endoscopic Clip for Anastomosis is a Class II medical device under the classification criteria of the NMPA; (ii) the clinical trial for the Endoscopic Clip for Anastomosis had been successfully completed; (iii) we were required to conduct such clinical trial prior to filing the registration application for the Endoscopic Clip for Anastomosis, and such clinical trial forms a key part of the application required by the NMPA; (iv) to his knowledge, the reviewing process for the Endoscopic Clip for Anastomosis has been carried out smoothly, and there is no substantive legal or administrative impediment for us to obtain the registration certificate for such medical device and to commence sales for it thereafter; and (v) the NMPA has no objection for us to proceed to further clinical trials for the Endoscopic Clip for Anastomosis (including but not limited to post-launch clinical trials). Our PRC Legal Adviser is of the view that each of the NMPA and the Zhejiang MPA is a competent

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authority, and the NMPA Official being interviewed is competent, to provide the aforementioned confirmations. In January 2022, the Zhejiang MPA issued a *One-off Notification Letter* (一次性告知書) requiring us to provide certain supplemental application materials. The Company did not encounter any material impediment when preparing the supplemental application materials. On June 6, 2022, the supplemental application materials had been successfully submitted to the Zhejiang MPA. We had received the Zhejiang MPA approval for the Endoscopic Clip for Anastomosis in August 2022. Other than the above, we have not had any material regulatory communication with the NMPA or its local counterparts regarding the Endoscopic Clip for Anastomosis, and there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approval for the Endoscopic Clip for Anastomosis as of the Latest Practicable Date.

Commercialization Strategies

We expect to take the following marketing measures to enhance market promotion for the Endoscopic Clip for Anastomosis: (i) seeking cooperation with KOLs in each regional market; (ii) collaborating with KOLs and top medical centers to establish our regional training center and carry out training and academic activities. In particular, we plan to participate in or hold academic conferences and salons in various locations (e.g., National Academic Conference on Digestive System Diseases (全國消化系統病學術會議) and Shanghai Gastroenterology Academic Conference (上海市消化學術年會)), provide multiple training sessions per year in Beijing, Shanghai, Wuhan and other cities to provide hands-on training in animals and clinical surgery; (iii) conducting larger-scale clinical trials to obtain more real-world clinical data, publishing additional research paper comprising of real-world clinical data based on further R&D activities to enhance the market acceptance, and leveraging the advantages of this product, such as wide clamping range and full thickness closure, to introduce it to hospitals and increase market share; and (iv) improving our marketing network by spreading the professional sales staff nationwide, and providing sufficient professional training to our distributors with respect to the features, usage and functions of this product. We will continue to adopt a distributorship model, and will sell the Endoscopic Clip for Anastomosis to hospitals primarily through distributors.

For pricing strategies, see the paragraphs headed “— Sales and Marketing — Pricing” in this section.

Further Development Plan

We plan to initiate post-launch clinical studies and conduct one- to two-year follow-ups for patients who use the Endoscopic Clip for Anastomosis to further evaluate its safety and efficacy. In particular, we intend to design and finalize the clinical trial protocol, as well as engage the CRO, in 2023, to enroll patients from 2024 to 2026, and to conduct follow-up visits from 2025 to 2027. The post-launch studies will focus on evaluating the long-term efficacy of the Endoscopic Clip for Anastomosis in the closure treatment of perforation, bleeding and tissue defects, and it is expected to involve approximately 12 clinical trial institutions, with 200 to 500 patients enrolled in approximately ten cities. Since the R&D and registration activities overseas were still at an early stage, as of the Latest Practicable Date, we had no material communication with the competent authorities overseas. If we have any consultations with the competent authorities overseas in the future, we will conduct our overseas R&D activities and registration activities in accordance with such consultations.

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We also plan to sponsor and initiate the clinical trial required for the registration of the Endoscopic Clip for Anastomosis in Europe. In particular, we expect to update the product design in accordance with applicable European standards and conduct design verification in 2022, to complete the relevant clinical trial from 2023 to 2024, to submit the CE Mark registration application in 2025, and to commercialize the product in Europe shortly after receiving the approval in 2026. We expect that our continuing R&D efforts in relation to the Endoscopic Clip for Anastomosis would primarily focus on the closure treatment of soft tissue in digestive tract, and we currently do not have plans to expand the indication of this product candidate.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR ENDOSCOPIC CLIP FOR ANASTOMOSIS SUCCESSFULLY.

Other Products and Product Candidates

Vascular Interventional Cryotherapy Products

1. AF Cryoablation System

Our AF Cryoablation System (心臟冷凍消融系統) is a self-developed cryoablation system indicated for the treatment of paroxysmal atrial fibrillation. The AF Cryoablation System treats atrial fibrillation by freezing and destroying abnormal heart tissues that create irregular heartbeats in a minimally invasive procedure. For details, see “Industry Overview—The Vascular Interventional Cryotherapy Device Market—Atrial Fibrillation and Treatment” in this document.

Our AF Cryoablation System is a Class III medical device under the classification criteria of the NMPA. We initiated a prospective, multi-center, single-arm target value clinical trial for the AF Cryoablation System on 176 human subjects in October 2019 to evaluate its efficacy and safety in the treatment of paroxysmal atrial fibrillation. We had completed this clinical trial and issued the final clinical trial report in May 2022. We submitted the registration application for our AF Cryoablation System with the NMPA in July 2022, and currently expect to receive the NMPA approval for the AF Cryoablation System in or around the second quarter of 2023.

Product Structure

Our AF Cryoablation System consists of a cryoablation equipment (冷凍消融設備), a AF cryoablation catheter (房顫冷凍消融導管), a steerable sheath (可調彎鞘), and an intracardiac mapping catheter (心內標測導管) as described below.

Cryoablation Equipment (冷凍消融設備)

The cryoablation equipment mainly includes a freezing unit and a control system. Its primary function is to deliver cryogen to the AF cryoablation catheter. It achieves stable and controlled delivery of liquid nitrogen using multivariable coupling control (多變量耦合控制), a technology based on the pressure-temperature-flow three parameters that enables controlled regulation of cryogen. It also has a multi-dimensional safety monitoring system (多維安全監測系統) in place, including a fluid flow status monitoring system (流體流動狀態監測系統), a fluid leakage monitoring system (流體洩漏監測系統) and a system for preventing external liquid into the catheter, to ensure safety of use. The control system features a touch-screen control monitor, through which physicians can start and stop the flow of refrigerant during a procedure and manage patients’ data and therapy variables in a safe and efficient way.

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AF Cryoablation Catheter (房顫冷凍消融導管)

The AF cryoablation catheter is a flexible balloon catheter used in conjunction with the cryoablation equipment to ablate cardiac tissue for patients with atrial fibrillation. It mainly includes three parts: a device connection part, an operation control part and a blood contact part. During operation, the device connection part is connected to the interface of the cryoablation equipment, and the physician can hold the operation control part to control the movement of the cryoablation catheter. The blood contact component will be guided by the relevant imaging equipment to enter the blood vessel and allow the balloon to reach the designated area, and the outer surface of the blood contact part will be in direct contact with the blood.

Steerable Sheath (可調彎鞘)

The steerable sheath is a sheath used to help position the cryoablation catheter, which consists of a steerable sheath tube and dilator.

Intracardiac Mapping Catheter (心內標測導管)

The intracardiac mapping catheter is a diagnostic catheter used for mapping electrical conduction between the left atrium and pulmonary veins during the cryoablation procedure. It includes a single-use sterile intracardiac catheter and connecting pigtailed.

Diagram 1 below illustrates the cryoablation equipment of the AF Cryoablation System, and diagram 2 below illustrates the AF cryoablation catheter, the steerable sheath and the intracardiac mapping catheter of the AF Cryoablation System:

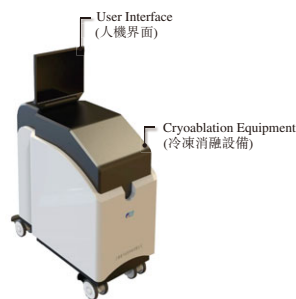


Diagram 1

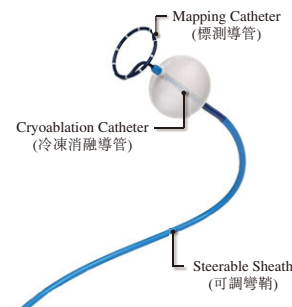


Diagram 2

Operation Procedure

Under conscious sedation or general anesthesia, the physician places a right ventricular electrode via the femoral vein route. Coronary sinus electrodes are placed via the femoral (or subclavian or internal jugular) vein route. Through the femoral vein route, procedural access is established. Single puncture of the interatrial septum is conducted to establish left atrial access. A pulmonary venogram is performed to show the pulmonary veins, and an appropriate size AF cryoablation catheter is selected according to the actual condition of the pulmonary veins. The septal puncture sheath is withdrawn through a guidewire and the adjustable curved catheter sheath is replaced into the left atrium. The intracardiac mapping catheter is placed into the AF cryoablation catheter, after which the entire system is placed into the left

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atrium via the adjustable curved sheath. The cryoballoon is inflated and dilated in the atrium and the pulmonary veins (antrum) are blocked. The degree of balloon occlusion is checked by intra-pulmonary venography. Pulmonary vein potentials can be recorded with an intracardiac mapping catheter prior to ablation.

The physician starts the freezing cycle to ablate target tissues. During the cryoablation, the cryoablation equipment provides and delivers the cryoablation refrigerant, liquid nitrogen, to the target area through the AF cryoablation catheter, causing extracellular ice and intracellular ice in the myocardial cells in the target area, which in turn leads to freezing damage to the myocardial cells, thus realizing the purpose of myocardial tissue ablation. The system rewarms after the cooling of cells. In the process of rewarming, ice crystal melting will cause intracellular recrystallization, which brings in further damage to the target myocardial cells, thereby reducing atrial fibrillation recurrence rate. Following the cryoablation treatment, the catheter and sheath will be removed and no permanent implant is left behind.

Key R&D and Registrational Activities

We sponsored all the clinical trials for the AF Cryoablation System. For details of our roles and responsibilities in the R&D and the conduct of clinical trials, see “—Research and Development—Product Development” and “—Research and Development—Clinical Trials” in this section. The following table illustrates the key R&D and registrational activities related to the AF Cryoablation System:

R&D activities	Nature	Initiation Date	Completion Date
Type testing	Pre-clinical product testing	June 2018	April 2019
An animal study on dogs	Pre-clinical animal study	October 2018	December 2018
A prospective, multi-center, single-arm target value clinical trial	Human clinical trial	October 2019 ⁽¹⁾	May 2022 ⁽²⁾

Registrational activities	Relevant Authority	Submission Date	Actual/Expected Approval Date
“Green Path” application ⁽³⁾	NMPA	May 2019	August 2019
Registration application	NMPA	July 2022	Second quarter of 2023

Notes:

- (1) The initiation date of this clinical trial refers to the date on which the first patient was enrolled according to the clinical trial protocol.
- (2) The completion date of this clinical trial refers to the date on which the final clinical trial report was issued.
- (3) Refers to an application for the designation of “innovative medical device” and admittance to the relevant expedited approval process.

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Pre-clinical Animal Study

We started the animal study on dogs for the AF Cryoablation System in October 2018 and finished it in December 2018. We assessed the safety of the AF Cryoablation System by observing the damages in extra-pulmonary tissues (e.g. esophagus and phrenic nerves), and assessed the efficacy of the AF Cryoablation System by observing electrical isolation in pulmonary veins.

In this animal study, cryoablation with our AF Cryoablation System had a high immediate success rate for achieving electrical isolation of pulmonary veins, with no serious complications observed during the procedure. Furthermore, there was no significant injury to esophageal mucosa or phrenic nerves in the animals immediately after the procedure or at one month after the procedure. Therefore, the animal study indicated the safety and efficacy of the AF Cryoablation System.

Clinical Trial

We initiated a prospective, multi-center, single-arm target value clinical trial in October 2019 to evaluate the effectiveness and safety of the AF Cryoablation System in the treatment of paroxysmal atrial fibrillation. A total of 176 subjects were enrolled and we conducted follow-ups with the subjects up to 12 months after the procedures. The clinical trial involved ten hospitals, led by Zhongshan Hospital, Fudan University (復旦大學附屬中山醫院). Based on the final clinical trial report issued in May 2022, our AF Cryoablation System demonstrated good safety and efficacy results.

The primary endpoints of the clinical trial included (i) the rate of treatment success at 12 months postoperatively, which refers to the absence of any atrial fibrillation, atrial flutter, or atrial tachycardia lasting not less than 30 seconds without taking antiarrhythmic drugs at three to 12 months after the procedures, and (ii) the immediate surgical success rate, defined as the number of subjects who successfully achieve electrical isolation in each pulmonary vein immediately following the procedures as a percentage of the total number of subjects. Among the 176 enrolled subjects, 172 subjects were included in FAS, 171 subjects were included in the PPS, and 176 subjects were included in the safety set.

All of the subjects for the clinical trial met the following conditions:

- the subject is aged between 18 and 75 years old;
- the subject is a patient with symptomatic paroxysmal atrial fibrillation;
- the subject has taken at least one Class I or Class III antiarrhythmic drug that is not effective, or the subject cannot tolerate the drug therapy; and
- the subject understands the purpose of the trial, and voluntarily participates in this trial and provides signed informed consent.

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Safety Indicators

The safety of the AF Cryoablation System was primarily evaluated by the all-cause mortality rate (全因死亡率), the incidence of device-/procedure-related adverse events (器械/手術相關不良事件發生率), and the incidence of serious adverse events (嚴重不良事件發生率). The incidence of device-/procedure-related adverse events refers to the number of subjects who experience device- or procedure-related adverse events during the clinical trial as a proportion in all the subjects. The incidence of serious adverse events refers to the number of subjects who have serious adverse events during the clinical trial as a percentage in all the subjects. The safety analysis was performed on the safety set.

According to the trial results, the all-cause mortality rate, the incidence of device- or procedure-related adverse events and the incidence of serious adverse events were relatively low, showing that our AF Cryoablation System has a good safety profile. The table below set out details of safety indicators:

	Safety Set (N=176)
Device-related adverse events ⁽¹⁾	4 (2.27%)
Procedure-related adverse events ⁽²⁾	44 (25.00%)
Serious adverse events ⁽³⁾	30 (17.05%)
All-cause mortality ⁽⁴⁾	1 (0.57%)

Notes:

- (1) Four subjects experienced the following adverse events that were considered possibly related to the device: one subject had a mild adverse event, which was skin allergy; two subjects had moderate adverse events, including subcutaneous hematoma and coronary artery spasm; and one subject had a moderate adverse event of phrenic nerve palsy and a serious event of phrenic nerve palsy which was further elaborated in note (3) below.
- (2) 44 subjects experienced adverse events possibly or definitely (as the case may be) related to the procedure, including 40 subjects that had mild or moderate adverse events possibly or definitely related to the procedure, primarily paroxysmal atrial fibrillation, skin allergy and phrenic nerve palsy; and four subjects that had serious adverse events possibly or definitely related to the procedure as further elaborated in note (3) below.
- (3) 30 subjects experienced serious adverse events after the procedure, including 26 subjects with serious adverse events unrelated to the device and the procedure; three subjects with serious adverse events definitely or likely unrelated to the device but definitely or possibly related to the procedure, which were pericardial effusion, vein thrombosis and vascular vagal response; one subject with a serious adverse event possibly related to the device and definitely related to the procedure, which was phrenic nerve palsy. This subject had been discharged from hospital as his conditions had been improved after treatment.
- (4) One subject died 7 months after the procedure. The cause of death was unknown and the investigator determined that it was not related to the device.

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Efficacy Indicators

The primary efficacy indicators of the clinical trial included (i) the rate of treatment success at 12 months postoperatively and (ii) the immediate surgical success rate. Secondary efficacy indicators primarily included the early-stage recurrence rate, late-stage recurrence rate, average duration of surgical operation per subject, average cryoablation duration per pulmonary vein, and average number of cryoablation treatments. The following table sets out details of major efficacy indicators:

	FAS	PPS
Primary efficacy indicators		
Rate of treatment success at 12 months postoperatively ⁽¹⁾	142 (82.56%; N=172)	142 (83.04%; N=171)
Immediate surgical success rate ⁽²⁾	168 (97.67%; N=172)	167 (97.66%; N=171)
Major secondary efficacy indicators		
Early-stage recurrence rate ⁽³⁾	25 (14.53%; N=172)	25 (14.62%; N=171)
Late-stage recurrence rate ⁽⁴⁾	23 (13.61%; N=169)	23 (13.61%; N=169)
Average duration of surgical operation per subject	120.37±31.08 min (N=172)	120.49±31.13 min (N=171)
Average cryoablation duration per pulmonary vein	4.16±1.83 min (N=673)	4.17±1.83 min (N=669)
Average number of cryoablation treatments per subject	6.35±1.81 (N=172)	6.36±1.81 (N=171)
Average number of cryoablation treatments per pulmonary vein	1.62±0.73 (N=673)	1.63±0.73 (N=669)

Notes:

- (1) Refers to the proportion of subjects who do not require arrhythmia medication and do not experience any events of atrial fibrillation, atrial flutter or atrial tachycardia of more than 30 seconds duration during follow-ups at three months to twelve months postoperatively. For this indicator, the 95% CI for FAS was 76.89% to 88.23% and the 95% CI for PPS was 77.42% to 88.67%, higher than the target value of 73%.
- (2) Refers to the proportion of subjects who successfully achieve electrical isolation in each pulmonary vein immediately following the procedures. For this indicator, the 95% CI for FAS was 94.15% to 99.36% and the 95% CI for PPS was 94.12% to 99.36%, higher than the target value of 90%.
- (3) Refers to the proportion of subjects who experience atrial fibrillation, atrial flutter or atrial tachycardia at three months postoperatively.
- (4) Refers to the proportion of subjects who experience atrial fibrillation, atrial flutter or atrial tachycardia at three months to twelve months postoperatively.

The trial results indicated that its primary efficacy indicators satisfied the target value and secondary efficacy indicators met clinical requirements, demonstrating the good efficacy of our AF Cryoablation System.

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While only patients with drug-refractory symptomatic paroxysmal atrial fibrillation were enrolled in the clinical trial of the AF Cryoablation System, this does not mean that when the product is approved by NMPA, the only indication approved would be drug-refractory recurrent symptomatic paroxysmal atrial fibrillation. According to Frost & Sullivan, atrial fibrillation is a quivering or irregular heartbeat which happens when abnormal electrical impulses suddenly start firing in the atria. The mechanism of action of cryoablation is to freeze and destroy abnormal heart tissues to block these irregular electrical signals and restore regular heartbeats. Although some paroxysmal atrial fibrillation (e.g., drug-refractory paroxysmal atrial fibrillation and recurrent paroxysmal atrial fibrillation) are harder to be treated than others (e.g., paroxysmal atrial fibrillation that can be easily controlled with drugs, new-onset paroxysmal atrial fibrillation, and non-symptomatic paroxysmal atrial fibrillation), the mechanism of action of the cryoablation therapy is still the same, and therefore the therapy can be used for the treatment of all these sub-types of paroxysmal atrial fibrillation. If clinical trials demonstrate that the AF Cryoablation System is a safe and effective treatment for drug-refractory recurrent symptomatic paroxysmal atrial fibrillation (which are relatively harder to be treated), then for the other sub-types of paroxysmal atrial fibrillation that are relatively easier to be treated, this product candidate would also be feasible.

In the clinical trial for the AF Cryoablation System, we enrolled patients with drug-refractory recurrent symptomatic paroxysmal atrial fibrillation in order to better demonstrate the product candidate's safety and effectiveness in treating paroxysmal atrial fibrillation, and also due to stronger incentives of patients with recurrent paroxysmal that have obvious symptoms and cannot be controlled by drugs to enroll in a clinical trial to test the safety and efficacy of a novel therapy. However, this does not mean that this product candidate cannot be used to treat paroxysmal atrial fibrillation patients that are relatively easier to be treated. As of the Latest Practicable Date, we were not aware of any legal or administrative requirements indicating that we have to conduct additional clinical trials on each sub-type of paroxysmal atrial fibrillation patients before obtaining the registration certificate for the product candidate with an indication covering those other sub-types of paroxysmal atrial fibrillation, and had not received any notification from the NMPA or any other regulatory authority that (i) the clinical data obtained from the clinical trial conducted for the AF Cryoablation System is inadequate, or that (ii) when the product candidate is approved, its indication would be limited only to drug-refractory recurrent symptomatic paroxysmal atrial fibrillation.

Market Opportunity and Competition

According to Frost & Sullivan, there is an accelerating population of atrial fibrillation patients in China. According to Frost & Sullivan, the number of atrial fibrillation patients in China has increased from 10.8 million in 2016 to 11.6 million in 2020, which is estimated to further climb to 16.6 million in 2030. The application of ablation therapy outperforms antiarrhythmic drug therapy in maintaining sinus rhythm and improving the patient's quality of life, according to Frost & Sullivan. Common ablation techniques include radiofrequency ablation, cryoablation and others. Cryoablation is one of the common ablation treatments for atrial fibrillation, particular for paroxysmal atrial fibrillation, according to Frost & Sullivan. Cryoablation offers various benefits over the other types of ablation treatment, such as ease of operation, low recurrence rate of atrial fibrillation, less pain during operation. See "Industry Overview—The Vascular Interventional Cryotherapy Device Market—Atrial Fibrillation and Treatment" in this document for more details.

The market size of atrial fibrillation cryotherapy catheters in China increased from RMB48.4 million in 2016 to RMB255.0 million in 2020 at a CAGR of 51.5%, according to Frost & Sullivan. Driven by the rising prevalence of atrial fibrillation and increasing penetration of cryoablation treatment, Frost & Sullivan estimates that the market size of atrial fibrillation cryotherapy catheters in China is expected to continue to grow to RMB5,103.0 million in 2030.

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As of the Latest Practicable Date, there was only one cryoablation device for the treatment of atrial fibrillation approved for commercialization in China, namely the Arctic Front Advance of Medtronic, according to Frost & Sullivan. We were one of the four companies conducting clinical trials in China for cryoablation devices for atrial fibrillation, and were the only one which uses low-pressure liquid nitrogen as cryogen based on public information, according to Frost & Sullivan.

For a detailed description of market opportunities and competitive landscape of our AF Cryoablation System, see “Industry Overview—The Vascular Interventional Cryotherapy Device Market—Atrial Fibrillation and Treatment” in this document.

Material Communication With Competent Authorities

In August 2019, the AF Cryoablation System was recognized as an “innovative medical device” by the NMPA, making it eligible for an expedited approval process in accordance with the Special Procedures for Examination and Approval of Innovative Medical Devices (創新醫療器械特別審查程序) in China. For details, see “Regulatory Overview—Laws and Regulations Relating to Administration of Medical Devices—Special Examination Procedures for Innovative Medical Devices (“Green Path”)” in this document. We completed the record filings (備案) for the prospective, multi-center, single-arm target value clinical trial for the AF Cryoablation System in July 2019 with the Shanghai MPA, and initiated such clinical trial in October 2019. We have provided the NMPA (and/or its local branches) with updates as to the progress of the clinical trial by promptly submitting reports of severe adverse events from time to time. On December 29, 2021, we conducted a face-to-face interview, namely the December 29 NMPA Interview, with the NMPA Official, with representatives from the Joint Sponsors, our PRC Legal Adviser and the Joint Sponsors’ PRC legal adviser present. During the December 29 NMPA Interview, the NMPA Official confirmed, among other things, that (i) the AF Cryoablation System is a Class III medical device under the classification criteria of the NMPA; (ii) we were required to conduct the clinical trial for the AF Cryoablation System prior to filing the registration application, and such clinical trial forms a key part of the application required by the NMPA; (iii) the confirmations he provided with respect to our Bladder Cryoablation System and our Endoscopic Clip for Anastomosis are also applicable, *mutatis mutandis*, to our AF Cryoablation System, and there is no need for us to arrange for another interview with the NMPA after we submit the product registration application for our AF Cryoablation System, in order to confirm that the NMPA has no objection for us to commence sales of the AF Cryoablation System; (iv) if the NMPA becomes aware of any substantive legal or administrative impediment for us to obtain the registration certificate for such medical device and to commence sales for it thereafter, the NMPA will notify us in a timely manner in accordance with the applicable laws and regulations; and (v) the NMPA has no objection for us to proceed to further clinical trials for the AF Cryoablation System (including but not limited to post-launch clinical trials). Our PRC Legal Adviser is of the view that the NMPA is a competent authority, and the NMPA Official being interviewed is competent, to provide the aforementioned confirmations. We submitted the registration application for our AF Cryoablation System with the NMPA in July 2022. Other than the above, we have not had any material regulatory communication with the NMPA or its local counterparts regarding the AF Cryoablation System, and we were not aware of any material concern raised by the NMPA or its local counterparts in connection with the AF Cryoablation System as of the Latest Practicable Date. Based on, among others, the December 29 NMPA Interview, we currently expect to receive the NMPA approval for the AF Cryoablation System in or around the second quarter of 2023.

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Further Development Plan

We plan to sponsor and initiate the clinical trial required for the registration of the AF Cryoablation System in Europe. In particular, we expect to update the product design in accordance with applicable European standards and conduct design verification from 2023 to 2024, to complete the relevant clinical trial and submit the CE Mark registration application from 2025 to 2027, and to obtain the approval from 2027 to 2028, and to commercialize the product in Europe shortly after receiving the approval in 2028. Since the R&D and registration activities overseas were still at an early stage, as of the Latest Practicable Date, we had no material communication with the competent authorities overseas. If we have any consultations with the competent authorities overseas in the future, we will conduct our overseas R&D activities and registration activities in accordance with such consultations.

In addition, we intend to expand the indication of the AF Cryoablation System from paroxysmal atrial fibrillation to persistent atrial fibrillation. For the indication expansion, we expect to finalize the initial clinical trial protocol and select the CRO from 2024 to 2025. We plan to complete patient enrollment and follow-up visits from 2025 to 2027. We expect to obtain the approval for commercialization in China around 2028. We may consider conducting R&D and registration activities for expanding the indications overseas after receiving CE Mark for the product with the present indication.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR AF CRYOABLATION SYSTEM SUCCESSFULLY.

2. *Cryo-RDN System*

Our Cryo-RDN System (Cryofocus 冷凍消融系統) is a self-developed cryoablation system designed for the treatment of hypertension. RDN is a minimally-invasive procedure intended to deliver energy to overactive nerves in the kidney, which is a cause of hypertension, so as to decrease their activity and treat hypertension. Our Cryo-RDN System delivers liquid nitrogen to the target area of the renal artery to perform circumferential ablation, which damages nerve tissues through the formation and rewarming of ice balls, thus achieving the treatment of hypertension. The Cryo-RDN System is a Class III medical device under the classification criteria of the NMPA. We aim to make this product candidate the world’s first cryoablation product that specifically focuses on the treatment of hypertension. For details, see “Industry Overview—The Vascular Interventional Cryotherapy Device Market—Hypertension and Treatment” in this document.

Product Structure

The Cryo-RDN System primarily consists of a cryoablation equipment (冷凍消融設備), a cryoablation catheter (冷凍消融導管) and a guiding catheter (導引導管). The cryoablation equipment mainly includes a freezing unit and a control system, and its major function is to deliver cryoablation refrigerant, namely liquid nitrogen, precisely to the catheter during a cryoablation procedure. Its control system features a touch-screen control monitor, through which physicians can start and stop the flow of refrigerant during a procedure and manage therapy variables in a safe and efficient way. The cryoablation catheter is a flexible balloon catheter designed to deliver liquid nitrogen to ablate target tissue. The guiding catheter is a single-use sterile guiding catheter used to provide an access channel to assist the delivery of the cryoablation catheter to target locations in the vascular.

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Diagram 1 below illustrates the cryoablation equipment of the Cryo-RDN System, and diagram 2 below illustrates the cryoablation catheter and the guiding catheter of the Cryo-RDN System:



Diagram 1

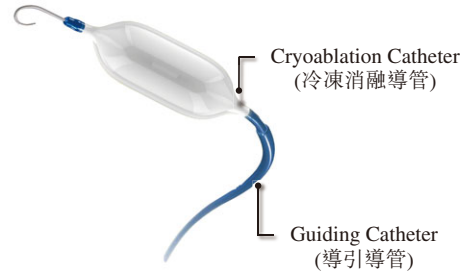


Diagram 2

Operation Procedure

During the procedure, the physician first performs renal angiography to confirm renal artery anatomy, and then advances a properly sized cryoablation balloon to the distal segment of the main renal artery through a guiding catheter and guidewires. Afterwards, the cryoablation equipment provides and delivers the cryogen, liquid nitrogen, to the target area through the catheter to form ice balls, which causes ice crystals to form in the target area. The formation and rewarming of ice balls causes immediate damage and rupture death of the cells in the ablated area, thus resulting in permanent necrosis of the renal sympathetic nerve cells located at the outer membrane of the renal artery and achieving the purpose of inhibiting sympathetic excitation and treating hypertension. Following the treatment, the catheter will be removed and no permanent implant is left behind.

Clinical Trials

Feasibility Clinical Trial

We completed a multi-center feasibility clinical trial in China for our Cryo-RDN System in July 2018 to preliminarily evaluate its safety and efficacy in treating resistant hypertension. This clinical trial was conducted in Zhongshan Hospital, Fudan University (復旦大學附屬中山醫院) and Shanghai Tenth People's Hospital (上海市第十人民醫院). A total of six subjects were enrolled, and received cryoablation RDN therapy with our Cryo-RDN System. We conducted follow-up visits with all the enrolled subjects up to six months after the procedures. The primary endpoint was the number of subjects with office SBP reduction of 10 mmHg or more at 6 months after operation. The safety endpoint was the incidence of adverse events which refers to the proportion of cases with adverse events in total cases.

All of the subjects for the feasibility clinical trial met the following conditions:

- the subject is aged between 18 and 75 years old;

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- the subject has taken three or more classes of antihypertensive drugs including diuretics, and has continuously taken the same type of antihypertensive drugs for not less than 2 weeks, and has agreed not to change their antihypertensive drug regimen for at least the next 6 months;
- the subject has office SBP \geq 140 mmHg after averaging the result of three measurements;
- the subject’s renal vascular anatomical morphology qualifies for the RDN procedure; and
- the subject agrees to cooperate with the study and provides signed informed consent.

The clinical trial results preliminarily demonstrated the safety and efficacy of the Cryo-RDN System in the treatment of resistant hypertension. The chart below summarizes the blood pressure level of enrolled patients at baseline and follow-ups in this clinical trial:

	<u>Baseline</u>	<u>1 Month</u>	<u>6 Months</u>
Office BP (mm Hg)			
Office SBP	157.17±15.05	141.33±18.66	135.50±12.99
Office DBP	102.00±9.63	92.17±11.02	86.50±10.29
Ambulatory BP (mm Hg)			
24-h SBP	145.83±5.49	142.83±13.44	133.67±11.41
24-h DBP	89.67±9.93	85.50±8.17	81.17±11.18

Source: study results expected to be published on the Journals of the American College of Cardiology

According to the study results in relation to this clinical trial, which are expected to be published on the Journals of the American College of Cardiology (“JACC”) soon, no serious adverse events occurred in the perioperative period and no adverse events were reported based on renal function and angiography in this clinical trial; antihypertensive effect was reported in all the enrolled patients with resistant hypertension in this clinical trial. In particular, patients’ average 24-hour SBP and DBP decreased by 12.17±8.35 mm Hg and 8.50±3.83 mm Hg, respectively, over a 6-month follow-up period. Office SBP and DBP decreased by 13.33±12.27 mm Hg and 6.50±19.52 mm Hg after 1 month and 21.67±11.40 mm Hg and 15.50±17.41 mm Hg after 6 months, respectively. According to the study results which are expected to be published on JACC soon, although further long-term randomized clinical trials with larger sample sizes are needed for confirmation, the results of this study indicate that this cryoablation technique with our Cryo-RDN System could be a breakthrough in the clinical treatment of resistant hypertension.

Confirmatory Clinical Trial

We commenced a confirmatory clinical trial in China for our Cryo-RDN System in July 2019, which is a prospective, multi-center, randomized controlled and single-blind clinical trial aiming to investigate the safety and efficacy of the Cryo-RDN System in the treatment of resistant hypertension. The confirmatory clinical trial involves ten hospitals. We plan to enroll a total of 200 subjects and conduct follow-ups with the subjects up to 24 months after the procedures. With drug standardization, the

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subjects will be randomized in a 1:1 ratio to a study group, where the subjects will receive the treatment using the Cryo-RDN System, and a control group, where the subjects will undergo renal angiography alone. The primary endpoint is the difference in the change in 24-h SBP from baseline at 6 months postoperatively between the study group and the control group.

All of the subjects for the confirmatory clinical trial meet the following conditions:

- the subject is aged between 18 and 80 years old;
- the subject has continually taken antihypertensive drugs for not less than 3 months and has taken the specific antihypertensive drugs prescribed in the protocol for not less than 28 days, after which, the subject has office SBP \geq 140 mmHg, office DBP \geq 90 mmHg and 24h-SBP \geq 135 mmHg; and
- the subject agrees to cooperate with study procedures and provides written informed consent to participate in this clinical trial.

As of the Latest Practicable Date, we had enrolled three subjects for this confirmatory clinical trial, and had completed the necessary follow-up visits for these trial subjects. As we wanted to further expedite the clinical trial progress, we replaced the CRO and SMO with companies that we are more familiar with or more suitable for this clinical trial. Under the relevant agreements, the new CRO, Beijing Hanlande Pharmaceutical Technology Development Co., Ltd. (北京翰蘭德醫藥科技發展有限公司), is in charge of managing and monitoring the implementation of this clinical trial, and providing progress or summary reports; the new SMO, Beijing Zhuyan Medical Technology Co., Ltd. (北京助研醫學技術有限公司), is responsible for assisting researchers to complete supporting duties in relation to the clinical trial, such as collecting source data and filing project-related documents. We provide the CRO and SMO with their required materials and make payments in accordance with the payment schedule agreed by parties. The transition to the new CRO and SMO has been completed in August 2022 and we expect the clinical trial for the Cryo-RDN system to be completed as originally scheduled.

We plan to make the product registration submission for this product candidate with the NMPA in the third quarter of 2024. We currently expect to obtain the NMPA approval for the Cryo-RDN System in the second half of 2025.

Market Opportunity and Competition

According to Frost & Sullivan, the number of hypertension patients in China has increased steadily from 297.1 million in 2016 to 325.9 million in 2020 at a CAGR of 2.3%, and is predicted to further increase to 390.1 million in 2030. In 2020, approximately 15.0% and 62.5% of hypertension patients in China suffered from resistant hypertension and uncontrolled hypertension, respectively. Pharmacotherapy are less effective in controlling blood pressure at certain hours during the day. Although antihypertensive medications are effective in treating uncontrolled hypertension, patients' adherence to pharmacotherapy has been poor. As a result, there are unmet medical needs for effective, long-term alternative therapies for the treatment of uncontrolled and resistant hypertension. The RDN therapy is one of the very few therapies with proven clinical efficacy to treat resistant hypertension, and has many advantages over other traditional treatment solutions, according to Frost & Sullivan.

As of the Latest Practicable Date, there were no RDN product commercialized in China and only seven market players in China had RDN product candidates in the clinical trial stage, according to Frost & Sullivan. While most RDN studies employ radiofrequency current or ultrasound as the energy sources for ablating the renal sympathetic nerves, recent studies in animals and humans have suggested that

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cryoablation-based RDN is efficient and safe, according to Frost & Sullivan. See “Industry Overview—The Vascular Interventional Cryotherapy Device Market—Hypertension and Treatment” in this document for more details. We aim to make our Cryo-RDN System the world’s first cryoablation product that specifically focuses on the treatment of hypertension. Frost & Sullivan further estimates that the size of the RDN product market in China will grow rapidly to reach RMB1,069.9 million by 2030 and the first-movers in this market with advanced product features will capture considerable market shares.

Material Communication With Competent Authorities

Our Cryo-RDN System was recognized as an “innovative medical device” by the NMPA in February 2017, and is therefore eligible for an expedited approval process. We completed a feasibility clinical trial for this product candidate in July 2018, and commenced a confirmatory clinical trial in July 2019. As of the Latest Practicable Date, other than completing the necessary record filings for the clinical trials and the above-mentioned communication, we had not engaged in any material regulatory communications with the NMPA for the Cryo-RDN System.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CRYO-RDN SYSTEM SUCCESSFULLY.

3. *Pulmonary Hypertension Cryoablation System*

Our Pulmonary Hypertension Cryoablation System (肺動脈高壓冷凍消融系統) (“**PH Cryoablation System**”) is a self-developed cryoablation system designed for treating pulmonary hypertension. It employs a balloon catheter to perform circumferential cryoablation on the sympathetic nerve of pulmonary artery, effectively isolating the sympathetic nerve signaling and thus treating pulmonary hypertension.

Our PH Cryoablation System includes a cryoablation equipment and cryoablation catheters. The cryoablation equipment consists of a vacuum system, a refrigeration system and a control system, and the cryoablation catheter includes a freezing medium transmission system and balloon freezing unit.

As of the Latest Practicable Date, the PH Cryoablation System was in the stage of pre-clinical study. We plan to initiate the feasibility clinical trial in the second quarter of 2023. We currently expect to receive the NMPA approval for the PH Cryoablation System in the first half of 2026. We had not engaged in any material regulatory communications with the NMPA for the PH Cryoablation System.

NOTES Interventional Cryotherapy Products

1. *COPD Cryospray System*

Our COPD Cryospray System (慢阻肺冷凍噴霧治療系統) is a spray cryotherapy system developed by the Company, which is indicated to perform cryotherapy for patients suffering from COPD with chronic bronchitis. Our COPD Cryospray System ablates and deactivates the diseased airway mucosal epithelium by spraying liquid nitrogen under the bronchoscope to achieve therapeutic effect. The COPD Cryospray System is a Class III medical device under the classification criteria of the NMPA. For more information on market opportunities and competitive landscape, see “Industry Overview—The NOTES Interventional Cryotherapy Device Market— The Respiratory Interventional Cryotherapy Device Market—COPD and Treatment” in this document.

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Our COPD Cryospray System consists of a cryotherapy equipment and a spray cryotherapy catheter. It is used in conjunction with bronchoscopy. When the catheter enters the body, the cryotherapy equipment delivers liquid nitrogen to the distal end of the catheter and sprays the liquid nitrogen onto the surface of the target airway tissue in a circumferential manner, freezing and ablating the diseased airway mucosal epithelium while leaving behind the extracellular matrix that allows for healthy new cells to repopulate. The COPD Cryospray System ablates the tracheobronchial lumens of the right and left lungs according to the fixed parameters and sites set based on the tracheobronchial location.

Diagram 1 below illustrates the cryotherapy equipment, and diagram 2 below illustrates the spray cryotherapy catheter:



Diagram 1

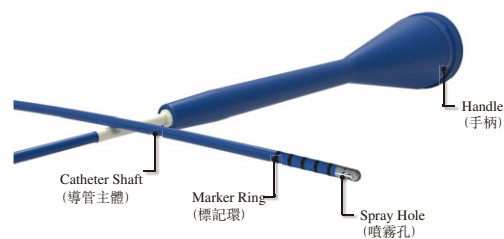


Diagram 2

We initiated a prospective, open label, and single-arm feasibility clinical trial for our COPD Cryospray System in April 2021 to preliminarily evaluate its safety and efficacy in treating moderate, severe or extremely severe COPD (GOLD Stage II-IV) with chronic bronchitis. The clinical trial will be conducted on 12 subjects in Shanghai Tenth People’s Hospital (上海市第十人民醫院) in China.

As of the Latest Practicable Date, we had enrolled ten patients in the feasibility clinical trial for our COPD Cryospray System. We plan to complete the feasibility clinical trial and to initiate a confirmatory clinical trial in the first quarter of 2023. We currently expect to make the product registration submission for this product candidate with the NMPA in the second half of 2025, and to receive the NMPA approval for this product candidate in the second half of 2026. Other than completing the necessary record filings for the feasibility clinical trial, we had not engaged in any material regulatory communications with the NMPA for the COPD Cryospray System.

2. Asthma Cryoablation System

Our Asthma Cryoablation System (哮喘冷凍消融系統) is a self-developed cryoablation system for treating moderate and severe asthma. Currently the most common treatment for asthma is to control symptoms with drugs, including inhalers. For more information on market opportunities and competitive landscape, see “Industry Overview—The NOTES Interventional Cryotherapy Device Market—The Respiratory Interventional Cryotherapy Device Market—Asthma and Treatment” in this document.

The Asthma Cryoablation System consists of a cryotherapy equipment and an airway cryoablation catheter. During the procedure, the Asthma Cryoablation System destroys the vagus nerve in the lungs through cryoablation, reducing the release of over-activated acetylcholine that is a cause of asthma, and decreasing mucus secretion, thus achieving the effect of treating asthma.

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We initiated a single-center, single-arm and open-label feasibility clinical trial for our Asthma Cryoablation System in February 2021 to evaluate its safety and efficacy in treating severe asthma. The feasibility clinical trial will be conducted on 20 subjects in the Shanghai East Hospital, Tongji University (同濟大學附屬東方醫院) in China.

As of the Latest Practicable Date, we had enrolled 15 patients in the feasibility clinical trial for our Asthma Cryoablation System. We expect to complete the feasibility clinical trial and to initiate a confirmatory clinical trial in the first quarter of 2023, and expect to make the product registration submission for the product candidate with the NMPA in the second half of 2025. We currently expect to receive the NMPA approval for the product candidate in the second half of 2026. As of the Latest Practicable Date, other than completing the necessary record filings for the feasibility clinical trial, we had not engaged in any material regulatory communications with the NMPA for the Asthma Cryoablation System.

3. *Malignant Stenosis Cryoablation System*

Our Malignant Stenosis Cryoablation System (惡性狹窄冷凍消融系統) is a self-developed cryoablation system indicated to ablate malignant airway tumor tissue and reduce the time of airway restenosis. For more information on market opportunities and competitive landscape, see “Industry Overview—The NOTES Interventional Cryotherapy Device Market—The Respiratory Interventional Cryotherapy Device Market—Airway Stenosis and Treatment” in this document.

The Malignant Stenosis Cryoablation System consists of a cryotherapy equipment and an airway cryoablation catheter. During the procedure, the Malignant Stenosis Cryoablation System ablates tumor cells in the lumen and luminal wall of the trachea with the ultra-low temperature generated by the cryoablation system, and then further destroys tumor cells through rewarming. The cryoablation balloon allows for more complete ablation of malignant tumors on a larger scale and delays restenosis time.

We initiated a confirmatory clinical trial for our Malignant Stenosis Cryoablation System in April 2021, which is a prospective, multi-center and randomized controlled clinical trial aiming to evaluate the safety and efficacy of the Malignant Stenosis Cryoablation System in treating malignant airway stenosis. The clinical trial will be conducted on 200 subjects in seven hospitals in China, such as Zhongshan Hospital, Fudan University (復旦大學附屬中山醫院) and Shanghai Pulmonary Hospital (上海市肺科醫院).

As of the Latest Practicable Date, we had enrolled 86 patients in the confirmatory clinical trial for our Malignant Stenosis Cryoablation System. We currently expect to complete the clinical trial for this product candidate and to make the product registration submission with the NMPA in the third quarter of 2023, and to receive the NMPA approval in the fourth quarter of 2024. Other than completing the necessary record filings for the clinical trial, we had not engaged in any material regulatory communications with the NMPA for the Malignant Stenosis Cryoablation System.

4. *Benign Stenosis Cryoablation System*

Our Benign Stenosis Cryoablation System (良性狹窄冷凍消融系統) is a self-developed cryoablation system based on liquid nitrogen for ablating benign airway stenosis lesion. This product candidate can dilate and shape the airway stenosis with the balloon dilation and perform cryoablation treatment and reduce the time of airway restenosis. For more information on market opportunities and competitive landscape, see “Industry Overview—The NOTES Interventional Cryotherapy Device Market—The Respiratory Interventional Cryotherapy Device Market—Airway Stenosis and Treatment” in this document.

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The Benign Stenosis Cryoablation System has substantially the same product structure and operation procedures as those of the Malignant Stenosis Cryoablation System. In comparison to the Malignant Stenosis Cryoablation System, the Benign Stenosis Cryoablation System includes a balloon dilation function that allows freezing balloons to dilate stenosis. After the balloon reaches the stenosis through the bronchoscope, the dilation and freezing are performed simultaneously under a specified pressure.

We initiated a single-center, open-label, and single-arm feasibility clinical trial for our Benign Stenosis Cryoablation System in August 2021 to evaluate its safety and efficacy in treating benign airway stenosis. The feasibility clinical trial will be conducted on ten subjects in the Sir Run Run Shaw Hospital affiliated with the Zhejiang University School of Medicine (浙江大學醫學院附屬邵逸夫醫院). We plan to conduct follow-up visits with the subjects up to three months after the procedures.

As of the Latest Practicable Date, we had enrolled five patients in the feasibility clinical trial for our Benign Stenosis Cryoablation System. We expect to complete the feasibility clinical trial and to initiate a confirmatory clinical trial in the first quarter of 2023. We expect to make the product registration submission for the product candidate with the NMPA in the fourth quarter of 2024, and to receive the NMPA approval for this product candidate in the first half of 2026. Other than completing the necessary record filings for the feasibility clinical trial, we had not engaged in any material regulatory communications with the NMPA for the Benign Stenosis Cryoablation System.

5. *Peri-Pulmonary Nodule Cryoablation System*

Our Peri-Pulmonary Nodule Cryoablation System (肺周結節冷凍消融系統) is a self-developed cryoablation system for treating peri-pulmonary nodules. It is currently in the stage of pre-clinical study. We plan to initiate a feasibility clinical trial for this product candidate in the second quarter of 2023. We currently expect to submit registration application with the NMPA for the product candidate in the second half of 2026, and to receive the NMPA approval for this product in the second half of 2027. As of the Latest Practicable Date, we had not engaged in any material regulatory communications with the NMPA for the Peri-Pulmonary Nodule Cryoablation System.

6. *Cough Cryospray System*

Our Cough Cryospray System (咳嗽冷凍噴霧治療系統) is a self-developed cryoablation system for treating chronic cough. Diseases causing chronic cough include COPD, asthma, eosinophilic bronchitis and others, and for chronic cough of definite aetiology, treatment is usually customized according to the aetiology. The Cough Cryospray System has substantially the same product structure as that of the COPD Cryospray System. In terms of the operation procedures, the Cough Cryospray System ablates the visible lesions in the airways, whereas the COPD Cryospray System ablates the tracheobronchial lumens of both the right and left lungs according to the fixed parameters and sites set based on the tracheobronchial location.

We initiated a single-center feasibility clinical trial for our Cough Cryospray System in China to evaluate its safety and efficacy in treating chronic cough. The feasibility clinical trial will be conducted on 20 human subjects. We plan to conduct follow-up visits with the enrolled subjects up to eight weeks following the procedure. We had enrolled eight eligible subjects for this clinical trial as of the Latest Practicable Date, and plan to complete the feasibility clinical trial in the first quarter of 2023. We currently expect to make the product registration submission with the NMPA for this product candidate in the first half of 2025, and to receive the NMPA approval for this product candidate in the second half of 2026. We had not engaged in any material regulatory communications with the NMPA for the Cough Cryospray System.

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7. *Tuberculosis Cryospray System*

Our Tuberculosis Cryospray System (結核冷凍噴霧治療系統) is a spray cryotherapy system developed by the Company for treating tracheobronchial tuberculosis. The Tuberculosis Cryospray System has substantially the same product structure as that of the COPD Cryospray System. In terms of the operation procedures, the Tuberculosis Cryospray System ablates the visible lesions in the airways, whereas the COPD Cryospray System ablates the tracheobronchial lumens of both the right and left lungs according to the fixed parameters and sites set based on the tracheobronchial location.

We initiated an open-label, single-center and single-group feasibility clinical trial for our Tuberculosis Cryospray System in March 2022 to evaluate its safety in treating tracheobronchial tuberculosis. The feasibility clinical trial will be conducted on two subjects in Shanghai Pulmonary Hospital (上海市肺科醫院). We plan to conduct follow-up visits with the subjects up to eight weeks after the procedures. We had enrolled two eligible subjects for this clinical trial as of the Latest Practicable Date, and expect to complete this clinical trial in the first quarter of 2023. We currently expect to submit registration application with the NMPA for the product candidate in the second half of 2025, to receive the NMPA approval for this product candidate in the second half of 2026. We had not engaged in any material regulatory communications with the NMPA for the Tuberculosis Cryospray System.

8. *Cryoadhesion System*

Our Cryoadhesion System (冷凍粘連治療系統) is a cryoadhesion device used for biopsy, stenosis recanalization and foreign body retrieval. It employs subcritical refrigeration technology (亞臨界製冷技術) and heat transfer with controlled pressure technology (控壓傳熱技術) for rapid freezing and adhesion. This product candidate was developed by Beijifeng Biotechnology (Shanghai) Co., Ltd. (北極豐生物科技(上海)有限公司), a subsidiary of ours. See “History, Development and Corporate Structure—Our Subsidiaries” in this document.

This product candidate consists of a flexible cryoprobe (冷凍探頭) and an accompanying cryosurgery equipment (配套冷凍設備). During the operation, the cryoprobe is connected to the cryosurgery equipment, and the distal end of the cryoprobe is brought into contact with the target tissue or foreign body under endoscopic guidance for cryoadhesion to achieve tissue biopsy, stenosis recanalization and foreign body removal.

The Cryoadhesion System was in the stage of pre-clinical study as of the Latest Practicable Date, is expected to enter into the confirmatory clinical trial stage in the fourth quarter of 2022. We plan to make the product registration submission with the NMPA in the fourth quarter of 2022. We currently expect to obtain the NMPA approval for this product candidate in the first quarter of 2024. We had not engaged in any material regulatory communications with the NMPA for the Cryoadhesion System.

9. *Gastric Cryoablation System*

Our Gastric Cryoablation System (胃部冷凍消融系統) is a self-developed cryoablation system indicated for performing cryoablation on gastric tumors to treat gastric cancer. Our Gastric Cryoablation System is a Class III medical device under the classification criteria of the NMPA.

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The Gastric Cryoablation System consists of a cryotherapy equipment (冷凍治療設備) and a cryotherapy catheter (冷凍治療導管). The cryotherapy equipment provides continuous liquid nitrogen supply and real-time vacuum insulation and detection, ensuring fast and effective ablation and providing excellent insulation performance to reduce energy loss and improve efficiency. The cryotherapy equipment also incorporates an automatic pressure adjustment function to enhance operational safety. The cryotherapy catheter is flexible to allow for easy bending of the gastroscope, and the balloon in the cryotherapy catheter enables a broad contact area with the target tissue so that the cryoablation can be conducted in a relatively large area through the thick gastric wall.

During the procedure, the cryoablation equipment provides a stable delivery of liquid nitrogen and the catheter can pass through an electronic gastroscope into the stomach. The distal end of the catheter is connected to a pre-folded balloon, which can expand after passing through the electronic gastroscope to contact the target gastric mucosa, creating an ultra-low temperature at the balloon through the stable delivery of liquid nitrogen within the balloon to destroy target cells. When reaching the set freezing time, the system stops freezing process, and starts rewarming cycle which further destroys the target cells.

We initiated a single-center, open-label and single-arm feasibility clinical trial for the Gastric Cryoablation System in July 2020. The primary objective of this trial was to observe clinical events that were possibly or positively related to the therapy within 91 days after the cryotherapy, while efficacy variables were also investigated, including endoscopic tumor size, PET-CT findings, overall survival, progression-free-survival and tumor response. A total of ten subjects were enrolled in the trial and received the cryoablation treatment with prescribed follow-up visits up to 91 days after the procedures.

All of the subjects for the feasibility clinical trial meet the following conditions, among others:

- the subject is diagnosed with advanced gastric cancer with no other effective treatment options and limited prognosis with available therapies (<2 years), whose pathological type is adenocarcinoma or neuroendocrine tumor and the expected survival is more than three months.
- the subject is aged between 18 and 80 years old; and
- the subject’s vital organs, including heart, lungs, liver and kidneys, function normally.

As of the Latest Practicable Date, we had completed all the follow-up visit and were in the process of preparing the statistical analysis report for the feasibility clinical trial. We plan to make the product registration submission for this product candidate with the NMPA in the second half of 2025. We currently expect to obtain the NMPA approval for the Gastric Cryoablation System in the second half of 2026. Other than completing the necessary record filings for the feasibility clinical trial, we had not engaged in any material regulatory communications with the NMPA for the Gastric Cryoablation System.

10. *Esophageal Cryospray System*

Our Esophageal Cryospray System (食道冷凍噴霧治療系統) is used to perform endoscopic spray cryotherapy on patients with intermediate to advanced esophagus cancer to reduce the size of the tumor, alleviate the symptoms of dysphagia and improve their quality of life. Our Esophageal Cryospray System is a Class III medical device under the classification criteria of the NMPA. For more information on market opportunities and competitive landscape, see “Industry Overview—The NOTES Interventional Cryotherapy Device Market—The Tumor Interventional Cryotherapy Device Market—Esophagus Cancer and Treatment” in this document.

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Patients with intermediate to advanced esophagus cancer may have trouble swallowing due to esophageal stricture as a result of tumor occupancy. Our Esophageal Cryospray System can spray liquid nitrogen directly on the surface of the tumor to destroy the tumor cells, thus reducing the volume of the tumor, alleviating the patient’s dysphagia, and improving the quality of life. This product candidate has a similar product structure as our COPD Cryospray System since they are both spray cryotherapy systems. The Esophageal Cryospray System is used in conjunction with the gastroscopy, and performs local cryoablation of diseased esophageal tissues through direct spray of liquid nitrogen. It can achieve ultra-low freezing temperature without a long precooling time, and also offer fast rewarming and adapt to various lesion tissues with different kinds of surfaces.

We initiated a prospective, single-center and single-arm feasibility clinical trial for our Esophageal Cryospray System in March 2022 to evaluate its safety, feasibility and preliminary in treating dysphagia of patients with intermediate to advanced esophagus cancer. The feasibility clinical trial will be conducted on 20 subjects in Zhongshan Hospital, Fudan University (復旦大學附屬中山醫院). We plan to conduct follow-up visits with the subjects up to four weeks after the procedures. We had enrolled five eligible subject for this clinical trial as of the Latest Practicable Date, and plan to complete the feasibility clinical trial by the first quarter of 2023. We currently expect to make the product registration submission with the NMPA in the second half of 2025, and to receive the NMPA approval for the Esophageal Cryospray System in the first half of 2027.

Non-Cryotherapy Products and Product Candidates

1. Pulmonary Nodule Localization Needle

Our Pulmonary Nodule Localization Needle (肺結節定位針), also known as the Disposable Pulmonary Nodule Localization Needle, is a single-use localization needle indicated for CT-guided localization of lung nodules in patients with lung nodules prior to undergoing thoracoscopic surgery. Our Pulmonary Nodule Localization Needle adopts a combination of multi-hook localization and flexible wire, which greatly reduces the risk of dislocation after localization to ensure safe and effective resection of pulmonary nodules during surgery. According to Frost & Sullivan, the Pulmonary Nodule Localization Needle is the first medical device specifically for the localization of pulmonary nodules in China. For details of the market and competitive landscape of this product, see “Industry Overview—The Pulmonary Nodule Localization Needle Market” in this document.

The Pulmonary Nodule Localization Needle contains an introducer needle (穿刺針), a pushing device (推送裝置), an localization anchor (錨定定位針), a localization wire (定位線) and other components. During the procedure, the physician first determines the location of the pulmonary nodule by CT, punctures the introducer needle under CT guidance to the pulmonary nodule or its adjacency, and then releases the localization anchor to fix it to the nodule or its adjacency. The physician then pulls the localization wire to determine the position of the localization anchor to locate the nodule for lung nodule resection.

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Diagram 1 below illustrates the whole Pulmonary Nodule Localization Needle, and diagram 2 below illustrates each components of the Pulmonary Nodule Localization Needle:



Diagram 1

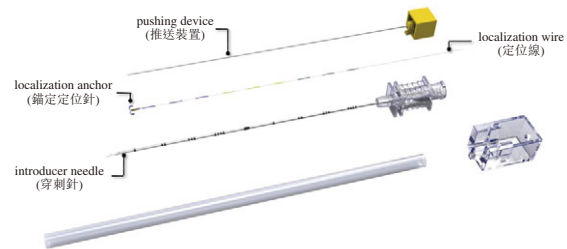


Diagram 2

Key features and advantages of the Pulmonary Nodule Localization Needle are summarized below:

- Precise localization of lung nodule. During the operation, the physician first punctures the introducer needle under CT guidance and then releases the localization and flexible localization wire (柔性定位线) to accurately locate and fix the lung nodule.
- Enhancing the precision and safety of the surgery. The scale display on the localization wire allows for precise excision of diseased tissue and specimen extraction. This product can avoid displacement after localization, reducing damage to normal tissue, the incidence of intraoperative conversion to open chest surgery and postoperative complications.
- Optimization of surgical approach and shortening of surgical time. Precise localization of lung nodules enables accurate resection of lung nodules while preserving as much healthy lung tissue as possible. During surgery, the localization wire can be gently lifted to expose adjacent tissues, allowing for a more efficient surgical operation and a shorter surgical time.
- Flexible surgical arrangement. Patients can move normally after localization of nodules with this product, and pain is significantly reduced compared to traditional localization. In general, the physician can choose to perform the operation within 24 hours of localization.

In April 2017, we completed a multi-center and single-arm target value clinical trial in China for our Pulmonary Nodule Localization Needle to evaluate its efficacy and safety profiles. This clinical trial was conducted in four hospitals in China. A total of 80 subjects were enrolled, and received localization of lung nodules with this product prior to their pulmonary nodule resection surgery. All of the subjects for the clinical trial met the following conditions:

- the subject is aged between 18 and 75 years old;
- the subject has solid or ground glass pulmonary nodules with diameters of 1cm or less as confirmed on transthoracic CT, and total thoroscopic pulmonary wedge resection, segmental lung resection or lobectomy is proposed;
- the subject has no significantly enlarged hilar or mediastinal lymph nodes on CT of the chest; and
- the subject agrees to participate in the clinical trial and provides written informed consent.

BUSINESS

The primary efficacy endpoint was the localization success rate. Localization is considered successful if after the CT-guided localization with our Pulmonary Nodule Localization Needle, CT scan confirms that the localization anchor is released and positioned in or around the lesion (within 10 mm of the lesion margin) and that the device is pushed and retrieved smoothly, with no dislodgement or breakage of any components of the device during the procedure. According to the final clinical trial report, the localization success rate was 96.25%; 77 of the 80 trial subjects experienced successful localization of lung nodules, and the unsuccessful localization for the remaining 3 patients was not caused by defects of the Pulmonary Nodule Localization Needle.

The safety endpoint was the incidence of adverse events, which primarily include pneumothorax and bleeding caused by puncture. According to the final clinical trial report, the incidence of adverse events was 35.00%; 28 of the 80 trial subjects experienced adverse events but none of the adverse events was related to the Pulmonary Nodule Localization Needle.

As a result, the clinical trial demonstrated the good efficacy and safety profile of the Pulmonary Nodule Localization Needle.

The Pulmonary Nodule Localization Needle received the NMPA registration certificate in March 2019 and was subsequently commercialized in China in May 2019, and obtained CE Marking in January 2019. The Pulmonary Nodule Localization Needle is classified as Class III medical device by the NMPA. As of the Latest Practicable Date, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approval for the Pulmonary Nodule Localization Needle.

2. *Laparoscopic Single Port Multi-Channel Access Platform*

Our Laparoscopic Single Port Multi-Channel Access Platform (單孔多通道腹腔鏡手術入路系統), also known as the Disposable Multi-Channel Laparoscopic Access Platform, is a self-developed system used in laparoscopic surgery as a channel for the endoscope, instruments and hands during surgery. It is applicable for single incision laparoscopic surgery, NOTES, reduced-port laparoscopic surgery, or hand-assisted laparoscopic surgery. For details of the market and competitive landscape of this product, see “Industry Overview—The Laparoscopy Market” in this document.

The Laparoscopic Single Port Multi-Channel Access Platform consists of a single-port platform (單孔平台), a wound retractor (開創保護器), an introducer needle (穿刺針), and trocar sleeves (穿刺套管). When using this product, the wound retractor is first placed at the incision site, with its inner sleeve ring placed inside the body and its outer sleeve ring turned inward and close to the incision skin. Subsequently, and a trocar sleeve is inserted with an introducer needle into the single-port platform, and the number of trocar sleeves is determined according to the surgical requirements. After the trocar sleeve is secured to the membrane of the single-port platform, the introducer needle is removed, and the single-port platform is combined with the outer sleeve ring of the wound retractor. Different sizes of surgical instruments can enter through the trocar sleeves.

BUSINESS

See below an illustrative diagram of the Laparoscopic Single Port Multi-Channel Access Platform:



Key features and advantages of the Laparoscopic Single Port Multi-Channel Access Platforms are summarized below:

- Each Laparoscopic Single Port Multi-Channel Access Platform includes five different trocar sleeves (穿刺套管) that can be used to customize the number and type of instrument channels and accommodate various surgical needs. In addition, the position and direction of the trocar sleeves are freely selectable when it is inserted into the single-port platform, and can be adjusted during the procedure. This product is compatible with three surgical plans, including single incision laparoscopic surgery, reduced-port laparoscopic surgery, and hand-assisted laparoscopic surgery.
- The gel membrane of the single-port platform features appropriate softness that allows the surgical instruments to maintain better stability for more delicate operations, resulting in smaller incisions, less bleeding and fewer post-operative complications. Its single-port platform and the wound retractor can be separated intraoperatively to allow for easy specimen retrieval and addition of laparoscopic instruments at any time during the procedure.

In June 2016, we completed a multi-center, randomized and controlled clinical trial in China for our Laparoscopic Single Port Multi-Channel Access Platform to evaluate its efficacy and safety profiles. This clinical trial was conducted in two hospitals in China. A total of 144 patients were enrolled and randomized in a 1:1 ratio to a study group that used our Laparoscopic Single Port Multi-Channel Access Platform, and a control group that used another company's puncture outfit for routine laparoscopic procedures. The evaluation indicators include, among others, whether the surgical access is established smoothly by the test device, the performance of the test device with the endoscope during surgery, the ease of removing specimens or tissue during surgery, the infection and healing of the incision, and the adverse events caused by the device.

BUSINESS

According to the clinical trial results, there was no statistically significant difference in the evaluation results on the indicators between the study group and the controlled group, this product’s clinical satisfaction rate is not inferior to the control product, and its efficacy, safety and operability meet the expected objectives and needs for clinical use. No adverse events or side effects occurred in the trial. In conclusion, the clinical trial demonstrated that the Laparoscopic Single Port Multi-Channel Access Platform has a good safety and efficacy profile and is recommended for clinical use.

The Laparoscopic Single Port Multi-Channel Access Platform received the Zhejiang MPA registration certificate in February 2017 and was subsequently commercialized in China in April 2017, and obtained CE Marking in January 2019. It is a Class II medical device under the classification criteria of the NMPA. As of the Latest Practicable Date, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approval for the Laparoscopic Single Port Multi-Channel Access Platform.

3. *Atrial Fibrillation Pulsed Field Ablation System*

Our Atrial Fibrillation Pulsed Field Ablation System (房顫脈衝電場消融 (PFA) 系統) (“**AF PFA System**”) is indicated for use in the interventional treatment of paroxysmal atrial fibrillation. It destroys myocardial tissue with high voltage electrical impulses to achieve electrical isolation of the pulmonary vein vestibule, resulting in the therapeutic effect. This product candidate was developed by Huifeng Biotechnology (Shanghai) Co., Ltd. (輝豐生物科技(上海)有限公司), a subsidiary of ours. See “History, Development and Corporate Structure—Our Subsidiaries” in this document.

The AF PFA System is composed of a PFA equipment and a PFA ablation catheter. The PFA equipment includes a pulsed electric field generator (脈衝電場發生裝置) and a control system (控制系統), and the PFA ablation catheter includes a pulsed electric field transmission unit (脈衝電場傳輸單元) and a pulsed electric field ablation unit (脈衝電場消融單元). This product candidate has several technical advantages, including selectivity of tissue damage (對組織損傷具有選擇性) and high safety.

As of the Latest Practicable Date, the AF PFA System was in the stage of pre-clinical study. We expect to initiate the feasibility clinical trial for this product candidate in the second quarter of 2023, and to obtain the NMPA approval for the AF PFA System in the first half of 2026. We had not engaged in any material regulatory communications with the NMPA for the AF PFA System.

4. *Anti-Gastroesophageal Reflux System*

Our self-developed Anti-Gastroesophageal Reflux System (抗胃食管反流系統) is a surgical device indicated for treating gastroesophageal reflux disease (“**GERD**”) in the magnetic sphincter augmentation procedure. The magnetic sphincter augmentation procedure is designed to treat GERD by increasing the tension of the lower esophageal sphincter (“**LES**”) to achieve anti-reflux effect.

The Anti-Gastroesophageal Reflux System is composed of an anti-gastroesophageal reflux implant device and an esophageal measurement tool. The anti-gastroesophageal reflux implant device includes a number of interconnected beads, and each bead contains an internal magnet part and an external titanium part. Diminished anti-reflux function of LES is a cause of GERD. If the anti-reflux function of LES is enhanced or restored, the corresponding GERD symptoms may be relieved or eliminated. Our Anti-Gastroesophageal Reflux System works by fixing an implanted device to the LES functional area outside the esophagus, with magnetic beads in the implanted device generating magnetic attraction force to strengthen LES, thus restoring the anti-reflux function of LES and treating GERD.

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We initiated a multi-center confirmatory clinical trial in August 2018 to evaluate the safety and efficacy of the Anti-Gastroesophageal Reflux System. We will enroll 100 subjects suffering from the GERD, and will conduct follow-up visits up to 12 months after the procedures. The trial involves 11 hospitals, led by the Shanghai Chest Hospital (上海市胸科醫院). We had completed the enrollment of all subjects as of the Latest Practicable Date, and we expect to complete this clinical trial in the second quarter of 2023. We currently expect to make the product registration submission with the NMPA in the first quarter of 2024 and to obtain the NMPA approval for the Anti-Gastroesophageal Reflux System in the first half of 2025. Other than completing the necessary record filings for the feasibility clinical trial, we had not engaged in any material regulatory communications with the NMPA for the Anti-Gastroesophageal Reflux System.

5. *Other Non-Cryotherapy Products*

Our non-cryoablation products also include our Wound Retractor (開創保護器), Ureteral Dilation Balloon Catheter (輸尿管擴張球囊導管), Laparoscopic Biopsy Bag (腹腔鏡用活檢袋) (also known as Endoscopic Biopsy Bag), and Laparoscopic Surgical Instrument (腹腔鏡手術器械). They are all single-use medical consumables classified as Class II medical devices under the criteria of the NMPA. The Wound Retractor is indicated for use in small incision surgery and minimally invasive surgery, which can extend the incision field, prevent incision from injury and reduce infection. This product received the Zhejiang MPA registration certificate in May 2014 and was commercialized in China in January 2016, and obtained CE Marking in 2019. The Ureteral Dilation Balloon Catheter is used for trans-luminal dilation of ureteral strictures, as well as for ureteral dilation prior to ureteroscopy or ureteral stone manipulation. It received the Zhejiang MPA registration certificate in December 2018 and obtained CE Marking in 2019, and was commercialized in January 2020. Our Laparoscopic Biopsy Bag is used to remove the biopsy sample from the surgical area during endoscopy. It received the Zhejiang MPA registration certificate in May 2014 and was commercialized in April 2015. Our Laparoscopic Surgical Instrument is used for grasping, separating and shearing through the puncture channel in conjunction with laparoscopy. This product received the Zhejiang MPA registration certificate in October 2018 and was commercialized in July 2020. As of the Latest Practicable Date, there had not been any material unexpected or adverse changes since the date we received the relevant regulatory approvals for these non-cryoablation products.

OUR TECHNOLOGIES

Our product portfolio is mainly built upon four core technologies, namely, liquid nitrogen cryoablation technology, flexible catheter technology, balloon catheter technology and metered spray catheter technology. Our technologies complement each other and create a synergy effect for our developing innovative product candidates.

- **Liquid nitrogen cryoablation technology (液氮冷凍消融技術)*.** According to Frost & Sullivan, the Company owns the only key technology that enables the use of low-pressure liquid nitrogen in balloon cryoablation systems in the world. This liquid nitrogen cryoablation technology allows rapid delivery of liquid nitrogen to a treatment site as well as fast cooling of a target tissue to deactivate it. It is compatible with various cryoablation catheters for different indications. Utilizing this technology, our cryoablation products achieve accurate control of cryogenic energy output and ablation range.
- **Flexible catheter technology (柔性導管技術).** Our flexible catheter technology enables us to develop thin-diameter flexible catheters that meet the needs of cardiovascular and natural orifice interventional surgery. We adopt cryogenic energy dissipation control technique (冷量耗散控制技術) to achieve real-time vacuum heat insulation, allowing our products to efficiently deliver cryogen to the target treatment site.

BUSINESS

- **Balloon catheter technology (球囊導管技術).** Our balloon catheter technology is the first technology that achieves low-pressure liquid nitrogen balloon catheter in the world, enabling the whole cryoablation system to function at low pressure and considerably improving product safety. This technology aids in the development of various balloon structures tailored for a variety of indications, such as narrow balloon, concave balloon, balloon with integrated dilation and freezing functions, while maintaining a large balloon contact area and a broad ablation range.
- **Metered spray catheter technology (噴霧導管技術).** Our products, which make use of the metered spray catheter technology, allow physicians to precisely control the amount of liquid nitrogen sprayed, resulting in uniform and consistent spray for efficient non-contact cryoablation.

Note:

Liquid nitrogen cryoablation technology owned by the Company was developed out of Mr. Thach Buu DUONG’s liquid nitrogen technology, which was progressively assigned to the Company in 2014 and 2016 after the Company’s establishment, in combination with the existing cryoablation technologies that the Company developed on its own.

Mr. Thach Buu DUONG, jointly with Mr. Zeng Min Frank, Mr. Xin Chaohua and Mr. Liu Peng (the “**Inventors**”) developed certain technologies pertaining to liquid nitrogen cryotherapy (in the form of five inventions), which were applied for five patents (application numbers: 13566071, 14026010, 14170267, 13800402, and 13942387) in the U.S. by the Inventors from 2012 to 2014 progressively. During the application periods of such five inventions, the Inventors executed five assignments to assign each of such inventions to Horizon Scientific Corp. (“**Horizon**”), a sole proprietorship company owned by Mr. Zeng Min Frank, for a consideration of one U.S. dollar per invention. Pursuant to the assignments, the Inventors shall perform any act necessary to obtain grant of valid U.S. patents for their respective inventions to Horizon, and Horizon, as the assignee, has full right to convey the entire interest assigned.

In February 2014, Horizon executed two assignments to assign its entire interests in inventions with patent application numbers of 13800402 and 13942387 to the Company free of charge, respectively. In March 2016, Horizon executed an assignment to assign its entire interests in inventions with patent application numbers of 14026010 and 14170267, and patented invention (with application number of 13566071, patent number of 9101343) to the Company, for the consideration of one U.S. dollar. As confirmed by the Company, the considerations for the assignments were commercially agreed by the assignors and assignees.

As confirmed by the PRC Intellectual Property Legal Adviser, the five inventions are all successfully patented (patent numbers: 9101343, 9468484, 9439709, 9072500 and 9381055) (jointly “**LNT Patents**”) and registered at the United States Patent and Trademark Office, which are legally and solely owned by the Company. As further confirmed by the PRC Intellectual Property Legal Adviser, the Company is now the sole owner of the LNT Patents, and none of the LNT Patents is subject to any third party claim.

The inventors of four of these five inventions (patent numbers: 9101343, 9468484, 9439709 and 9072500) were Mr. Thach Buu DUONG and Mr. Zeng Min Frank; and the inventors of the other invention (patent number: 9381055) were Mr. Thach Buu DUONG, Mr. Zeng Min Frank, Mr. Xin Chaohua and Mr. Liu Peng. When the patent application for the latter invention was made (in July 2013), Mr. Xin Chaohua was a R&D consultant of the Company, and Mr. Liu Peng was a R&D staff of the Company. They were involved in the R&D activities of the Company at the time, and provided valuable assistance to Mr. Thach Buu DUONG during the inventing process, particularly with respect to the development of balloon catheters that could be used in the cryoablation system. They later voluntarily terminated their employment/consultancy relationship with the Company for personal reasons, after amiable discussions with our management team. We never had any material disagreement or dispute with them on any matter (including but not limited to matters regarding intellectual property rights). During the Track Record Period and up to the Latest Practicable Date, Mr. Xin Chaohua and Mr. Liu Peng were not involved in the R&D activities of our Company.

BUSINESS

RESEARCH AND DEVELOPMENT

Our research and development team develops clinically effective and commercially attractive products with a focus on cryoablation devices. We have independently developed a number of innovative medical devices, such as our Core Products, the Bladder Cryoablation System and the Endoscopic Clip for Anastomosis.

As of the Latest Practicable Date, we had two Core Products, 15 other product candidates in various stages of development, as well as six additional commercialized products in the market. In 2020, 2021 and the eight months ended August 31, 2022, we incurred research and development expenses of RMB42.3 million, RMB89.8 million and RMB35.8 million, respectively. For details, see “Financial Information—Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income—Research and Development Expenses” in this document. We intend to optimize our product portfolio by strengthening our research and development of new products, expanding our product pipeline and improving our existing product candidates.

Our R&D Team

We have a dedicated product development team that comprises an in-house R&D team of 83 staff and a clinical operation team of 37 staff as of the Latest Practicable Date (including certain management members undertaking product development functions). Our product development team is jointly led by Mr. DIAO Yuepeng, Mr. LIU Yulong, Mr. Thach Buu DUONG, Dr. ZHAO Kuiwen and Mr. CHEN Zhimin, industry experts with an average of over ten years of experience in the medical device industry or in the field of engineering research and development. See “Directors, Supervisors and Senior Management” in this document for details. We have 16 key R&D personnel responsible for the development of the Core Products and other pipeline products. Each of the key R&D personnel holds a bachelor’s or higher degree, and had remained with the Group for over five years on average. All the key R&D personnel involved in the development of the Core Products and other pipeline products were still employed by us, and are expected to remain within the Group by the time of the [REDACTED] and in the foreseeable future.

Our 83 R&D personnel can be largely divided into the following sub-teams based on different business units: (i) 25 R&D staff of the Company, with 96% holding bachelor’s or higher degrees, who mainly focus on the vascular interventional cryotherapy field including the R&D of the AF Cryoablation System, the Cryo-RDN System and the Pulmonary Hypertension Cryoablation System; (ii) 45 R&D staff of Ningbo SensCure, with 78% holding bachelor’s or higher degrees, who mainly focus on the NOTES interventional cryotherapy and disposable medical devices, including the R&D of the Bladder Cryoablation System, the Endoscopic Clip for Anastomosis, the COPD Cryospray System and several other devices; and (iii) 13 R&D staff of another two subsidiaries of the Company, who worked on the R&D of the Cryoadhesion System and the Atrial Fibrillation Pulsed Field Ablation System, as of the Latest Practicable Date.

We have entered into legally-binding confidentiality and non-competition agreements with our key employees and employees involved in our research and development activities. For details, see “—Employees” in this section. Historically, Mr. DIAO Yuepeng, our deputy vice president, developed certain proprietary technologies by himself, outside of his normal working hours and without utilizing any resources of our Company. Mr. Diao had transferred the relevant proprietary technologies to us, and had agreed with us that all the relevant intellectual property rights (including any patents to be registered in the future in relation to such proprietary technologies) will be solely owned by us (with Mr. Diao serving as the first inventor). During the Track Record Period and up to the Latest Practicable Date, we did not have any disputes with Mr. Diao or any other of our employees with respect to intellectual property rights.

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Product Development

Our research and development process typically involves the following steps:

- **Project proposal.** Before we initiate a new product development project, we typically coordinate with principal investigators, and physicians to get well informed of market demands and technology pain points, and conduct market research to collect the market information related to the market trends and demands. A new product proposal is analyzed by multiple functional teams before approval. Notably, our research and development team conducts economic and feasibility analysis, with costs, product functions and market potential taken into consideration.
- **Product approval.** After a project has passed all internal assessments, representatives from our research and development, procurement, quality control and regulatory, product registration, production and management teams collectively review the project proposal and determine whether the project should proceed and also set a detailed project timetable. The research and development team shares their studies on project feasibility. The procurement team assists with determining raw material requirements. The quality control team helps ensure that the product design complies with all applicable laws and regulations. The production team then produces and modifies product samples. Based on feedback from functional teams, the management will then determine whether a project should proceed.
- **Design and development.** Our new medical device product design and development is guided by our internal control protocol prepared with reference to the risk management standards under ISO 14971:2019. For details, see “—Quality Control” in this section.
- **Pre-clinical product verification and validation.** All new products will go through several rounds of internal and external *in vivo* and *in vitro* testing, through which our management team will collect feedback from our employees and physicians on the product functionalities so that we can refine our designs and resolve technical issues in order to satisfy clinical needs. We may conduct pre-clinical animal studies to evaluate our product design or make improvements to its safety and efficacy.
- **Clinical study.** We may also conduct early feasibility study to evaluate the device functionality and preliminary clinical safety when non-clinical testing is unable to provide the necessary information to advance the device development process. We collaborate with hospitals in China and globally to conduct clinical trials for our product candidates. For details, please see “—Clinical Trials” below in this section.
- **Registration and launch.** The registration procedure and timeline for our product candidates vary in different jurisdictions. Our quality control team is mainly responsible for regulatory filings and communications with applicable competent authorities. Our team members have extensive experience and in-depth understanding on registration requirements and procedures, as well as other regulatory compliance guidelines in practice. We expect to launch our products shortly after receiving the relevant regulatory approvals or registrations.

For details of our product candidates, see “—Our Products and Product Candidates” in this section.

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Clinical Trials

We have a dedicated clinical operation team responsible for the day-to-day management of the clinical trials of our pipeline products. As of the Latest Practicable Date, our clinical operation team consisted of 37 staff most of whom possessed bachelor’s or higher degrees. We conduct clinical trials of our product candidates in order to obtain the requisite regulatory approvals and collect post-procedure data that can improve and enhance the design and features of our product candidates. In addition, robust clinical data are an important marketing tool for increasing credibility for our brand and products. The goal of a clinical trial is to measure the clinical efficacy and safety of a device.

We generally sponsor and conduct all the R&D activities, including clinical trials of our Core Products, on our own and at its own cost through our Company or wholly-owned subsidiaries. Ningbo SensCure, one of our wholly-owned subsidiaries, is the sponsor of all the registrational clinical trials of the Core Products in China. We are responsible for initiating, applying for, organizing, funding and monitoring clinical trials for our Core Products. The R&D process of our products including Core Products did not involve any third parties, except for the necessary suppliers such as CROs, SMOs and clinical trial institutions that were engaged by us to support the conduct of clinical trials. For details of our collaboration with such suppliers, see “—Collaboration with Clinical Trial Institution”, “—Relationships with CROs and SMOs” and “—Relationship with Principal Investigators” in this section. We select qualified clinical trial institutions to carry out clinical trials on human subjects. We first prepare a clinical trial protocol plan that describes in detail the clinical trial’s purpose, timeline, methods, procedures and risks. We then meet with investigators in clinical trial institutions to discuss the clinical trial protocol plan. Following such meeting, we prepare and send a proposal to the ethics committee of each participating clinical trial institution including our clinical trial protocol plan, patient consent forms, investigator report forms and agreements with the participating clinical trial institution. During the clinical trial, we monitor trial progress and patient reactions pursuant to clinical trial protocols. In addition, we provide investigators with qualified sample products, establish quality control and quality assurance systems for clinical trials, work with investigators to study possible adverse events and offer insurance coverage for patients participating in clinical trials. As of the Latest Practicable Date, we had initiated 15 clinical trials in China. Our clinical data and practices are designed to meet the standards of GCP and ICH-GCP.

Collaboration with Clinical Trial Institution

The NMPA maintains a catalog of hospitals that it has approved as clinical trial centers, from which we select a number of hospitals to conduct our clinical trials. The factors we commonly consider when selecting such institutions include their credentials, expertise, technology, equipment and patient demographics. Before selecting institutions, we meet with physicians at potential candidate hospitals to discuss our clinical trials’ purpose and requirements. For each clinical trial, we and the institution generally enter into a new agreement setting out the clinical trial’s purpose, timeline, procedures, methods and risks. Then, we work together with the principal investigators for the trial to design a clinical trial protocol for submission to the clinical trial institution’s ethics committee. The clinical trials must be conducted in accordance with the protocol approved by the ethics committee. The ethics committee must reevaluate and approve any amendments to the protocol.

We cooperate with prestigious hospitals in China to conduct our clinical trials. For the AF Cryoablation System, we have cooperated with ten hospitals in China, with Zhongshan Hospital, Fudan University (復旦大學附屬中山醫院) as the lead clinical trial institution. For the Bladder Cryoablation System and the Endoscopic Clip for Anastomosis, we have cooperated with six and four hospitals, respectively, in China.

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Pursuant to the legally-binding agreements with these participating clinical trial institutions, the institutions are required to conduct the clinical trials strictly in accordance with the protocol, to collect data, and to issue case reports at the end of each clinical trial. The lead institution will prepare formal reports based on the case reports submitted by all participating institutions. In return for the institutions' services, we make scheduled payments as agreed in the agreements. Under the agreements, we own all the intellectual property in relation to the clinical trial while the participating institutions may publish or otherwise use the clinical trial results for academic activities with our prior approval.

Relationships with CROs and SMOs

We collaborate with reputable CROs and SMOs for the support of our clinical trials. When selecting CROs and SMOs, we consider a number of factors, including their expertise, experience and reputation. The CROs and SMOs must comply with all applicable laws and regulations as well as follow our protocols to ensure that all clinical trial results are accurate and authentic.

During the Track Record Period, we engaged industry-renowned CROs to provide certain services in the clinical trials for our products in China. Under the relevant agreements, the CROs are generally responsible for preparing ethical committee application, assisting in selecting clinical trial institutions, managing and monitoring the implementation of clinical trials, collecting and keeping records of patients' information and providing progress or summary reports. We provide the CROs with their required materials and information and make payments in accordance with the payment schedule agreed by parties. The CROs are obligated to keep all non-public information and data from the trials confidential, and return related materials to us at the end of our contract term. During the Track Record Period, we also engaged the SMOs to assist researchers to complete certain supporting duties in relation to our ongoing clinical trials, including collecting source data and providing progress reports, among others. To the knowledge of our Directors, other than the ordinary business relationship, none of our CROs and SMOs (including their directors, shareholders and senior management), had any past or present relationships (including, without limitation, business, employment, family, trust, financing or otherwise) with our Group, our shareholders, Directors, Supervisors, senior management or any of their respective associates. Under the agreements, we own all intellectual property and trial results and the CROs and SMOs must maintain strict confidentiality with respect to the information they acquired from us during clinical trials.

Relationship with Principal Investigators

In addition to our collaboration with clinical trial institutions, CROs and SMOs, we also maintain continuous communications with principal investigators, physicians and hospitals, who are informed of our latest research and development progress. The principal investigators we work with not only provide us with important feedback on clinical needs but also present the clinical use of our product candidates in academic settings, which we believe can invite wider discussion of our product candidates and in turn contribute to our research and development efforts. Furthermore, we host meetings for key participants in our industry with respect to our research and development efforts and product candidates. We have presented our products in multiple industry conferences, where we keep industry participants updated of our latest research and development progress.

BUSINESS

OUR PRODUCTION FACILITIES AND PROCESSES

Production Facilities

We have established two production facilities, one located in Ningbo, Zhejiang province (“**Ningbo Facility**”) and another located in Shanghai, China (“**Shanghai Facility**”). For more details of our properties, see “—Properties” in this section. As of the Latest Practicable Date, we had a team of 117 employees dedicated to the production of our products and product candidates.

Our Ningbo Facility produces both commercialized products and sample products for product development purposes. During the Track Record Period, we have launched six minimally-invasive surgical consumables, mainly including the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform, all of which were manufactured in our Ningbo Facility. We also produce, assemble and test sample products related to NOTES in our Ningbo Facility, such as the COPD Cryospray System and the Bladder Cryoablation System, for clinical trials, design validation and product development.

Our production in our Shanghai Facility is currently limited to producing, assembling and testing sample products related to vascular intervention, such as the AF Cryoablation System and the Cryo-RDN System, for the purpose of clinical trials, design validation and product development.

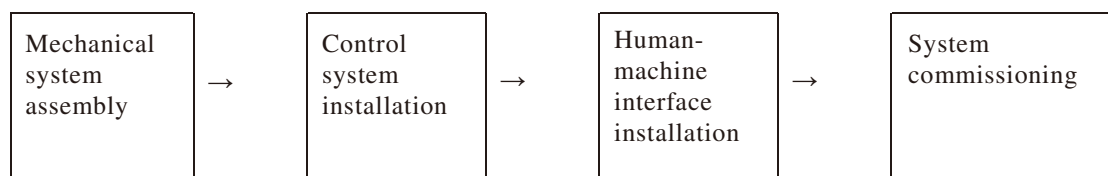
Production Process

Cryotherapy Product

For the Bladder Cryoablation System and other cryotherapy products, the production process typically includes the production of our active devices for cryotherapy (“**Cryotherapy Equipment**”), such as cryoablation equipment or cryosurgery equipment, and accompanying medical consumables (“**Cryotherapy Consumables**”), such as cryoablation catheters and cryoprobes, and generally involves the following steps:

Cryotherapy Equipment

Set forth below is an illustrative flowchart for the production process of the Cryotherapy Equipment.



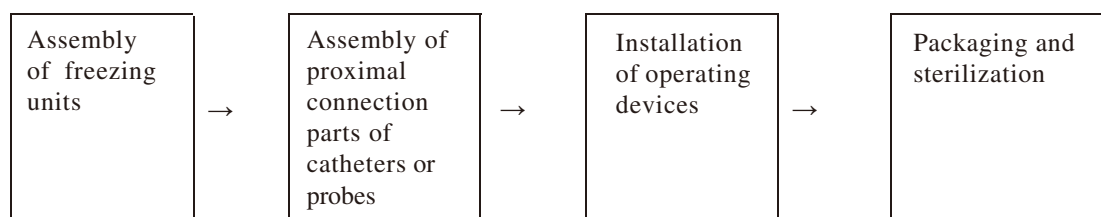
BUSINESS

The following is a brief description of the key steps in our manufacturing process of the Cryotherapy Equipment.

- **Mechanical system assembly.** We install mechanical devices such as the main frame and fluid path of the equipment.
- **Control system installation.** We install the main control board of the control system and assemble circuit components.
- **Human-machine interface installation.** We install the human-machine interface display system.
- **System commissioning.** We test various modules and components, and connect and fit them according to the design so that the whole equipment achieves the intended function.

Cryotherapy Consumable

Set forth below is an illustrative flowchart for the production process of the Cryotherapy Consumables.

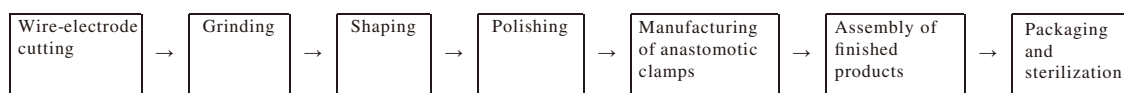


The following is a brief description of the key steps in our manufacturing process of the Cryotherapy Consumables.

- **Assembly of freezing units.** We assemble the intravascular or intracavitary fluid pathway and weld the balloon or probe.
- **Assembly of proximal connection parts of catheters or probes.** We assemble the components which connects the Cryotherapy Equipment to freezing units.
- **Installation of operating devices.** We install and commission operation control components to ensure that Cryotherapy Consumables perform as expected.
- **Packaging and sterilization.** The product is packaged and sterilized.

Endoscopic Clip for Anastomosis

Set forth below is an illustrative flowchart for the production process of the Endoscopic Clip for Anastomosis.



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The following is a brief description of the key steps in our manufacturing process of the Endoscopic Clip for Anastomosis.

- **Wire-electrode cutting.** We cut sheet metal into blanks of parts for anastomotic clamps.
- **Grinding.** We grind the blanks of parts to make them smooth.
- **Shaping.** Heating treating is conducted to shape the blanks of parts.
- **Polishing.** We polish the blanks of parts for anastomotic clamps.
- **Manufacturing of anastomotic clips.** We assemble blanks of parts into anastomotic clamps.
- **Assembly of finished products.** We assemble other components such as clamping caps, releasers and wire hooks with the anastomotic clamps to make the finished product.
- **Packaging and sterilization.** The finished product is packaged and sterilized.

All the steps in our production process are conducted in compliance with the applicable GMP requirements. We typically conduct each of the above steps in-house, except for certain sterilization steps. We have implemented quality management systems as part of our manufacturing processes. For more details, see "—Quality Control" in this section.

Other Commercialized Products

Our production process typically involves the following steps for commercialized products, mainly including the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform:

- **Raw material quality inspection.** We examine the quality of the raw materials purchased.
- **Cleaning.** We determine whether the raw materials need to be cleaned based on their manufacturing environment. Raw materials produced in clean workshops do not need to be cleaned, while raw materials produced in non-clean workshops need to be cleaned before use.
- **Making semi-finished products.** we make semi-finished products through various production processes, including cutting, shaping, welding, gluing, dyeing, molding, assembling.
- **Semi-finished products quality inspection.** We conduct a comprehensive quality inspection on semi-finished products.
- **Production of finished products.** we assemble semi-finished products into final products through various production processes.
- **Finished product quality inspection.** We conduct a comprehensive quality inspection on finished products.

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- **Packaging of finished products.** The final finished products are packed.
- **Sterilization.** we transport the packaged final products to third-party sterilization service providers for professional sterilization.
- **Ex-factory inspection.** We conduct ex-factory quality inspection on the sterilized finished products.

All the steps in our production process are conducted in compliance with the applicable GMP requirements. We typically conduct each of the above steps in-house, except for certain sterilization steps. We select sterilization service providers based on their qualifications and sterilization ability, and we only enter into an agreement with service providers that meet our standards. Our integrated production process increases our production efficiency and reduces our dependence on third parties, and enables us to adjust our production quickly to respond to changes in market demand for our products. We have implemented quality management systems as part of our manufacturing processes. For more details, see “—Quality Control” in this section.

Production Capacity, Production Volume and Utilization Rates

During the Track Record Period, our commercialized products mainly included the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform. The following table sets forth their production capacity, actual production volume and utilization rate for the periods indicated:

	For 2020	For 2021	Eight Months Ended August 31, 2022
Pulmonary Nodule Localization Needle			
Production capacity (units) ⁽¹⁾	100,000	100,000	66,666
Actual production volume (units)	28,147	59,821	61,873
Utilization rate (%) ⁽²⁾	28	60	93
Laparoscopic Single Port Multi-Channel Access Platform			
Production capacity (units) ⁽¹⁾	18,000	18,000	12,000
Actual production volume (units)	8,181	9,306	6,433
Utilization rate (%) ⁽²⁾	46	52	54

Notes:

- (1) The production capacities of our commercialized products were estimated based on (i) the number of working hours needed for a production worker to manufacture one unit of the relevant product; (ii) the number of production workers designated by us for the manufacturing of the relevant product during the respective year/period; (iii) each of our production workers works eight hours per day and 250 days per year; and (iv) our production lines for the relevant product operated on a one-shift per day basis.
- (2) Utilization rate equals actual production volume divided by production capacity.

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We commenced commercialization of the Endoscopic Clip for Anastomosis in October 2022 and expect to commercialize the Bladder Cryoablation System in December 2022. Based on currently existing facilities and equipment, annual production capacity for our Core Products is estimated to be 10,000 units for the Endoscopic Clip for Anastomosis and 20 cryoablation equipment and 5,000 catheters for the Bladder Cryoablation System. We plan to increase physician acceptance and market penetration for our Core Products through various initiatives, such as academic promotion, physician training, and publication of additional real-world clinical data. In line with the expected growth in market acceptance and product sales, we will gradually enhance our production capacity for our Core Products by upgrading our manufacturing facilities, purchasing new machineries and equipment.

PRODUCT WARRANTY, RETURN, RECALL AND EXCHANGES

For our commercialized products, our internal policy is to assume responsibility as required by law if the competent regulatory authorities find that our products are defective. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any such finding. We may be required by applicable laws and regulations to recall our products if they are defective and have caused, or are likely to cause, harm to patients. We may also decide to voluntarily recall our products for a number of reasons. We had not experienced any product recall. Our product return and exchange policy generally does not allow any product return or product exchange, except that in case of any product defect, we will consider returning or exchanging products by taking into account the specific scenario. We had not experienced any material product return or product exchange request due to product defects.

Product Liability

Should there occur any misdiagnosis or faulty management of patients involving the use of our products including the Core Products, we may be held liable under certain circumstances. According to our PRC Legal Adviser, there are mainly three circumstances in which we may be liable:

- if a patient gets injured due to the fault or operating error of the medical personnel during the process of diagnosis and treatment, the medical institute is liable for all damages and compensation arising therefrom;
- if a patient’s injury is due to the inherent product defect of our products, we may be held liable for the patient’s damages; and
- if a patient’s injury is caused by both the operating errors of the medical personnel and the inherent product defects, the medical institution and us may be jointly and severally liable. If the percentage of fault can be determined between the infringing parties, each of them will be ultimately liable for an amount equivalent to their corresponding fault. If the percentage of fault can not be determined, then each of the infringing parties bears the liability equally.

Currently, we have maintained product liability insurance in China. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any product liability claims.

For further information, see “Risk Factors—Risks Relating to Manufacture and Supply of Our Products and Product Candidates—We may be exposed to potential product liability claims, and our insurance coverage may be inadequate to protect us from all the liabilities we may incur” and “Regulatory Overview—Other Laws and Regulations—Laws and Regulations on Product Liability” in this document.

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SALES AND MARKETING

We have several commercialized medical consumables on the market, mainly including the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform. For details, see “—Our Products and Product Candidates—Other Products and Product Candidates—Non-Cryotherapy Products and Product Candidates” in this section. Currently, we primarily sell and market our commercialized products in China. During the Track Record Period, approximately 99.7% of our total revenue was generated in Mainland China, with approximately 0.3% generated from overseas countries or areas.

We use a combination of our in-house sales and marketing team, our connections with hospitals and a network of distributors to sell our products in China. As of the Latest Practicable Date, we had a sales and marketing team of 14 people in China, who tracks and analyzes applicable local laws and regulations and government policies as well as market data of our products in order to formulate national and regional marketing strategies more effectively.

We received the NMPA approval for the Bladder Cryoablation System in June 2022, and obtained the Zhejiang MPA approval for the Endoscopic Clip for Anastomosis in China in August 2022. We will continue to adopt a distributorship model and sell our commercialized products to hospitals primarily through distributors. We plan to increase physician acceptance and market penetration through academic promotion, physician training, and publication of additional real-world clinical data based on further R&D activities.

With our established and expanding sales and marketing teams and our experience in managing our comprehensive distribution network, we believe we are well prepared for the future launch of our Core Products, the Bladder Cryoablation System and the Endoscopic Clip for Anastomosis, as well as other innovative products. We are of the view that cryotherapy products are the key driver of our business growth, which will become an increasingly dominant component of our business going forward as the cryotherapy product candidates are gradually commercialized, although we still expect non-cryotherapy products to bring us considerable income in the future.

Our Marketing Model

We employ a strategic marketing model to promote and sell our products. Under this model, we promote our products in China through academic marketing, by establishing research and clinical collaboration and training relationships with hospitals.

To increase awareness of our products and technologies, we conduct educational symposia and provide training to physicians, hospital executives and researchers in the field. Our highly trained sales and marketing team focuses on interacting with physicians to educate them about, and train them in the use of, our products. Such interaction is fostered through regular visits to and communications with physicians, on-site demonstration of our products to physicians, our sponsorship of conferences, seminars and physician education programs and other activities. Although patients are the end users of our products, physicians and procurement departments of hospitals decide what products to stock and physicians typically recommend to patients what products to use. Based on our experience, as physicians become more knowledgeable and experienced with our products, they will be more likely to recommend our products. In addition to accelerating market awareness and adoption of our products, our communications with physicians provide us with continual feedback on our products and trends in the market which helps guide our research and development projects.

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We have taken an active role in the key conferences in China, which serve as good opportunities to educate and train physicians in the relevant fields, and a platform for us to present our products’ innovative and advanced features. Because of our advanced technology and our extensive experience in China, our products have been among the central topics of academic discussions and examples for training, and our research and development experts and management have been invited as speakers to introduce their practices in this field. We have sponsored and participated in various academic conferences that gathered international experts. By hosting seminars and training sessions, presenting exhibitions and sharing our clinical results during such conferences, we are able to enhance physicians’ awareness of our products. Our existing relationships with hospitals also help promote our products among physicians and hospitals through on-site education and training.

As part of our marketing model, we have organized and will continue to organize on-site training and demonstrations in hospitals, in order to build or enhance their capability to conduct such operations and to promote our products. We plan to expand our sales and marketing team and utilize our established relationships with hospitals and physicians to increase sales of our products.

Besides our primary academic marketing model, we also rely on our distributors to sell our products. Each of our distributors has its own sales force that focuses on marketing in its particular territory and assigned hospitals. Distributors have engaged in promoting our products through their network of hospitals and physicians. For details, see “—Our Sales and Distribution Arrangements —Management of our Distribution Network” below in this section.

Our Sales and Distribution Arrangements

In line with industry practice, we adopt a distributorship model and we generally do not sell our products directly to hospitals. During the Track Record Period and up to the Latest Practicable Date, we sold and marketed our products mainly in China. As our products and product candidates gain more approvals for marketing in countries and regions outside China, we will enhance our sales and marketing activities overseas and anticipate increased sales from overseas markets in the future.

We operate a single-layer distribution system, where we engage distributors to sell our products to the hospitals. We do not voluntarily engage any sub-distributors, and we require our distributors not to engage any sub-distributors without our prior consent. In the event that our distributors do have compelling commercial reasons to engage sub-distributors, we require them to make formal applications to us, and we would not approve such applications if we discover that such arrangements violate the “Two-Invoice System”. We chose the distributorship model primarily because we believe it enables us to extend hospital coverage and promote our products to a larger number of hospitals in a cost-effective manner, while focusing on research and development activities. See “—Management of our Distribution Network” below in this section for details.

During the Track Record Period, approximately 99.7% of our total revenue was generated in Mainland China. In terms of domestic sales of our products, we had a total of 37, 53, 57 and 60 distributors who had entered into fixed-term distribution agreements with us, respectively, as of December 31, 2020 and 2021, August 31, 2022 and up to the Latest Practicable Date. A substantial majority of our revenue was derived from such distributors during the Track Record Period.

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The following table sets forth the changes in the number of our such distributors who had entered into fixed-term distribution agreements with us for domestic sales for the periods indicated:

	<u>For 2020</u>	<u>For 2021</u>	<u>From January 1, 2022 to August 31, 2022</u>	<u>From September 1, 2022 to the Latest Practicable Date</u>
Distributors				
As of the beginning of the period	32	37	53	57
Newly engaged	16	18	22	4
Terminated ⁽¹⁾	11	2	18	1
As of the end of the period	37	53	57	60

Note:

- (1) During the Track Record Period and up to the Latest Practicable Date, we terminated the business relationship with 32 distributors, primarily because we refined our distribution network and chose to discontinue our cooperation with certain distributors that we considered did not respond quickly and effectively to our marketing strategies. There were no material dispute or litigation between us and the terminated distributors.

Besides the above distributors, we also cooperated with a number of distributors on an ad hoc basis for domestic sales. Such distributors did not enter into any fixed-term distribution agreements with us, but generally obtained a temporary authorization from us. According to the temporary authorization, such distributors placed purchase orders with us from time to time when their covered hospitals are in need of our products. Although we had 54, 53, 30 and 53 such distributors as of December 31, 2020 and 2021, August 31, 2022 and up to the Latest Practicable Date, respectively, we generally do not sell a substantial amount of goods to such distributors without fixed-term distributorship agreements. We believe that this arrangement allows us to efficiently identify and select distributors who can effectively advance the marketing and sales of our products, so as to screen distributors based on their capabilities. This arrangement also brings us greater visibility and increased coverage by leveraging such distributors’ customer bases. According to Frost & Sullivan, it is an industry norm to engage distributors in an ad hoc manner. Therefore, we may continue to engage such distributors on an ad hoc basis going forward, while the relevant sales to such distributors are expected to remain a small portion of our total sales.

During the Track Record Period, we also engaged distributors for overseas sales which contributed to approximately 0.3% of our total revenue. For further information, see the paragraphs headed “—Overseas Market” in this section.

In 2020, 2021 and the eight months ended August 31, 2022, our sales to distributors who had entered into fixed-term distribution agreements amounted to RMB8.2 million, RMB21.6 million and RMB14.7 million, accounting for 90.5%, 96.2% and 89.6% of our total revenue, respectively. In 2020, 2021 and the eight months ended August 31, 2022, our sales to distributors without fixed-term distribution agreements amounted to RMB0.9 million, RMB0.9 million and RMB1.7 million, accounting for 9.5%, 3.8% and 10.4% of our total revenue, respectively. We generally do not grant credit terms to our distributors. As of the Latest Practicable Date, we had an outstanding balance due from a third party of RMB74 thousand, representing the outstanding balance due from a purchaser who was granted a one-year credit term in 2018 and failed to repay the full amount of purchase. This outstanding balance had been fully impaired, and we required all of our distributors to make prepayment prior to the product delivery during the Track Record Period.

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We believe that most of the existing distributors engaged by us have the capabilities to sell cryotherapy products based on their established distribution network, local resources and industry reputation, and we do not need to completely rebuild our distribution network. Our Bladder Cryoablation System and other cryotherapy products are innovative in the Chinese market, and we plan to introduce them first to Class III hospitals after receiving approval for commercialization. As of the Latest Practicable Date, the distributors engaged by us had sold our commercialized products to several hundred Class III hospitals, demonstrating their strong distribution capabilities and resources in line with our commercialization strategies for cryotherapy devices. For future sales of cryotherapy products, we will select suitable distributors among existing distributors based on their experience in the cryotherapy related fields, their relationships with hospitals and physicians within their designated territories, as well as their promotion and bidding capabilities. We will reassess their financial condition and market management capabilities before and after sale. Meanwhile, we will also consider engaging new distributors for cryotherapy products following the same considerations and standards after measuring market demands. For further information regarding selection of distributors, see the paragraphs headed “—Management of our Distribution Network—Selection of Distributors” in this section. For risks associated with engaging distributors for cryotherapy products, see “Risk Factors—Risks Relating to Our Products and Product Candidates—Risks Relating to the Commercialization of Our Product Candidates—If our distributors fail to expand or maintain their sales network, or if we fail to educate or manage our distributors effectively, our sales may decline” in this document.

Management of our Distribution Network

Selection of Distributors

Our sales and marketing team screens and selects distributors whom we believe have the required qualifications and capabilities and are suited to our strategic marketing model, and establishes and maintains resource sharing with our distributors to effectively execute our marketing strategies specifically tailored to each geographic location and the hospitals located within their locations.

Upon selecting distributors, we will first evaluate their qualifications. We select our distributors based on their experience in the medical device industry. In addition, they must possess the requisite business licenses and permits to sell medical devices in the respective jurisdictions and must have established relationships with hospitals and physicians within their designated territories. Before we appoint a distributor, we assess its sales staff and management team to ensure that they have the appropriate knowledge, experience and professional skills. We also consult with the hospitals regarding our choice of distributors. During the Track Record Period, none of our distributors had any past or present relationship (business or otherwise) with our Group, our shareholders, directors, supervisors, senior management or any of their respective associates.

Rights and Obligations of Sales and Distributions

We do not allow overlap of distributors among hospitals for the same product. Distribution relationships between our distributors and the respective hospitals are exclusive. Our distributors are responsible for collecting payments from hospitals, and are required to pay us for the products regardless of whether they receive payments from the hospitals. We generally issue our invoice to each distributor when such distributor places an order for our products.

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A substantial majority of our revenue was derived from distributors with which we had entered into a written distribution agreement during the Track Record Period. We entered into a master agreement with each of such distributors, with addenda that specify terms including designated products to be distributed and their unit prices, as well as the designated distribution area and hospitals. The principal terms of the master agreement are summarized below:

Duration and option to renew	The term of the agreement is specified in each agreement subject to early termination and renewal clause(s).
Designated geographical regions and hospitals	The geographical regions and/or hospitals for which a distributor is responsible are designated. A distributor is prohibited from selling our products outside its designated geographical regions or hospitals.
Transfer of contractual rights to sub-distributors	We typically require the distributors to notify us and obtain our approval before selling our products to any sub-distributors.
Target sales amount	We may specify the type and target amount of products that the distributors shall purchase from us in the relevant distribution agreement.
Transportation	Typically, we are responsible for transporting our products and bear the costs and risk of loss of the transportation.
Product returns	In general, the distributor may not return products to us or exchange products except that a product has quality issues.
Obsolete stock return	None
Warranty	We ensure that the quality of our products complies with relevant national standard and take responsibility of quality defects.
Termination	The agreement may be terminated by us when, among other things, the distributor fails to comply with relevant laws and regulations, or breaches any undertaking in the agreement and fails to remedy such breach as requested by us.
Regulatory compliance	The distributor is required to obtain relevant permits and qualifications to sell and distribute medical devices.
Use of the trademark	We do not allow our distributors to use our trademarks or logos, unless they have obtained our written confirmation.

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We regularly evaluate the performance of distributors primarily based on the amount of products they purchase from us during a specific period. We generally don't grant credit terms to our distributors, and generally require our distributors to make prepayment in full before delivery of our products. During the Track Record Period, our distributors did not materially breach our contract terms, and we did not have any disputes with them relating to the settlement of trade receivables. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors which could adversely affect our reputation, business operation or financial contribution.

Distributor Inventory Management

Our distributors generally place orders with us based on actual demands from end customers or estimation of such demand. As of December 31, 2020 and 2021 and August 31, 2022 and up to the Latest Practicable Date, the amount of unsold inventory held by our distributors was RMB0.4 million, RMB2.9 million, RMB2.3 million and RMB2.8 million, respectively, representing 2.5%, 7.5%, 4.2% and 4.4% of the cumulative amount sold to our distributors since the commercialization of our products and up to the relevant year/period end. We believe that our sales to distributors during the Track Record Period reflected genuine market demand and the risk of channel-stuffing is relatively low, considering the following measures and conditions.

- **Credit term.** We generally require our distributors to make prepayment in full before delivery of our products. We believe that this would require our distributors to effectively manage their inventory and cash flow, and ensure that orders are made based on actual demand. Going forward, we generally will not grant credit terms to distributors except for major distributors determined on a case-by-case basis after our prudent assessment.
- **Sales and inventory check.** The distribution agreements require our distributors to report their inventory level every month in writing to us, and to maintain sales records of our products for traceability, and upon request, to send the sales records to us. We check distributors' sales records including invoices to ensure that the sales data provided by distributors reflect genuine sales to end customers. To the knowledge of our Directors, a substantial majority of the products we sold to our distributors had been resold to the end users (i.e., hospitals), and the amount of unsold inventory held by our distributors as of December 31, 2020 and 2021, August 31, 2022 and the Latest Practicable Date were immaterial.
- **Strict return policy.** We generally do not accept product returns except for products with quality defects. Therefore, we believe that our distributors tend to only purchase products that they can reasonably expect to sell and keep their inventory level relatively low. During the Track Record Period, we did not experience any material product return from distributors or end customers.
- **Distributor independence.** During the Track Record Period and up to the Latest Practicable Date, to the best knowledge of our Directors, all of our distributors and sub-distributors were Independent Third Parties, none were controlled by our current or former employees, and none had any past or present relationship (including, without limitation, business, employment, family, trust, financing or otherwise) with our Company, our subsidiaries, Directors, Supervisors, shareholders, senior management or any of their respective associates.

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Implication of and Compliance with the “Two-Invoice System”

According to our PRC Legal Adviser, while the progress of implementation of the “Two-Invoice System” for high-value medical consumables varies in different provinces in China, such requirement currently does not have any substantial adverse legal consequence on our Company, if not totally inapplicable. To date, no local competent authorities of the provinces in which our products were sold during the Track Record Period and up to the Latest Practicable Date has taken the position that the “Two-Invoice System” applies to our products.

With respect to our commercialized products and product candidates that are expected to be launched in the future, in the event that such products were deemed to have implicated the “Two-Invoice System” by the local competent authorities of the provinces that had implemented the “Two-Invoice System” strictly, we would ensure that the products that we sell to distributors be directly resold to hospitals instead of any sub-distributors, by imposing contractual obligations upon our distributors under our distribution agreements to be entered into with such distributors. When it comes to other provinces, we will adopt internal control measures and conduct periodic monitoring of the distributing activities of our distributors (such as requiring them to file with us invoices issued to hospitals) in order to secure their compliance with the requirements of the “Two-Invoice System.” We would also promptly seek to enter into supplemental agreements with our distributors, pursuant to which they would be obligated to resell our products directly to hospitals, should these provinces elect to implement strictly the “Two-Invoice System” as related to our products. Such arrangement, as we believe, would not significantly impact our sales or financial position as we can cooperate with other distributors if our distributors refuse to enter into the said supplemental agreements with us. In addition, we have adopted a series of internal control measures to monitor the implementation of the Two-Invoice System in different provinces to ensure our continuous compliance with the related rules, regulations and policies. Such measures include but not limited to the following: (i) providing regular trainings to our management and sales and marketing team to enhance their understanding of the Two-invoice System and related rules and regulations; (ii) requiring our sales and marketing team to timely adjust the distribution strategy according to the latest implementation status of the Two-invoice System; and (iii) communicating regularly with distributors, sub-distributors and end customers to ensure that our products are not resold by distributors or sub-distributors without authorization. For details, see the paragraphs headed “— Internal Control Over Business Operations” in this section.

Our Directors confirmed that during the Track Record Period and up to the Latest Practicable Date, we (i) had not been deemed to have violated or circumvented any law, regulations, rules or policies in relation to the “Two-Invoice System”, (ii) had not been disqualified from participating in public tendering processes in any province, (iii) were not subject to any administrative fines or penalties by the competent authorities in relation to the “Two-Invoice System”, and (iv) had not received any warning or notice from any competent authorities in relation to the compliance of the “Two-Invoice System”.

We have no contractual relationship with sub-distributors engaged by our distributors, and thus do not recognize any revenue attributable to sub-distributors. In 2020, 2021 and the eight months ended August 31, 2022, the sales of our products which were resold by our distributors to sub-distributors was approximately RMB1.0 million, RMB3.1 million and RMB1.9 million, accounting for 11.4%, 13.7% and 11.5% of our revenue for the corresponding periods, respectively. During the Track Record Period and up to the Latest Practicable Date, our Directors were not aware of any resale of our products by any distributor to any sub-distributor, or any resale of our products by any sub-distributor, in provinces, autonomous regions and municipalities where the “Two-Invoice System” has been mandatorily

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implemented. In addition, as confirmed by our PRC Legal Adviser, as of the Latest Practicable Date, there were no promulgated laws or regulations clearly setting forth the administrative penalty on our Company if our distributors resell our products to sub-distributors without our permission in violation of the relevant laws and regulations in relation to the “Two-Invoice System”. As confirmed by our PRC Legal Adviser, during the Track Record Period and up to the Latest Practicable Date, we had not violated or circumvented any applicable PRC laws rules or regulations relevant to the “Two-Invoice System” in all material aspects.

Overseas Market

During the Track Record Period, only 0.3% of our total revenue was generated from overseas sales, including sales in South America and Europe that recognize CE Mark. The products sold overseas included the Laparoscopic Single Port Multi-Channel Access Platforms and the Wound Retractors, both of which had obtained CE Mark before such sales. In particular, for each of these two products, we started to sell each of these two products in Europe in March 2021. We have not commercialized the Pulmonary Nodule Localization Needle and Ureteral Dilation Balloon Catheter in Europe even though they have obtained CE Mark, because we focus mainly on the development of cryotherapy products and, to a lesser extent, the expansion of the domestic market, and thus we have not vigorously marketed our products in Europe. We engaged distributors to sell our products overseas, which primarily obtained authorization from us and placed purchase orders from us from time to time. All of our overseas distributors during the Track Record Period and up to the Latest Practicable Date are Independent Third Parties. Our relationship with them is not that of a principal and an agent, but that of a customer and a supplier.

Our commercialization of the Core Products in overseas markets will take place gradually after their commercialization in China. We plan to first conduct further R&D activities including clinical trials to obtain approval for commercialization, such as CE Mark, in the target markets. Upon receiving approval, we expect to identify and collaborate with overseas KOLs to promote the relevant products and to enhance our brand awareness (e.g., by attending international academic conferences), and to seek suitable overseas distributors and leverage their local resources to expand markets. Meanwhile, we also expect to collect more post-launch real-world data and endeavor to gain international recognition. There are some distinctions between our business plans and strategies in China and overseas markets. For commercialization of the Core Products in China, we rely on both our own sales and marketing team and our distributors to expand our sales network, and plan to recruit additional experienced sales managers and local sales personnel to enhance marketing capacities. In contrast, for overseas markets, as we are still in the process of forming our own overseas sales and marketing team, we may rely on major distributors with strong marketing and distribution capabilities to carry out overseas commercialization strategies. For details of the overseas market expansions for our Core Products and major product, see the paragraphs headed “—Our Products and Product Candidates—Our Core Products—1. Bladder Cryoablation System—Further Development Plan”, “—Our Products and Product Candidates—Our Core Products—2. Endoscopic Clip for Anastomosis—Further Development Plan” and “—Our Products and Product Candidates—Other Products and Product Candidates—Vascular Interventional Cryotherapy Products—1. AF Cryoablation System—Further Development Plan” in this section. For the non-core or non-major product candidates, we had not formulated concrete and detailed plans as to their indication expansions or overseas market expansions as of the Latest Practicable Date.

Pricing

We had six commercialized products in the market during the Track Record Period. We sell products to our distributors at the price determined by us from time to time.

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With respect to the prices at which our products are sold to our distributors (the “**Ex-factory Prices**”), we determine such prices based on a number of factors. We conduct extensive market research with hospitals, physicians and patients as well as regulatory bodies before pricing our products, and take into account various factors such as feedbacks collected from these parties, our costs, the prices of competing products, if any, the differences in safety and efficacy profiles between our products and comparable competing products, the estimated demands for our products, and the possibility that our products being subject to the centralized procurement programs organized by local governments. For overseas distributors, the Ex-factory Prices are determined on a case by case basis. For details of the average selling prices of our commercialized products, see “Financial Information—Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income—Revenue” in this document.

With respect to the prices at which our products are resold to hospitals by distributors, we are generally required to, and sometimes voluntarily choose to, participate in public tender processes organized by government agencies or the relevant hospitals, to determine such prices. Before such tender processes, our management team will work together with our sales and marketing team to determine the acceptable price range and our bidding strategy. Once the tender processes are finished and if we are confirmed as the winning bidder, our products will be admitted into the hospitals’ qualified product pool for future procurement by the relevant hospitals.

In particular, we plan to set reasonable Ex-factory Prices and end-user prices for our Core Products. In respect of the Bladder Cryoablation System, as no competing product had been commercialized as of the Latest Practicable Date, we will mainly refer to reasonable prices of similar products for use in the urology department, and also consider a number of factors, such as the estimation of market conditions, production costs, as well as market supplies and demands, when setting prices. In respect of the Endoscopic Clip for Anastomosis, we do not intend to directly follow competitors’ historical pricing strategy or base prices solely on the prices of competing products. Instead, we will take into account a number of factors, such as the estimation of market conditions, production costs, market supplies and demands, as well as the features of our product including its detachable structure and other factors. Prices of competing products will be one of these numerous factors, but not the denominating factor. We intend to set the price that we believe can help us to quickly capture the market while ensuring profitability. With our competitive advantages, we believe we can set appropriate prices to quickly capture the market and establish industry barriers. In the future, we will continue to iterate and innovate our products. We believe that such strategies can help us achieve expedited commercial adoption of our products and maintain our competitiveness in the industry.

OUR CUSTOMERS

The aggregate sales to our five largest customers for 2020, 2021 and the eight months ended August 31, 2022 were RMB3.3 million, RMB8.2 million and RMB6.6 million, respectively, representing 37.0%, 36.5% and 40.3% of our revenue for the respective period. Sales to our largest customer for 2020, 2021 and the eight months ended August 31, 2022 were RMB0.8 million, RMB1.9 million and RMB1.8 million, respectively, representing 8.8%, 8.4% and 10.8% of our revenue for the respective period. Since we adopt a distributorship model, our five largest customers for 2020, 2021 and the eight months ended August 31, 2022 were our distributors. We generally do not grant credit terms to our distributors, and our distributors generally settle with us by bank transfers.

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The table below summarizes the sales to our five largest customers for the periods indicated:

Five Largest Customers for 2020	Customer Background	Products Sold	Length of Business Relationship	Sales Amount	Percentage of Total Sales
				RMB'000	%
Customer A	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles	Since September 2020	800	8.8
Customer B	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles, Laparoscopic Single Port Multi-Channel Access Platforms and Wound Retractors	Since November 2018	738	8.2
Customer C	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles and Laparoscopic Single Port Multi-Channel Access Platforms	Since May 2017	704	7.8
Customer D	A China-based company that engages in, among others, the sales of medical devices	Laparoscopic Single Port Multi-Channel Access Platforms and Laparoscopic Surgical Instruments	Since October 2019	553	6.2
Customer E	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles	Since May 2019	540	6.0
Total				3,335	37.0

Five Largest Customers for 2021	Customer Background	Products Sold	Length of Business Relationship	Sales Amount	Percentage of Total Sales
				RMB'000	%
Customer F	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles and Laparoscopic Single Port Multi-Channel Access Platforms	Since April 2018	1,889	8.4
Customer G	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles, and Laparoscopic Single Port Multi-Channel Access Platforms and Wound Retractors	Since January 2021	1,644	7.3
Customer C	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles and Laparoscopic Single Port Multi-Channel Access Platforms	Since May 2017	1,593	7.1
Customer H	A China-based company that engages in the sales of medical devices	Pulmonary Nodule Localization Needles	Since December 2019	1,586	7.1
Customer I	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles	Since August 2020	1,487	6.6
Total				8,198	36.5%

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Five Largest Customers for the Eight Months Ended August 31, 2022	Customer Background	Products Sold	Length of Business Relationship	Sales Amount <i>RMB'000</i>	Percentage of Total Sales %
Customer G	A China-based company that engages in, among others, the sales of medical devices	Mainly Pulmonary Nodule Localization Needles	Since January 2021	1,773	10.8
Customer A	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles	Since September 2020	1,394	8.5
Customer C	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles and Laparoscopic Single Port Multi-Channel Access Platforms	Since May 2017	1,330	8.1
Customer J	A China-based company that engages in, among others, the sales of medical devices	Pulmonary Nodule Localization Needles	Since January 2021	1,080	6.6
Customer F	A China-based company that engages in, among others, the sales of medical devices	Mainly Laparoscopic Single Port Multi-Channel Access Platforms	Since April 2018	1,042	6.3
Total				6,619	40.3

We sell our commercialized products to hospitals primarily through distributors. As of August 31, 2022, we cooperated with 57 distributors who had entered into fixed-term distribution agreements with us for the sales of our commercialized products in China.

During the Track Record Period, none of our Directors, Supervisors, or any Shareholders, who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following the completion of the [REDACTED] nor any of their respective associates had any interest in any of our five largest customers.

OUR SUPPLIERS AND RAW MATERIALS

Purchases from our five largest suppliers for 2020, 2021 and the eight months ended August 31, 2022 amounted to RMB9.2 million, RMB13.4 million and RMB3.7 million, respectively, representing 31.6%, 24.3% and 9.6% of our total purchases for the respective period. Purchases from our largest supplier for 2020, 2021 and the eight months ended August 31, 2022 amounted to RMB4.3 million, RMB5.8 million and RMB0.9 million, respectively, representing 14.8%, 10.6% and 2.3% of our total purchases for the respective period. In 2020 and the eight months ended August 31, 2022, our suppliers mainly included raw material suppliers and research service providers. In 2021, we (i) engaged a financial consulting service provider in connection with our Series B Financing, (ii) engaged several construction or decoration service providers when building our manufacturing facility in Shanghai, and (iii) engaged several professional service providers in connection with the [REDACTED]. We believe such purchases were primarily one-off purchases in nature, and expect that our major suppliers would change back to raw material suppliers and research service providers after such one-off purchases are fully settled.

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We generally settle with our suppliers by bank transfer. Credit terms granted to us are determined on a case-by-case basis based on milestone payments contemplated under the supply agreements. The table below summarizes the purchases from our five largest suppliers for the periods indicated:

<u>Five Largest Suppliers for 2020</u>	<u>Supplier Background</u>	<u>Products/Services Purchased</u>	<u>Length of Business Relationship</u>	<u>Purchase Amount</u>	<u>Percentage of Total Purchase</u>
				<i>RMB'000</i>	<i>%</i>
Supplier A	CRO	Clinical research organization services	Since March 2019	4,300	14.8
Supplier B	SMO	Site management organization services	Since April 2019	1,689	5.8
Supplier C	US-based raw material supplier	Raw material (steerable sheaths)	Since January 2019	1,409	4.8
Supplier D	Clinical trial center	Clinical trial center	Since June 2015	1,032	3.5
Supplier E	China-based raw material supplier	Raw material (balloons and mapping catheters)	Since October 2016	774	2.7
Total				9,203	31.6

<u>Five Largest Suppliers for 2021</u>	<u>Supplier Background</u>	<u>Products/Services Purchased</u>	<u>Length of Business Relationship</u>	<u>Purchase Amount</u>	<u>Percentage of Total Purchase</u>
				<i>RMB'000</i>	<i>%</i>
Supplier F	China-based financial consulting service provider	Financial consulting services	Since June 2020	5,809	10.6
Supplier G	China-based decoration service provider	Decoration services	Since April 2021	3,037	5.5
Supplier C	US-based raw material supplier	Raw material (steerable sheaths)	Since January 2019	1,546	2.8
Supplier H	China-based construction service provider	Construction services	Since April 2021	1,524	2.8
Supplier I	China-based decoration service provider	Office decoration and furniture procurement	Since April 2021	1,456	2.6
Total				13,371	24.3

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Five Largest Suppliers for the Eight Months Ended August 31, 2022	Supplier Background	Products/Services Purchased	Length of Business Relationship	Purchase	Percentage of Total
				Amount	Purchase
				<i>RMB'000</i>	<i>%</i>
Supplier J	US-based raw material supplier	Raw material (mainly sensors and displays)	Since December 2014	865	2.3
Supplier K	China-based raw material supplier	Raw material (mainly medal connectors)	Since April 2015	771	2.0
Supplier L	China-based raw material supplier	Raw Material (tubes and handles)	Since August 2019	742	1.9
Supplier M	China-based raw material supplier	Raw Material (turbomolecular pumps)	Since January 2016	703	1.8
Supplier N	CRO	Clinical research organization services	Since September 2019	621	1.6
Total				3,701	9.6

All of our five largest suppliers during the Track Record Period are Independent Third Parties. None of our Directors, Supervisors, or any Shareholder who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED] nor any of their respective associates had any interest in any of our five largest suppliers during the Track Record Period.

Raw Materials

For our cryotherapy products, we primarily use raw materials including outer tubes, balloons, microcomputer, vacuum pumps and solenoid valves. For our non-cryotherapy products, we primarily use raw materials including stainless steel tubes, braided tubes and handles. In 2020, 2021 and the eight months ended August 31, 2022, our costs of sales amounted to RMB4.4 million, RMB6.9 million and RMB5.2 million, respectively.

We select our raw material suppliers based on a number of factors, including the licenses and qualifications of suppliers, quality of raw materials, after-sales service and price. We use reputable suppliers from China, the United States and other countries. Based on the current market conditions, we intend to maintain stable working relationships with our major suppliers of raw materials. However, we cannot assure that we will maintain our working relationships with our major suppliers on similar terms, if at all. Although we maintain a list of backup suppliers if any supplier fails to timely deliver raw materials, we are still subject to risks associated with shortage of raw materials. For details, see “Risk Factors—Risks Relating to Our Products and Product Candidates—Risks Relating to Manufacture and Supply of Our Products and Product Candidates—We rely on a limited number of suppliers, and may not be able to secure a stable supply of qualified raw materials at all times or at all” in this document.

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Our manufacturing team monitors a rolling forecast of demand for specific products while our research and development team provides specifics of raw materials to be purchased. We maintain a pool of qualified suppliers for internal purposes, which is reviewed periodically. As of the Latest Practicable Date, we had a pool of around 140 qualified suppliers of raw materials. We inspect raw material candidates from qualified suppliers in such pool and make necessary purchases according to inventory risks and costs associated with the raw materials and components needed.

Procurement Agreements with Suppliers

For our principal raw materials, we generally enter into an agreement with each supplier. The table below sets forth the principal terms of our typical procurement agreements:

Sales and pricing policy	The price or pricing mechanism is specified in each agreement or subject to negotiation pursuant to each agreement.
Transportation and delivery	Suppliers are responsible for transportation and delivery method is specified in each agreement or purchase order.
Payment	We usually make prepayments before shipment or otherwise as specified in each agreement or purchase order.
Raw materials quality	Suppliers are subject to standard quality control terms specified or referenced to in each agreement or purchase order.
Warranty	Suppliers warrant that the raw materials shall satisfy our requirements specified in supply agreements or purchase orders.
Return/Exchange	We examine raw materials when we receive them and may reject any raw materials that do not meet our requirements within specified periods upon receipt.
Confidentiality	Pursuant to each agreement, both parties shall keep confidential the information acquired in the performance of the agreement.

During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material difficulties in procuring our major raw materials and had not experienced significant fluctuations in the prices of our supplies. To the best knowledge of our Directors, there has been no material breach of our procurement agreements with our suppliers during the Track Record Period. Our Directors believe, after taking into consideration the impact of the potential outbreak of COVID-19, that we would not experience any material difficulties in procuring our major raw materials.

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INVENTORY MANAGEMENT

Our inventories consist of raw materials, work in progress, finished products and goods shipped in transit. We regularly monitor our inventories to reduce the risk of overstocking. We physically count all of our raw materials, work in progress, finished goods and goods shipped in transit twice a year to identify products that are damaged, expired or soon-to-be expired.

Our non-cryotherapy products generally have a shelf life of two to three years. We communicate frequently with our distributors to understand the feedback from end customers and anticipate their needs. In our day-to-day management, we connect directly with the distributors' sales personnel and with different sales and marketing teams of larger distributors, in order to closely communicate with them and monitor their sales. We require distributors to provide to us details of their sales volume to hospitals to assess actual market demand for our products and distributors' performance. In addition, we set minimum purchase amounts for certain distributors, which serve as annual sales goals instead of strict purchase requirements. Our Directors confirm that we did not experience any material shortage in supply or overstock of inventories during the Track Record Period and up to the Latest Practicable Date.

We currently store all our inventories in our production facilities in Shanghai and Ningbo, Zhejiang. As of December 31, 2020 and 2021 and August 31, 2022, we had inventories of RMB8.1 million, RMB11.7 million and RMB15.8 million, respectively.

QUALITY CONTROL

We have designated safety personnel who are involved in every aspect of our daily operations to ensure the quality control of our products. As of the Latest Practicable Date, our quality control team consisted of 67 employees responsible for quality control of our product candidates and our commercialized products.

We have established a strict quality control system in accordance with the NMPA's regulations, and obtained ISO 13485:2016 certification, which demonstrates recognitions for our quality control system. Our quality control measures are carried out throughout our production process, including the following:

- **Raw material control and inspection:** we conduct comprehensive due diligence on our suppliers and only purchase raw materials from those who meet our internal supply management criteria. We also inspect samples from critical raw materials to help ensure there are no quality or other issues;
- **Production process control:** we arrange the production process according to the technologies used in 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, industry standards and regulatory requirements, 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
- **Environment control:** we design environment control protocol for our labs and production facilities, and monitor the implementation of the protocols.

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During the Track Record Period and up to the Latest Practicable Date, we have complied with all of our quality qualification requirements in material respects and have passed all of the inspections. In addition, we were not aware of any findings from the competent regulatory authorities indicating that our product candidates under clinical trials are defective and we had not experienced any material complaint or product return from subjects enrolled in our clinical trials or hospitals where we conducted our clinical trials.

COMPETITION

We operate in a rapidly evolving market, resulting from continuous product development and technological advances. We face potential competition with major international medical device companies as well as domestic medical device companies which are developing cryotherapy systems and other relevant products. We compete primarily based on the clinical performance of our products and pipeline products, our ability to commercialize products, research and development capabilities, product quality and brand recognition.

For further details of competition in the markets we serve, please see the paragraphs headed “—Our Products and Product Candidates” in this section and the section headed “Industry Overview” in this document.

INTELLECTUAL PROPERTY RIGHTS

We have built a comprehensive intellectual property portfolio to protect our technologies, inventions and know-how and ensure our future success with commercializing our products. As of the Latest Practicable Date, we had 110 registered patents, 18 registered trademarks, as well as 44 pending patent applications and 13 pending trademark applications in China and overseas. Among the 110 registered patents, 99 were self-developed and 11 were acquired from a third party. We believe there is no material legal impediment for us to obtain the approvals for these pending patents and trademarks.

The table below lists the material patents and patent applications directly in relation to the Bladder Cryoablation System, one of our Core Products, as of the Latest Practicable Date:

<u>Application Number</u>	<u>Invention Title</u>	<u>Patent Type</u>	<u>Jurisdiction</u>	<u>Status</u>	<u>Patent Expiry Date</u>	<u>Commercial Rights</u>	<u>Owner/ Applicant</u>
201510398917.6	A novel cryoablation catheter for intracavitary tumors and its operation method (一種新型的腔內腫瘤冷凍消融導管及其操作方法)	Invention	China	Issued	July 9, 2035	All rights	Ningbo SensCure
201520490977.6	A novel tumor cryoablation catheter (一種新型腫瘤冷凍消融導管)	Utility model	China	Issued	July 9, 2025	All rights	Ningbo SensCure
201721490983.7	An operating handpiece for use with cryoablation catheters under cystoscope (一種配套膀胱鏡下冷凍消融導管使用的操作手件)	Utility model	China	Issued	November 10, 2027	All rights	Ningbo SensCure

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The table below lists the material patents and patent applications directly in relation to the Endoscopic Clip for Anastomosis, one of our Core Products, as of the Latest Practicable Date:

<u>Application Number</u>	<u>Invention Title</u>	<u>Patent Type</u>	<u>Jurisdiction</u>	<u>Status</u>	<u>Patent Expiry Date</u>	<u>Commercial Rights</u>	<u>Owner/ Applicant</u>
201810614849.6	A detachable endoscopic anastomotic clamp (一種可拆解的內鏡吻合夾)	Invention	China	Issued	June 14, 2038	All rights	Ningbo SensCure
201820924609.1	An endoscopic anastomotic clip (一種內鏡吻合夾)	Utility model	China	Issued	June 14, 2028	All rights	Ningbo SensCure
US17087820	A detachable endoscopic anastomotic clamp (一種可拆解的內鏡吻合夾)	Invention	U.S.	Issued	June 13, 2039	All rights	Ningbo SensCure
EP2019820627	A detachable endoscopic anastomotic clamp (一種可拆解的內鏡吻合夾)	Invention	Europe	Pending	N/A	All rights	Ningbo SensCure
JP2021514468	A detachable endoscopic anastomotic clamp (一種可拆解的內鏡吻合夾)	Invention	Japan	Pending	N/A	All rights	Ningbo SensCure
BR112020023896	A detachable endoscopic anastomotic clamp (一種可拆解的內鏡吻合夾)	Invention	Brazil	Pending	N/A	All rights	Ningbo SensCure
AU2019284321	A detachable endoscopic anastomotic clamp (一種可拆解的內鏡吻合夾)	Invention	Australia	Issued	June 13, 2039	All rights	Ningbo SensCure
KR1020207033212	A detachable endoscopic anastomotic clamp (一種可拆解的內鏡吻合夾)	Invention	Korea	Pending	N/A	All rights	Ningbo SensCure

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The table below lists the material patents and patent applications directly in relation to the AF Cryoablation System, as of the Latest Practicable Date:

<u>Application Number</u>	<u>Invention Title</u>	<u>Patent Type</u>	<u>Jurisdiction</u>	<u>Status</u>	<u>Patent Expiry Date</u>	<u>Commercial Rights</u>	<u>Owner/ Applicant</u>
201710738574.2	A vacuum system (一種真空系統)	Invention	China	Issued	August 25, 2037	All rights	The Company
201710816282.6	A cryoablation catheter and a cryoablation system (一種冷凍消融導管及系統)	Invention	China	Issued	September 12, 2037	All rights	The Company
201911368273.0	A cryoablation system convenient for monitoring fluid flow state (一種便於流體流動狀態監測的冷凍消融系統)	Invention	China	Pending	N/A	All rights	The Company
201911368245.9	A cryoablation system with multiple safety detection and prevention devices (一種具有多重安全檢測及預防裝置的冷凍消融系統)	Invention	China	Pending	N/A	All rights	The Company
201820882590.9	A cryoablation system that uses vacuum to control energy delivery (一種利用真空度控制能量傳遞的冷凍消融系統)	Utility model	China	Issued	June 8, 2028	All rights	The Company
EP18855833.2	A cryoablation catheter and a cryoablation system (冷凍消融導管及系統)	Invention	Europe	Pending	N/A	All rights	The Company
JP2020535287	A cryoablation catheter and a cryoablation system (冷凍消融導管及系統)	Invention	Japan	Pending	N/A	All rights	The Company

We also own a number of registered trademarks for our Company and our corporate logo in China. For further details of our intellectual property, see Appendix VI to this document.

The term of an individual patent may vary based on the countries or regions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular country/region and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our issued patents or any of our patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same.

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We rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality arrangements with consultants, advisers and contractors. We have entered into confidentiality and non-competition agreements with our key employees and employees involved in research and development, and have also established internal policies governing the confidentiality of all company information and intellectual property management. For details, see “—Employees” in this section.

These agreements may not provide sufficient protection of our trade secrets and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises as well as physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. For details, see “Risk Factors—Risks Relating to Our Products and Product Candidates—Risks Relating to Our Intellectual Property Rights” in this document.

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any material proceedings in respect of intellectual property right infringement claims against us or initiated by us. However, there are risks if we fail to protect our intellectual property rights in the future. For details, see “Risk Factors—Risks Relating to Our Products and Product Candidates—Risks Relating to Our Intellectual Property Rights” in this document.

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 are committed to social responsibilities, and consider environmental, social and governance (“ESG”) essential to our continuous development, and we believe we have adequate policies ensuring compliance with all health, safety, social and environmental protection regulations.

Under the oversight of the Board, we actively identify and monitor the actual and potential impact of environmental, social and climate-related risks on our business, strategy and financial performance, and incorporate considerations for these issues into our business, strategic and financial planning. We focus on areas such as employee responsibility, environment responsibility and public responsibility. Corporate social responsibility is viewed as part of our core growth philosophy that will be pivotal to our ability to create sustainable value for our Shareholders by embracing diversity and public interests.

BUSINESS

Our quality control team is responsible for monitoring and enforcing the compliance of our operations with environment, health and safety laws and regulations. This responsibility is executed through training; formulation and implementation of strategies, policies, standards and metrics; communication of environmental, health and safety policies and procedures; environmental, health and safety audits; and incident response planning and implementation. With the oversight of our management, our quality control team will assess the likelihood of such risks occurring and the estimated magnitude of any impact.

Environmental Risks and Our Mitigating Measures

We do not operate in a highly polluting industry, but the manufacturing process of our products and product candidates for our clinical trials and research may generate solid and liquid waste and exhaust gas and disposable reagents (such as used filter membranes and used test tubes). Our business operations involve the use of hazardous and flammable chemical materials (such as waste adhesive and alcohol). We implemented safety guidelines setting out information about potential safety hazards and procedures for operating in our laboratory and manufacturing facilities.

We have engaged third-party waste treatment service providers to collect and treat hazardous waste produced in connection with our operations. We select such service providers by considering their quality, industry reputation and compliance with relevant regulatory agencies. We inspect their business licenses, relevant operating permits and certificates for hazardous waste before engaging such service providers and require them to treat and dispose our hazardous waste in accordance with the applicable PRC environmental laws and regulations. For 2020, 2021 and the eight months ended August 31, 2022, we spent approximately RMB9.9 thousand and RMB40.8 thousand and RMB1.5 thousand, respectively, with respect to environmental protection. The substantial increase in the costs incurred on environmental protection in 2021 was mainly due to our modification of sewage systems in accordance with stricter regulatory rules and regulations in recent years, the cost of which was due and incurred in 2021. Our Directors consider that the annual costs of compliance with the applicable health, safety, social and environmental laws and regulations were not material during the Track Record Period and we do not expect the costs of such compliance to be material going forward.

We have adopted stringent policies to ensure the proper handling, management and disposal of hazardous waste. We will continue to engage qualified third parties to dispose of our hazardous waste. We expect that the fees paid by us for hazardous waste disposal will increase as a result of our business growth, while the relevant expenses are expected to remain a small portion of our total operating expenses and will not significantly affect our financial position in the foreseeable future. In compliance with the relevant environmental laws and regulations, we have also adopted stringent policies to ensure the proper handling and management of hazardous and flammable chemical materials, and disposal of hazardous waste produced in our manufacturing process. For example, we have implemented our Hazardous Waste Management Measures (《危險廢物管理規定》) to ensure separate management, centralized disposal and full process control of hazardous waste to reduce waste and its environmental impact. We stay tuned on any possibilities of switching to raw materials with less environmental impact in the course of technological advancement and our research and development progress, and will duly assess the feasibility of adopting such raw materials and the regulatory framework thereof.

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Occupational Health and Safety-Related Risks and Our Mitigating Measures

We also identify occupational health and safety-related risks arising from our daily production. We strive to provide a safe working environment for our employees. We have implemented work safety guidelines setting out safety practices, accident prevention and accident reporting procedures. Our employees responsible for manufacturing and quality control and assurance are required to hold relevant qualifications, as well as wear the proper safety gear when working. We conduct regular safety inspections and maintenance for our manufacturing facility. We have implemented company-wide health, safety, social and environmental protection policies and standard operating procedures that include management systems and procedures relating to emissions of air, water and other media; waste water generation and treatment; process safety management; handling, use, storage, treatment and disposal of hazardous substances; worker health and safety requirements; noise and light pollution control; emergency planning and response. We have not had any significant workplace accidents since our inception.

Climate-Related Risks and Our Mitigating Measures

In the long term, we have also identified potential risks from climate change and other environmental issues that may have potential financial implications for us. For example, if we suffer from extreme weather conditions, our facilities may encounter disruptions and our operations may be directly impacted. Extreme weather may also cause disruptions for our suppliers, which may in turn adversely impact our ability to provide on-premise deployment, on-site meetings or technical support to our customers and end-users. In view of the nature of our business, we do not anticipate the climate change to have any material impact on our business operation. In case of extreme natural weather, we will actively respond to the relevant policies of local government, make contingency plans in addition to the life insurance to ensure the safety of our staff. In the case of acute physical risks such as direct damage to assets and indirect impacts from supply chain disruption as a result of extreme weather events, we will make the corresponding disaster preparedness plan. We believe that we have the ability to deal with climate crisis. As of the Latest Practicable Date, we had not experienced any material impact on our business operations, strategies or financial performance as a result of climate-related issues.

Our business operations are subject to environmental protection laws and regulations promulgated by the PRC government. For example, we are required by the relevant governmental authorities to carry out an environmental impact assessment before constructing factory or production equipment to minimize the impact of our business operations on the environment. Maintaining compliance with applicable environmental rules and regulations is costly. If we breach any environmental-related laws and regulations, or face any accusation of negligence in environmental protection, in addition to the potential fines and penalties, such incidents may also adversely affect our reputation and creditability. Our business opportunities may be negatively impacted. For the relevant risk factor, see "Risk Factors — Risks Relating to Our Operations — If we or our business partners 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" in this document. Notwithstanding the above, due to our effective internal control and risk management measures as outlined in details below, our business, results of operations and financial condition had not been materially adversely impacted by any climate-related incident during the Track Record Period and up to the Latest Practicable Date.

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Furthermore, besides the mitigating measures already in place, we are planning on adopting various strategies and measures to identify, assess, manage and mitigate environmental, social and climate-related risks, including but not limited to:

- reviewing and assessing the ESG reports of similar companies in the industry to ensure that all relevant ESG-related risks are identified on a timely basis.
- discussing among management from time to time to ensure all the material ESG areas are recognized and reported.
- discussing with key stakeholders on key ESG principles and practices to ensure that the significant aspects are covered.
- initiating a specific ESG risk management process to identify and consider ESG risks and opportunities separate from other business risks and opportunities.
- setting targets for environment KPIs with regard to factors including emission, pollution and other impact on the environment, to reduce emissions and natural resource consumption.

In respect of social responsibilities, we are committed to offering a fair and caring working environment to our employees. We hire employees based on their merits and it is our corporate policy to offer equal opportunities to our employees regardless of gender, age, race, religion or any other social or personal characteristics, and provide training programs to keep our employees stay abreast of industry and regulatory developments. In light of the recent COVID-19 outbreak, 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. For more details related to the impact of COVID-19 outbreak on our business, see “Summary—Outbreak of COVID-19” in this document.

In addition, we plan to review our key ESG performance on a regular basis. We may from time to time engage independent professional third parties to help us make necessary improvements. We will also adopt policies include reporting on the emission level of gas pollutants, waste water and solid waste to our management to the extent applicable and evaluation of such emission levels on a regular basis. If there is any deviation from the applicable emission standard, we will investigate the cause and will take rectification measures accordingly. We will prepare annual plan and report on the management of pollutants and waste and file such report with the relevant environmental authority for review.

We attach great importance to ESG and act proactively to conform with ESG standards. We are committed to minimizing environmental impacts and ensuring sustainability. Our Directors recognize the importance of good corporate governance to protect the interests of our Shareholders. After the [REDACTED], we will publish an ESG Report each year pursuant to Appendix 27 of the Listing Rules to analyze and disclose important environmental, social and governance matters, risk management and the accomplishment of performance objectives.

During the Track Record Period and up to the Latest Practicable Date, we had been in compliance with the relevant PRC laws and regulations in all material aspects, and had not been subject to any material claim or penalty in relation to health, safety, social and environmental protection, or been involved in any significant work place accident or fatality.

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EMPLOYEES

As of the Latest Practicable Date, we employed 376 full-time employees and substantially all of them were based in China. The following table sets forth the number of our full-time employees by function.

Function	Numbers of Full-Time Employees	Percentage
Management ⁽¹⁾	11	2.9%
Product Development (R&D and clinical operation) ⁽¹⁾	116	30.9%
Quality Control	67	17.9%
Supply chain	17	4.5%
Manufacturing	117	31.1%
Sales and marketing	14	3.7%
Financial and legal affairs	14	3.7%
Company affairs	20	5.3%
Total	376	100.0%

Note:

- (1) Our employees may undertake more than one functions from time to time. Taking into account the employees undertaking both product development and management functions who are classified as management members in this table, our product development team consisted of 120 employees including 83 employees for R&D and 37 employees for clinical operation as of the Latest Practicable Date.

We typically recruit our employees through recruiting websites, campus recruitments and internal referrals, and consider a number of factors, such as our needs and expansion plans, and the candidates’ work experience and educational background. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their salary, promotion and career development.

We enter into individual employment contracts with our employees covering matters including terms, wages, bonuses, employee benefits and grounds for termination. We make contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds for our employees as required by the applicable PRC laws and regulations, and did not have any material non-compliance in this regard during the Track Record Period and as of the Latest Practicable Date.

We have entered into confidentiality and non-competition agreements with key personnel, such as our management and research and development employees. The confidentiality and non-competition agreements typically include standard non-competition clauses that prohibit the employees from competing with us, directly or indirectly, during their employment and for two years after the termination of their employment. Pursuant to the confidentiality and non-competition agreements, any intellectual

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property conceived and developed mainly using the Company's resources, technology, information or data during their employment belongs to us, and they waive all relevant rights or claims to such intellectual property. For further details on the terms of such agreements with our key management, see "Directors, Supervisors and Senior Management—Key Terms of Employment Contracts" in this document. We have also established internal policies governing the confidentiality of company information and intellectual property management to prevent our employees from developing technologies and/or products in competing nature against the Company's business at their own capacity. Specifically, R&D activities outside of working hours cannot be conducted without prior consent from our management team, and if any technologies or products being developed outside of working is in competing nature against the Company's business, the relevant R&D personnel should inform the Company's management in a timely manner. We will take disciplinary actions, including dismissal, if employees are found to be in violation of the aforementioned internal policies.

We have also implemented various internal occupational health and safety procedures to maintain a safe work environment, including adopting protective measures at our production facilities, inspecting our equipment and facilities regularly to identify and address safety hazards, and providing regular training to our employees on safety awareness. We do not have an established labor union.

We believe that we maintain a good working relationship with our employees and we have not experienced any significant labor disputes or any significant difficulty in recruiting staff for our operations. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with occupational health and safety laws or regulations, and had not experienced any strikes, labor disputes or industrial actions which have had a material effect on our business.

PROPERTIES

Owned Properties

As of the Latest Practicable Date, we own the land use right of one parcel of land located in Shanghai, China with an area of 54,303 sq.m. On this parcel of land, we owned a building with an aggregate gross floor area of approximately 1,887 sq.m which is mainly used as our production facility. We obtained the real estate certificate indicating (i) our land use right of the above parcel of land and (ii) our ownership of the above-mentioned building. As of the Latest Practicable Date, those properties were in compliance with the uses prescribed in the real estate certificate and free of any mortgages. Our PRC Legal Adviser is of the view that we have valid legal title to these properties and the land use right for the land occupied by this building. These properties are used for non-property activities as defined under Rule 5.01(2) of the Listing Rules.

Leased Properties

As of the Latest Practicable Date, we leased ten properties in Ningbo and Shanghai, with an aggregate gross floor area of approximately 15,341 sq.m. These properties are used for non-property activities as defined under Rule 5.01(2) of the Listing Rules. We mainly use these properties as premises for our production, R&D, offices and employee dormitories. The following table sets forth a summary of our leased properties.

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No.	Location	Usage	GFA <i>(Approximate sq.m.)</i>	End of Lease Term
1	Ningbo	Manufacturing, office and R&D premise	5,116	December 31, 2022
2	Ningbo	Dormitory	869	December 31, 2022
3	Ningbo	Office	237	November 24, 2023
4	Ningbo	Office and R&D premise	6,036	December 31, 2023
5	Shanghai	Office and R&D premise	1,393	May 31, 2024
6	Shanghai	Dormitory	247	February 28, 2025
7	Shanghai	Dormitory	90	April 30, 2023
8	Shanghai	Office	534	April 30, 2026
9	Shanghai	Office	246	April 30, 2026
10	Shanghai	Office	573	April 30, 2026

Pursuant to the applicable PRC laws and regulations, property lease agreements must be registered with the local branch of the Ministry of Housing and Urban-Rural Development of the PRC. As of the Latest Practicable Date, we had not completed the relevant property leasing registrations for nine of our leased properties, primarily due to the difficulty of procuring our lessors’ cooperation to register such leases. The registration of such leases will require the cooperation of our lessors. We will take all practicable and reasonable steps to ensure that the unregistered leases are registered. For details of the risk associated with the unregistered lease agreements, see “Risk Factors—Risks Relating to Our Operations—We are exposed to risks relating to our failure to complete property leasing registrations for our leased properties” in this document. According to our PRC Legal Adviser, the failure to complete such leasing registration process does not affect the validity of the relevant property lease agreements, but we might be ordered to rectify this non-compliance by competent authorities and if we do not rectify within a prescribed period, a maximum penalty of RMB10,000 may be imposed on us as a result of such non-filing of each lease agreement. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any penalties arising from the non-registration of our lease agreements, and had not experienced any dispute arising out of, or in relation to, our leased properties.

According to [REDACTED] of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all our interests in land or buildings, for the reason that, as of the date of the most recent audited combined balance sheet of our Group, none of the properties owned and leased by us had a carrying amount of 15% or more of our combined total assets.

BUSINESS

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. We also maintain product liability insurance covering our clinical trials. We maintain social welfare insurance and commercial insurance for our employees in accordance with relevant PRC laws and regulations. In the future, to the extent that any of the foregoing types of insurances becomes mandatory due to changes of law or other reasons, we will acquire such insurance in compliance with law. Our Directors consider that our existing insurance coverage is sufficient for our present operations and in line with the industry practice in the PRC.

LICENSES, PERMITS AND APPROVALS

We are required to obtain various permits, licenses, approvals and certifications from government authorities as required under PRC laws and regulations. As of the Latest Practicable Date, we had obtained all requisite licenses, permits and certifications that are material for our operations, and such licenses, permits and certifications all remain in full effect.

The following table sets forth the key licenses and permits related to our products as of the Latest Practicable Date.

License/Permit	License/Permit No.	Validity Period	Authority
Medical Device Production Permit (《醫療器械生產許可證》)	Zhe Shi Yao Jian Xie Sheng Chan Xu No. 20120094 (浙食藥監械生產許20120094號)	January 11, 2022 – December 7, 2025	Zhejiang MPA
Medical Device Registration Certificate of the PRC	Guo Xie Zhu Zhun No. 20223010763 (國械註准20223010763)	June 24, 2022 – June 23, 2027	NMPA
Medical Device Registration Certificate of the PRC	Guo Xie Zhu Zhun No. 20223010768 (國械註准20223010768)	June 27, 2022 – June 26, 2027	NMPA
Medical Device Registration Certificate of the PRC	Guo Xie Zhu Zhun No. 20193150175 (國械註准20193150175)	March 13, 2019 – March 12, 2024	NMPA
Medical Device Registration Certificate of the PRC	Zhe Xie Zhu Zhun No. 20222020390 (浙械註准20222020390)	August 19, 2022 – August 18, 2027	Zhejiang MPA
Medical Device Registration Certificate of the PRC	Zhe Xie Zhu Zhun No. 20172020163 (浙械註准20172020163)	August 16 2021 – August 15, 2026	Zhejiang MPA
Medical Device Registration Certificate of the PRC	Zhe Xie Zhu Zhun No. 20172020409 (浙械註准20172020409)	April 18, 2022 – April 17, 2027	Zhejiang MPA
Medical Device Registration Certificate of the PRC	Zhe Xie Zhu Zhun No. 20182140468 (浙械註准20182140468)	December 14, 2018 – December 13, 2023	Zhejiang MPA
Medical Device Registration Certificate of the PRC	Zhe Xie Zhu Zhun No. 20182220238 (浙械註准20182220238)	April 13, 2018 – April 12, 2023	Zhejiang MPA
Medical Device Registration Certificate of the PRC	Zhe Xie Zhu Zhun No. 20182660239 (浙械註准20182660239)	April 13, 2018 – April 12, 2023	Zhejiang MPA
CE Marking	DD 60135890 0001	December 20, 2019 – April 15, 2023	TÜV Rheinland LGA Products GmbH

We intend to initiate the renewal procedures for each of the above key licenses, permits and certificates prior to their expiration dates. Our Directors are not aware of any reason that would cause or lead to the non-renewal of the licenses, permits and certificates. Our PRC Legal Adviser confirmed that as of the Latest Practicable Date, there was no legal impediment for us to renew the licenses, permits and certificates as long as we comply with the relevant legal requirements.

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AWARDS AND RECOGNITION

Our Company has received various awards, honors, and recognitions, including:

Awards, Honor or Recognition	Year	Awarding Organization
Shanghai Patent Pilot Enterprise (上海市專利工作試點企業)	2021	Shanghai Intellectual Property Administration (上海市知識產權局)
High-Tech Enterprise (高新技術企業)	2018	Ningbo Science and Technology Bureau (寧波市科學技術局), Ningbo Municipal Finance Bureau (寧波市財政局), and Ningbo Taxation Bureau, State Taxation Administration (國家稅務總局寧波市稅務局)
China Medical Device Technology Entrepreneurial Enterprise of the Year (年度中國醫療器械技術創新企業)	2018	The 11th China (Jinan) Pharmaceutical Industry Development Peak Summit (第十一屆中國(濟南)醫藥產業發展高峰論壇), All-China Federation of Industry and Commerce (中華全國工商業聯合會), All-China Federation of Industry and Commerce Medical and Pharmaceutical Chamber (中華全國工商業聯合會醫藥業商會), Jinan City Federation of Industry and Commerce (濟南市工商聯), Jinan City Health Care Commission (濟南市衛健委), Beijing Quanlianhuishang Medical Technology Consulting Co., Ltd.(北京泉練匯商醫藥科技諮詢有限公司)
The Second Prize of China Innovation and Entrepreneurship Competition (Ningbo) (中國創新創業大賽寧波賽區二等獎)	2020	Bureau of Science and Technology of Ningbo City (寧波市科學技術局)
2020 China Future Healthcare Top 100 — Value Area List — Cardiovascular and Cerebrovascular Implant Intervention Top 20 (2020未來醫療100強價值領域榜心腦血管植介入類Top 20)	2020	Vcbeat.top (動脈網)
2021 China Sci-Tech Enterprise Pioneer-10 (Bio-Medical Industry) (2021中國科創好公司生物醫療企業Pioneer-10)	2021	Cailianshe.com.cn (財聯社)、Chinastarmarket.cn (科創板日報)、Tianyancha (天眼查)、Shanghai United Media Group (上海報業集團)
Shanghai Technology SME (科技型中小企業)	2020	Science and Technology Commission of Shanghai Municipality (上海市科學技術委員會)

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LEGAL PROCEEDINGS AND REGULATORY COMPLIANCE

We may become a party to legal, arbitral or administrative proceedings arising in the ordinary course of our business. Our Directors confirmed that, during the Track Record Period and as of the Latest Practicable Date, we were not involved in any legal, arbitral or administrative proceedings that, individually or in aggregate, would have a material and adverse effect on our business, financial condition or results of operations, and we are not aware of any potential or threatened legal, arbitral or administrative proceedings to which we will be named as a party. Our Directors further confirm that none of our Directors or senior management personnel was personally involved in any of these legal, arbitral or administrative proceedings. Our PRC Legal Adviser confirmed that during the Track Record Period and up to the Latest Practicable Date, we had complied with applicable PRC laws and regulations in all material aspects. Our Directors confirmed that we were not involved in any material or systematic non-compliance incidents.

RISK MANAGEMENT

We are exposed to various risks for our operations so risk management is important for our business. For details of the various operational risks we face, see “Risk Factors” in this document. In addition, we are also exposed to various financial risks, such as credit, liquidity and foreign exchange risks that arise in the normal course of our business. For details, see “Financial Information—Risk Disclosure” in this document. In order to identify, assess and control the risks that may cause impediments to our business, we have designed and implemented various policies and procedures to help ensure effective risk management in our operations.

We have adopted a consolidated set of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. Our audit committee, and ultimately our Board, supervises the implementation of our risk management policies. Risks identified by senior management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Company and reported to our Board.

Our senior management implements the risk management policies, strategies and plans set by our Board. Our senior management is responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) providing guidance on our risk management approach to the relevant teams in our Company and supervising the implementation of our risk management policy by the relevant departments; and (iii) reporting to our audit committee on our material risks.

Each functional team monitors and evaluates the implementation of risk management and internal control policies and procedures on a regular basis. The Board typically meets in-person every quarter, as necessary. In order to formalize risk management across our Company and set a common level of transparency and risk management performance, the relevant teams will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) prepare a risk management report bi-annually for our chief executive officer’s review; (iv) continuously monitor the key risks relating to their operation or function; (v) implement appropriate risk responses where necessary; and (vi) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

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Before each Board meeting, an agenda is prepared with input from Directors. At Board meetings, depending on the agenda, different team heads will gather information relating to their functions and report to the Board on the relevant agenda items, as necessary. The Board secretary attends all Board meetings to ensure that there is no gap in communication between the two bodies. During Board meetings, the Board will on occasion further review and/or analyze particular issue and report their findings at the next Board meeting. Our Board believe that our corporate structure provides an appropriate system of checks and balances to improve our risk management procedures.

Our audit committee also reviews and approves our risk management policy to ensure that it is consistent with our corporate objectives, reviews and approves our corporate risk tolerance, monitors the most significant risks associated with our business operation and our management's handling of such risks, reviews our corporate risk in light of our corporate risk tolerance, and monitors and ensures the appropriate application of our risk management framework across our Company.

INTERNAL CONTROL OVER BUSINESS OPERATIONS

We have implemented various risk management policies to identify, assess and manage risks arising from our operations. Details on risk categories identified by our management, internal and external reporting mechanism, remedial measures and contingency management have been codified in our policies. For details of the potential risks associated with our business, see "Risk Factors" in this document. To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [REDACTED], we have adopted or will adopt, among other things, the following risk management and internal control measures:

- the establishment of an audit committee responsible for overseeing our financial records, internal control procedures and risk management systems. See "Directors, Supervisors and Senior Management—Board Committees—Audit Committee" in this document for the qualifications and experience of these committee members as well as a detailed description of the responsibility of our audit committee;
- the appointment of Mr. LIU Wei (our Chief Financial Officer and Board secretary) and Ms. LEUNG Wai Yan as the joint company secretaries of our Company to ensure the compliance of our operation with relevant laws and regulations. For their biographical details, see "Directors, Supervisors and Senior Management" in this document;
- the appointment of Maxa Capital Limited as our compliance adviser upon the [REDACTED] to advise us on compliance with the Listing Rules; and
- the engagement of external legal advisers to advise us on compliance with the Listing Rules and to ensure our compliance with relevant regulatory requirements and applicable laws, where necessary.

We have also adopted internal control measures to ensure that we have complied, and will continue to comply, with the relevant regulations in relation to the "Two-Invoice System", including:

- providing trainings periodically to members of our management team as well as our sales and marketing team, to enhance their knowledge about the "Two-Invoice System" and other applicable laws and regulations;

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- requiring our management team to closely monitor the progress of the implementation of the "Two-Invoice System" in different provinces;
- requiring our sales and marketing team to promptly adjust the distribution plans for our products based on the latest implementation status of the "Two-Invoice System" in different provinces;
- strictly enforcing the terms of our agreements with our distributors (particularly, prohibiting our distributors from selling our products outside the geographical regions specifically designated to the distributors, and from transferring their distributorship rights to sub-distributors without our prior approval);
- conducting regular inventory checks to ensure the inventories of ourselves and of our distributors are maintained at appropriate levels;
- frequently communicating with our distributors, the sub-distributors and the end customers using our products, and periodically conducting inspections, to ensure there is no unauthorized resale of our products to other sub-distributors.

In addition, we have adopted internal control measures to ensure our compliance with the applicable laws and regulations with respect to the handling of sensitive data involving commercial secrets or personal privacy, which measures primarily include:

- adopting strict requirements for desensitizing, collecting, using, reproducing, storing, and transferring sensitive data;
- providing trainings periodically to our senior management and employees to enhance their knowledge of the applicable laws and regulations regarding the protection of sensitive data;
- requiring any transfer of sensitive data (including but not limited to those in relation to clinical trial results) abroad or to foreign parties to be submitted to our Board for pre-approval; and
- desensitizing all sensitive data before transferring them to any third parties.

Finally, we have adopted or will adopt before the [REDACTED], various internal regulations against corrupt and fraudulent activities, which include measures against receiving bribes and kickbacks, and misuse of company assets. Major measures and procedures to implement such regulations include:

- authorizing our audit and supervision department to assume responsibility for daily execution of our anti-corruption and anti-fraud measures, including handling complaints, ensuring protection for the whistle-blower and conducting internal investigations;
- providing anti-corruption compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations, and including relevant policies and express prohibitions against non-compliance in staff handbooks; and

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- undertaking rectification measures with respect to any identified corrupt or fraudulent activities, evaluating the identified corrupt or fraudulent activities and proposing and establishing preventative measures to avoid future non-compliance.

Our Directors are of the view that such controls and measures are sufficient and effective to avoid the occurrence of corruption, bribery, or other improper conduct of our employees. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any government investigation or litigation with respect to claims or allegations of monetary and non-monetary bribery activities, and to the best knowledge of our Directors, none of our employees were involved in any bribery or kickback arrangements.

We have designated responsible personnel to monitor our ongoing compliance with relevant laws and regulations that govern our business operations, and to oversee the implementation of any necessary measures. Meanwhile, we plan to provide our Directors, senior management and relevant employees with continuing training programs and updates regarding the relevant laws and regulations on a regular basis, with a view to proactively identifying any concerns or issues relating to any potential non-compliance. We believe that we have established adequate internal procedures, systems and controls in relation to anti-corruption and anti-bribery law compliance.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Ningbo Linfeng was able to exercise approximately 41.39% voting rights in our Company through (i) its direct interest as to 27.91%, (ii) Ningbo Maishang as to 5.62%, (iii) Ningbo Hongyingkang as to 5.45% and (iv) Ningbo Kangrui as to 2.42%. The executive partner of each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui, namely, Shidi Biotechnology, is wholly owned by Ningbo Linfeng. Shidi Biotechnology is entitled to exercise the voting power held by each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui in our Company pursuant to their respective partnership agreements. For further details relating to Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui, see “History, Development and Corporate Structure — Employee Incentive Platforms” in this document.

As of the Latest Practicable Date, Shanghai Shidi was able to exercise approximately 47.66% voting rights in our Company through (i) its direct interest as to 6.27%; (ii) Ningbo Linfeng as to 27.91%, (iii) Ningbo Maishang as to 5.62%, (iv) Ningbo Hongyingkang as to 5.45% and (v) Ningbo Kangrui as to 2.42%. Ningbo Linfeng was owned as to 65% by Shanghai Shidi.

Pursuant to a concert party agreement dated April 26, 2021, Ms. Li and Mr. Lv confirm that they have been acting in concert in exercising Shareholders’ rights pertaining to our Group (including our Company and Ningbo SensCure) since January 1, 2014, and they have agreed to continue to act in concert and reach consensus on proposals related to the daily management and operation of our Group presented to general meetings of the Shareholders of our Company for voting.

As of the Latest Practicable Date, the Concert Parties were entitled to exercise voting rights of approximately 57.25% voting rights in our Company. In particular, Ms. Li was able to exercise approximately 47.66% voting rights in our Company through Shanghai Shidi which was wholly owned by Ms. Li. Mr. Lv was able to exercise approximately 9.59% voting rights in our Company through his personal capacity.

Immediately following the completion of the [REDACTED], the Concert Parties will be entitled to exercise voting rights of approximately [REDACTED]% in our Company. Therefore, the Concert Parties, Shanghai Shidi, Ningbo Linfeng, Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui will constitute a group of Controlling Shareholders of our Company under the Listing Rules.

Ms. Li is an individual industry investor. She has over 14 years of experience in finance and business management. From December 2002 to June 2007, she was a finance manager at Shenzhen Sanofi Pasteur Biological Products Co., Ltd. (深圳賽諾菲巴斯德生物製品有限公司), a company principally engaged in manufacturing of vaccines and an affiliate of Sanofi S.A. which is a multinational healthcare company. From April 2011 to June 2014, she was the deputy general manager of Shanghai Jianshi Bio-tech Co., Ltd. (上海建世生物科技有限公司), a company principally engaged in investments in the healthcare industry, where she was primarily responsible for the management of the company. Since July 2014, Ms. Li has been the chairperson of the board of directors of Shanghai Shidi, one of our Controlling Shareholders, where she has been primarily responsible for the management and investment decisions of the company. Ms. Li is the sister of Mr. LI Kejian (李克儉), our executive Director and the chairperson of our Board.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Ms. Li, through her spouse, Mr. WU Jianhui (鄔建輝) (“**Mr. Wu**”), became acquainted with Mr. Lv and has been a business partner of Mr. Lv over the years. Mr. Wu was a director of LifeTech Scientific Corporation, a company listed on the Stock Exchange (stock code: 1302), from September 2006 to March 2016 before he resigned from his directorship to facilitate the business ventures of Ms. Li, and is also an individual industry investor. He became acquainted with Mr. Lv when Mr. Lv served as a vice general manager of Lifetech Scientific (Shenzhen) Co., Ltd., a wholly-owned subsidiary of LifeTech Scientific Corporation, from January 2003 to February 2009.

As of the Latest Practicable Date, our Controlling Shareholders confirmed that they did not have any interest in a business, apart from the business of our Group, which competes or is likely to compete, directly or indirectly, with our business, and requires disclosure under Rule 8.10 of the Listing Rules. For further details, see “—Non-competition Arrangement” in this section.

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

Having considered the following factors, our Directors are satisfied that we are capable of carrying on our business independently of our Controlling Shareholders and their close associates after the [REDACTED].

Management Independence

Our Board comprises two executive Directors, three non-executive Directors and four independent non-executive Directors. Upon [REDACTED], Mr. LI Kejian (the chairperson of our Board and our executive Director), Mr. Lv (our non-executive Director) and Mr. ZHAO Chunsheng (our non-executive Director) will continue to hold directorships and/or senior management positions in our Controlling Shareholders and their respective close associates. For further details relating to such directorships and senior management positions, see “Directors, Supervisors and Senior Management” in this document. Save as disclosed above, none of our Directors and senior management members holds any directorship or senior management position in our Controlling Shareholders or their respective close associates.

Our Directors believe that our Board and senior management will function independently from our Controlling Shareholders for the following reasons:

1. a vast majority of the members of our Board, being six out of nine Directors, do not hold any role as a director or senior management in our Controlling Shareholders or their respective close associates. Our Board acts collectively by a majority decision according to the Articles, and no individual Director is allowed to transact or can alone make any decision on behalf of our Company unless authorized by our Board or in accordance with the provisions of the Articles and the PRC Company Law. Any view of a Director will be checked and balanced by the view of other members of our Board;
2. although Mr. LI Kejian is the brother of Ms. Li and holds an executive role in our Company, while performing his duties as an executive Director, he has been and will continue to be supported by the separate and independent senior management teams of our Group;
3. the roles of both Mr. Lv and Mr. ZHAO Chunsheng in our Group are non-executive in nature that they will not be involved in the daily management of our Group’s business;

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

4. each Director is aware of his/her fiduciary duties as a Director of our Company which require, among other things, that he/she acts for the benefit of and in the best interests of our Company and does not allow any conflict between his/her duties as a Director and his/her personal interest;
5. in the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Company and our Directors or their respective associates, the interested Director(s) shall abstain from voting at the relevant board meetings of our Company in respect of such transaction, and shall not be counted in the quorum;
6. Mr. LI Kejian and Mr. ZHAO Chunsheng will abstain from voting at the relevant board meetings in respect of any transactions involving other business interests of Ms. Li, Shanghai Shidi, Ningbo Linfeng and their close associates;
7. our Board comprises nine Directors, and four of them are independent non-executive Directors, who collectively represent more than one-third of the members of our Board. Our independent non-executive Directors have extensive experience in different areas and have been appointed in accordance with the requirements of the Listing Rules to ensure that the decisions of our Board are made after due consideration of independent and impartial opinions;
8. the daily management and operations of our Group are carried out by our senior management members all of whom are independent from our Controlling Shareholders and their close associates, and have substantial experience in the industry in which we are engaged. Accordingly, they are able to discharge their duties independently from our Controlling Shareholders; and
9. instances of potential conflicts have been minimized by virtue of the Non-Competition Undertaking (as defined below) and additional corporate governance measures will be implemented to address potential conflicts of interests between our Group and our Controlling Shareholders. For details relating to the additional corporate governance measures, see “—Corporate Governance Measures” in this section.

Having considered the above factors, our Directors are satisfied that they are able to perform their roles in our Company independently, and our Director are of the view that we are capable of managing our business independently from our Controlling Shareholders and their close associates, following the completion of the [REDACTED].

Operational Independence

There has been no sharing of the patents, R&D, commercial and human resources among our Group and the various companies held by our Controlling Shareholders and/or any of their respective close associates since our establishment. Although our Controlling Shareholders will retain a controlling interest in us after [REDACTED], we have full rights to make all decisions on, and to carry out, our own business operations independently. Our Company, through our subsidiaries, holds the licenses and qualifications necessary to carry on our current business, and has sufficient capital, facilities, technology

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

and employees to operate the business independently from our Controlling Shareholders. We have access to third parties independently from and not connected to our Controlling Shareholders for sources of suppliers and customers.

Based on the above, our Directors are satisfied that we will be able to function and operate independently from our Controlling Shareholders and their close associates.

Financial Independence

We have established our own finance department with a team of financial staff, who are responsible for financial control, accounting, reporting, group credit and internal control functions of our Company, and are independent from our Controlling Shareholders. We can make financial decisions independently and our Controlling Shareholders do not intervene with our use of funds. We have also established an independent audit system, a standardized financial and accounting system and a complete financial management system. In addition, we have been and are capable of obtaining financing from third parties without relying on any guarantee or security provided by our Controlling Shareholders or their respective associates. As of the Latest Practicable Date, there were no loans, advances and balances due to and from the Controlling Shareholders.

Based on the above, our Directors are of the view that they and our senior management are capable of carrying on our business independently of, and do not place undue reliance on, our Controlling Shareholders and their close associates after the [REDACTED].

NON-COMPETITION ARRANGEMENT

Business of Our Group

We are a medical device company in China with a main focus on the field of minimally-invasive interventional cryotherapy. Leveraging our liquid nitrogen cryoablation technology, we have developed a comprehensive product portfolio mainly focusing on two therapeutic areas: (i) natural orifice transluminal endoscopic surgery, or NOTES, for the treatment of urinary, respiratory, and digestive diseases (e.g., bladder cancer, chronic obstructive pulmonary disease, asthma, airway stenosis, gastric cancer, and esophageal cancer), and (ii) vascular interventional therapy for the treatment of atrial fibrillation, hypertension and other cardiovascular diseases. Apart from minimally-invasive interventional cryotherapy, our product pipeline also includes certain non-cryotherapy products in the categories of magnetic rings, digestive endoscopic anastomosis medical devices, single hole laparoscopic surgical approach system and related accessories, lung puncture localization, balloon dilatation catheters for endoscopic use and atrial fibrillation pulsed field ablation systems (“**Our Non-Cryotherapy Products**”, together with minimally-invasive interventional cryotherapy, “**Our Business**”).

Other Business Interests of Ms. Li, Shanghai Shidi, Ningbo Linfeng and Their Close Associates

Ms. Li is an individual industry investor with years of experience investing in healthcare and technology industries. The entities through which Ms. Li controls voting rights in our Company include Shanghai Shidi, Ningbo Linfeng, Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui. Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui are our ESOP Platforms, whereas Shanghai Shidi and Ningbo Linfeng are investment holding companies of Ms. Li to cover potential investments primarily in the medical devices industry (including the investment in our Group).

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In particular, Ningbo Linfeng owns and has been operating Linfeng Medical Technology Campus (麟澧醫療科技產業園) in Qianwan New Area, Ningbo City since November 2011. Linfeng Medical Technology Campus (麟澧醫療科技產業園) is a large-scale industrial campus with a total gross floor area of approximately 100,000 sq.m. and has shared built-in infrastructure and testing laboratories, which serves as an industrial base and incubation hub for the convenience of portfolio companies of Ningbo Linfeng, including our Group. As of the Latest Practicable Date, 20 portfolio companies of Ningbo Linfeng conducted their operations and/or R&D activities at this industrial campus including (i) our subsidiaries, Ningbo SensCure and Ningbo Shengjielong Medical Equipment Co., Ltd. (寧波勝杰隆醫療器材有限公司), and one of our ESOP Platforms, Ningbo Kangrui, (ii) 13 companies in the medical devices industry as included in the Other Business Interests (as defined below), and (iii) four companies engaged in other business activities including Ningbo Shidi Medical Technology Co., Ltd. (寧波仕地醫療科技有限公司) (a company principally engaged in provision of sterilization for medical devices), Ningbo Hangzhou Bay New District Muhe Property Co., Ltd. (寧波杭州灣新區沐禾物業有限公司) (a company principally engaged in property management and catering management), Ningbo Linstant Polymer Materials Co., Ltd. (寧波琳盛高分子材料有限公司) (a company principally engaged in the R&D, manufacturing and sales of polymer accessories for medical devices) and its subsidiary (“**Non-Medical Device Ningbo Linfeng Portfolio Companies**”). Each portfolio company controlled by Ningbo Linfeng mainly conducts its daily management and operation through its directors and senior management and where applicable, conducts its research and development through its dedicated in-house research and development team led by industry veterans with the relevant knowledge and experience. Further, apart from the abovementioned 20 portfolio companies of Ningbo Linfeng, as of the Latest Practicable Date, two portfolio companies of Shanghai Shidi (which are principally engaged in the R&D, manufacturing and sales of Chinese herbal pieces and the R&D of decocting technology and provision of decocting services, respectively) and four companies ultimately controlled by Mr. Lv (which are either investment holding vehicles of Mr. Lv or employee incentive platforms for companies controlled by Mr. Lv) also conducted their operations and/or R&D activities at the industrial campus.

The industrial campus was accredited as a “Key Project of Healthcare Industry in Zhejiang Province” (浙江省健康產業重點項目) by the Zhejiang Provincial Development and Reform Commission in 2017, was named as an “outstanding makerspace” (優秀眾創空間) by the Science Technology Department of Zhejiang Province in 2018, was named as a “national makerspace” (國家級眾創空間) by the Ministry of Science and Technology of the PRC (中國科學技術部) in 2020 and has been considered as a key technology enterprise incubator (重點科技企業孵化器) in Ningbo City.

As of the Latest Practicable Date, in addition to interests in our Company, Ms. Li, Shanghai Shidi, Ningbo Linfeng and their close associates (including Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui and/or Ms. Li’s spouse) also held equity interests in a number of entities in the medical devices industry, including the R&D, manufacturing and sales of (i) medical devices used in neurosurgical procedures, (ii) interventional products for the treatment of structural heart diseases, (iii) consumables used for anesthesia, (iv) consumables used in treating diabetes, (v) radiation imaging devices such as static computerized tomography (CT), (vi) medical devices used for vertebroplasty, (vii) medical devices used in dental procedures, (viii) chitosan-based medical products, (ix) endoscopes, (x) diagnostic medical devices and reagents used in morphological and molecular fields, (xi) laser medical devices for soft tissue cutting and hemostasis, (xii) craniomaxillofacial cosmetic instruments and materials, (xiii) medical wearable monitoring equipment, (xiv) passive medical devices used in treating arteriosclerosis associated with coronary heart diseases, and (xv) medical modeling products and personalized implant materials (together, “**Other Business Interests**”).

As shown above, each of the abovementioned Other Business Interests has a different business focus and involves products used in a different specialty or targeting different procedures or diseases from Our Business, and each of the Non-Medical Device Ningbo Linfeng Portfolio Companies has a different business nature from Our Business. Accordingly, such other businesses and companies in which Ms. Li, Shanghai Shidi, Ningbo Linfeng and their close associates are interested are different from Our Business and none of Ms. Li, Shanghai Shidi and Ningbo Linfeng currently has the intention of injecting

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

the Other Business Interests into our Group upon [REDACTED]. Each of Ms. Li, Shanghai Shidi and Ningbo Linfeng also confirms that the scope of the Other Business Interests will not expand into those fields causing any direct or indirect competition with Our Business as set out in details in “—Non-Competition Undertaking” in this section. On the basis of the above, our Directors are of the view that none of such other business interests held by Ms. Li and her close associates is a business that competes or will compete either directly or indirectly with our Group.

Besides, while there is no legal impediment for Ms. Li to act as a Director under the PRC laws, due to her personal business engagements and consistent with her practice with respect to her other investments, Ms. Li has given due regard and respect to the existing corporate governance structure and policies of the entities in which she has invested, including our Company. Since Ms. Li needs to cover a wide portfolio of healthcare companies and her previous experience focused on finance, accounting and investment matters, it is impractical for Ms. Li to focus solely on the management and operation of our Group. Further, due to her various investments and limited time, Ms. Li considered that she might not be able to devote sufficient time and effort to discharge a Director’s responsibilities effectively and therefore, it might not be in the interest of our Company and the Shareholders for her to act as a Director to be involved in the daily management of our Group. Although Ms. Li does not hold any position in our Group, by virtue of her interests as one of our Controlling Shareholders, she is able to exert substantial influence on the management of our Group at the shareholder level and contributes to our Group by way of her industry experience and resources.

Based on the independent due diligence work performed by the Joint Sponsors and confirmations of Ms. Li and after taking into account of the above, nothing has come to the attention of the Joint Sponsors that would reasonably cause them to cast material doubts on Ms. Li’s suitability to act as a Director under Rule 3.08 and Rule 3.09 of the Listing Rules.

Other Business Interests of Mr. Lv and His Close Associates

Apart from Our Business, as of the Latest Practicable Date, Mr. Lv, our non-executive Director, was able to exercise voting rights of approximately 50.53% in Jenscare Scientific Co., Ltd. (寧波健世科技股份有限公司) (“**Jenscare**”) together with Ms. Li as concert parties with regard to Jenscare. He is also currently an executive director, the chairman of the board of directors, the chief executive officer and the chief technology officer of Jenscare. Jenscare (its predecessor being Ningbo Jenscare Biotechnology Co., Ltd. (寧波健世生物科技有限公司), a limited liability company established in the PRC on November 8, 2011) is a joint stock company incorporated in the PRC with limited liability on March 23, 2021, and is principally engaged in the development of interventional products for the treatment of structural heart diseases. To the best knowledge of our Company, Jenscare has developed a series of treatment solutions targeting different types of structural heart diseases, including tricuspid valve diseases, aortic valve diseases, mitral valve diseases and heart failure. Given the differences between the products involved in Our Business and those of Jenscare (including the differences between their respective indications and clinical applications), our Company is of the view that there is no direct or indirect competition between Jenscare and our Company. Further, Mr. Lv’s role in our Group is non-executive in nature that he will not be involved in the daily management of our Group’s business.

As of the Latest Practicable Date, in addition to interests in our Company and Jenscare, Mr. Lv and his close associates also held equity interests in other entities in the medical devices industry, including the R&D, manufacturing and sales of (i) laser medical devices for soft tissue cutting and hemostasis and (ii) medical devices used for vertebroplasty, and (iii) medical wearable monitoring equipment.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

As shown above, each of the abovementioned other business interests of Mr. Lv and his close associates has a different business focus and involves products used in a different specialty or targeting different procedures or diseases from Our Business. Accordingly, the other businesses and companies in which Mr. Lv and his close associates are interested are different from Our Business and Mr. Lv currently has no intention of injecting such other business interests into our Group upon [REDACTED]. Mr. Lv also confirms that the scope of such other business interests will not expand into those fields causing any direct or indirect competition with Our Business as set out in details in “—Non-Competition Undertaking” in this section. On the basis of the above, our Directors are of the view that none of such other business interests held by Mr. Lv and his close associates is a business that competes or will compete either directly or indirectly with our Group.

Further, apart from our Company and Jenscare, as of the Latest Practicable Date, the Concert Parties did not have any other investments in which they, acting in concert, hold a controlling stake.

Based on the independent due diligence work conducted by the Joint Sponsors and after taking into the account the views of the Directors and confirmations of the Controlling Shareholders, nothing has come to the Joint Sponsors’ attention that would reasonably cause them to disagree with the view of the Directors that none of the Other Business Interests, Non-Medical Device Ningbo Linfeng Portfolio Companies held by Ms. Li or other business interests of Mr. Lv and his close associates competes or will compete either directly or indirectly with the Group in any material respect and requires disclosure under Rule 8.10 of the Listing Rules.

Non-Competition Undertaking

Our Controlling Shareholders [provided] a non-competition undertaking (the “**Non-Competition Undertaking**”) in favor of us, pursuant to which our Controlling Shareholders undertook not to, and to procure their respective close associate(s) (as appropriate) (other than our Group) not to, either directly or indirectly, compete with our business, which includes innovative products for minimally-invasive interventional cryotherapy and Our Non-Cryotherapy Products (“**Restricted Activities**”) and granted our Group the option for new business opportunities. Our Controlling Shareholders have further irrevocably undertaken in the Non-Competition Undertaking that, during the term of the Non-Competition Undertaking, they will not, and will also procure their respective close associate(s) (as appropriate) (other than our Group) not to, alone or with a third party, in any form, directly or indirectly, engage in, participate in, support to engage in or participate in any business that competes, or is likely to compete, directly or indirectly, with the Restricted Activities.

CORPORATE GOVERNANCE MEASURES

Our Directors recognize the importance of good corporate governance in protecting our Shareholders’ interests. We have adopted the following measures to safeguard good corporate governance standards and to avoid potential conflicts of interests between our Group and our Controlling Shareholders:

- (a) as part of our preparation for the [REDACTED], we have amended our Articles to comply with the Listing Rules. In particular, our Articles provide that a Director shall not vote on any resolution approving any contract or arrangement or any other proposal in which such Director or any of his/her close associates has a material interest nor shall such Director be counted in the quorum present at the meeting;

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (b) a Director with material interests shall make full disclosure in respect of matters that may have conflict or potentially conflict with any of our interests and abstain from the board meetings on matters in which such Director or his/her associates have a material interest, unless attendance or participation of such Director at such meeting of our Board is specifically requested by a majority of our independent non-executive Directors;
- (c) we are committed that our Board should include a balanced composition of executive Directors and independent non-executive Directors. We have appointed independent non-executive Directors and we believe our independent non-executive Directors possess sufficient experience and they are free of any business or other relationship which could interfere in any material manner with the exercise of their independent judgment and will be able to provide impartial, external opinions to protect the interests of our public Shareholders. Details of our independent non-executive Directors are set out in “Directors, Supervisors and Senior Management” in this document;
- (d) as required by the Listing Rules, our independent non-executive Directors shall review all connected transactions annually and confirm in our annual report that such transactions have been entered into in our ordinary and usual course of business, are either on normal commercial terms or on terms no less favorable to us than those available to or from independent third parties and on terms that are fair and reasonable and in the interest of our Shareholders as a whole;
- (e) our Company will disclose decisions on matters reviewed by our independent non-executive Directors either in our annual reports or by way of announcements as required by the Listing Rules;
- (f) where our Directors reasonably request the advice of independent professionals such as financial advisers, the appointment of such independent professionals will be made at our Company’s expense; and
- (g) we have appointed Maxa Capital Limited as our compliance adviser to provide advice and guidance to us in respect of compliance with the applicable laws and regulations in Hong Kong, as well as the Listing Rules, including various requirements relating to corporate governance.

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest that may arise between our Group and our Controlling Shareholders, and to protect our minority Shareholders’ interests after the [REDACTED].

CONTINUING CONNECTED TRANSACTIONS

OVERVIEW

Prior to the [REDACTED], the Group has entered into certain transactions with the following parties which will, upon [REDACTED], become connected persons of our Company.

<u>Connected Person</u>	<u>Business Nature</u>	<u>Connected Relationship</u>
Ningbo Linfeng	Investment holding	Ningbo Linfeng is one of our Controlling Shareholders and is therefore a connected person of our Company under Rule 14A.07(1) of the Listing Rules
Ningbo Shidi Medical Technology Co., Ltd. (寧波仕地醫療科技有限公司) (“ Ningbo Shidi ”)	Provision of sterilization for medical devices	Ningbo Shidi is a wholly-owned subsidiary of Ningbo Linfeng and is therefore a connected person of our Company under Rule 14A.13(1) of the Listing Rules
Ningbo Linstant Polymer Materials Co., Ltd. (寧波琳盛高分子材料有限公司) (“ Ningbo Linstant ”)	R&D, manufacturing and sales of polymer accessories for medical devices	Ningbo Linstant is a non-wholly owned subsidiary of Ningbo Linfeng and is therefore a connected person of our Company under Rule 14A.13(1) of the Listing Rules
Ningbo Hangzhou Bay New District Muhe Property Co., Ltd. (寧波杭州灣新區沐禾物業有限公司) (“ Muhe Property ”)	Property management and catering management	Muhe Property is a wholly-owned subsidiary of Ningbo Linfeng and is therefore a connected person of our Company under Rule 14A.13(1) of the Listing Rules

Details of continuing connected transactions of our Company with such connected persons following the [REDACTED] are set out below.

FULLY EXEMPT CONTINUING CONNECTED TRANSACTIONS

As our Company is eligible for [REDACTED] on the [REDACTED] under Chapter 18A of the Listing Rules as a biotech company, the revenue ratio under Rule 14.07 of the Listing Rules would not be an appropriate measure of the size of relevant continuing connected transactions set out in this section. As an alternative, we have applied a percentage ratio test based on the total expenses of our Group. Following the [REDACTED], the following transactions will be regarded as continuing connected transactions of our Company exempt from the reporting, announcement, annual review and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

CONTINUING CONNECTED TRANSACTIONS

Sterilization Services Agreement

a) Description of the Transaction

Our Company (for and on behalf of ourselves and our subsidiaries) entered into a sterilization services agreement dated [●] (the “**Sterilization Services Agreement**”) with Ningbo Shidi, pursuant to which our Group may engage Ningbo Shidi for its sterilization services. Ningbo Shidi provides sterilization services for medical devices and our Group requires such services for the sterilization of our medical devices.

Our Group and Ningbo Shidi will enter into separate individual agreements or work orders which will set out the specific terms and conditions according to the principles in the Sterilization Services Agreement. The Sterilization Services Agreement is effective from the [REDACTED] till December 31, 2024 and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

For the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022, the amounts incurred by our Group for the services provided by Ningbo Shidi under the Sterilization Services Agreement were RMB30,600, RMB202,721 and RMB99,000, respectively.

For the three years ending December 31, 2022, 2023 and 2024, the maximum aggregate transaction amounts payable to Ningbo Shidi under the Sterilization Services Agreement shall not exceed RMB418,000, RMB477,600 and RMB547,200, respectively.

The service fees will be charged at rates no less favorable to our Group than rates at which our Group pays independent third parties for comparable transactions, and will be determined by our Group and Ningbo Shidi through arm’s length negotiation based on factors applicable to all service providers, including but not limited to the nature, complexity, and value of tasks completed by Ningbo Shidi under each individual agreement/work order, the market rates, the fees charged for historical transactions of a similar nature and the then prevailing market rates by obtaining and comparing against fee quotes provided by other third party service providers.

b) Listing Rules Implications

The historical transactions entered into with Ningbo Shidi in respect of our purchases of sterilization services for medical devices have been, and the transactions contemplated under the Sterilization Services Agreement will be, entered into in the ordinary and usual course of business of our Company, on normal commercial terms or better. As each of the applicable percentage ratios in respect of the transactions contemplated under the Sterilization Services Agreement will, as our Company currently expects, be less than 5% on an annual basis and the total consideration on an annual basis is less than HK\$3 million, the transactions contemplated under the Sterilization Services Agreement would, upon [REDACTED], be exempt from the reporting, announcement, annual review and independent shareholders’ approval requirements pursuant to Rule 14A.76 of the Listing Rules.

CONTINUING CONNECTED TRANSACTIONS

Medical Devices Accessories Purchase Agreement

a) Description of the Transaction

Our Company (for and on behalf of ourselves and our subsidiaries) entered into a medical devices accessories purchase agreement dated [●] (the “**Medical Devices Accessories Purchase Agreement**”) with Ningbo Linstant, pursuant to which our Group may purchase from Ningbo Linstant certain polymer accessories such as sheaths, tubes, granular materials and molding tools. Ningbo Linstant is principally engaged in the R&D, manufacturing and sales of polymer accessories for medical devices. Such polymer accessories are required as we will make use of such accessories for the R&D activities and clinical trials of our Group.

Our Group and Ningbo Linstant will enter into separate individual agreements or work orders which will set out the specific terms and conditions according to the principles in the Medical Devices Accessories Purchase Agreement. The Medical Devices Accessories Purchase Agreement is effective from the [REDACTED] till December 31, 2024 and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

For the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022, the amounts incurred by our Group for the products purchased from Ningbo Linstant under the Medical Devices Accessories Purchase Agreement were RMB41,300, RMB14,159 and RMB63,180, respectively.

For the three years ending December 31, 2022, 2023 and 2024, the maximum aggregate transaction amounts payable to Ningbo Linstant under the Medical Devices Accessories Purchase Agreement shall not exceed RMB160,000, RMB430,000 and RMB630,000, respectively.

The fees will be charged at rates no less favorable to our Group than rates at which our Group pays independent third parties for comparable transactions, and will be determined by our Group and Ningbo Linstant through arm’s length negotiation with reference to a number of factors applicable to all suppliers, including but not limited to the market price of the products, quantities and method of procurement, specifications of the products, the fees charged for historical transactions of a similar nature and the then prevailing market rates based on unit prices for different polymer accessories.

b) Listing Rules Implications

The historical transactions entered into with Ningbo Linstant in respect of our purchases of certain polymer accessories have been, and the transactions contemplated under the Medical Devices Accessories Purchase Agreement will be, entered into in the ordinary and usual course of business of our Company, on normal commercial terms or better. As each of the applicable percentage ratios in respect of the transactions contemplated under the Medical Devices Accessories Purchase Agreement will, as our Company currently expects, be less than 5% on an annual basis and the total consideration on an annual basis is less than HK\$3 million, the transactions contemplated under the Medical Devices Accessories Purchase Agreement would, upon [REDACTED], be exempt from the reporting, announcement, annual review and independent shareholders’ approval requirements pursuant to Rule 14A.76 of the Listing Rules.

CONTINUING CONNECTED TRANSACTIONS

Catering Services Agreement

a) Description of the Transaction

Our Company (for and on behalf of ourselves and our subsidiaries) entered into a catering services agreement dated [●] (the “**Catering Services Agreement**”) with Muhe Property, pursuant to which Muhe Property may provide catering services to our employees. Muhe Property provides catering services to the enterprises and employees at the Campus and our Group requires such services for the benefit of our employees.

Our Group and Muhe Property will enter into separate individual agreements or catering orders which will set out the specific terms and conditions according to the principles in the Catering Services Agreement. The Catering Services Agreement is effective from the [REDACTED] till December 31, 2024 and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

For the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022, the amounts incurred by our Group for the catering services provided by Muhe Property under the Catering Services Agreement were nil, RMB105,614 and RMB277,284, respectively.

For the three years ending December 31, 2022, 2023 and 2024, the maximum aggregate transaction amounts payable to Muhe Property under the Catering Services Agreement shall not exceed RMB500,000, RMB700,000 and RMB900,000, respectively.

The service fees will be charged at rates no less favorable to our Group than rates at which our Group pays independent third parties for comparable transactions, and will be determined by our Group and Muhe Property through arm’s length negotiation based on factors applicable to all catering service providers, including but not limited to the raw material costs and labor costs borne by Muhe Property under each individual agreement/catering order, the number of our employees involved, the fees charged for historical transactions of a similar nature and the then prevailing market rates by obtaining and comparing against fee quotes provided by other third party service providers.

b) Listing Rules Implications

The historical transactions entered into with Muhe Property in respect of our purchases of catering services for our employees have been, and the transactions contemplated under the Catering Services Agreement will be, entered into in the ordinary and usual course of business of our Company, on normal commercial terms or better. As each of the applicable percentage ratios in respect of the transactions contemplated under the Catering Services Agreement will, as our Company currently expects, be less than 5% on an annual basis and the total consideration on an annual basis is less than HK\$3 million, the transactions contemplated under the Catering Services Agreement would, upon [REDACTED], be exempt from the reporting, announcement, annual review and independent shareholders’ approval requirements pursuant to Rule 14A.76 of the Listing Rules.

PARTIALLY EXEMPT CONTINUING CONNECTED TRANSACTIONS

Following the [REDACTED], the following transactions will be regarded as continuing connected transactions of our Company subject to the reporting, announcement and annual review requirements but exempt from the circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

CONTINUING CONNECTED TRANSACTIONS

Master Lease Agreement

a) *Description of the Transaction*

Our Company (for and on behalf of ourselves and our subsidiaries) entered into a master lease agreement dated [●] (the “**Master Lease Agreement**”) with Ningbo Linfeng (for and on behalf of itself and its subsidiaries), pursuant to which we may lease from Ningbo Linfeng properties in the Linfeng Medical Technology Campus (麟豐醫療科技產業園) located at No. 777, Binhai 4th Road, Hangzhou Bay New District, Ningbo (the “**Campus**”) for use as plants and staff quarters. Our subsidiary, Ningbo SensCure has been leasing properties in the Campus for its business operations prior to and throughout the Track Record Period. Any relocation may cause unnecessary disruption to our business operation and incur unnecessary costs.

Our Group and Ningbo Linfeng and/or its subsidiaries will enter into separate lease agreements which will set out the specific terms and conditions according to the principles in the Master Lease Agreement. The Master Lease Agreement is effective from the [REDACTED] till December 31, 2024 and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

As of December 31, 2020, December 31, 2021 and August 31, 2022, the total value of right-of-use assets relating to the leases entered into by our Group under the Master Lease Agreement was RMB189,998, RMB1,939,436, and RMB1,616,197, respectively. For the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022, the aggregate short-term lease payments and other charges under the Master Lease Agreement were RMB581,345, RMB608,380 and RMB724,072, respectively.

The Master Lease Agreement is on normal commercial terms or better. The rental was determined by our Group and Ningbo Linfeng through arm’s length negotiation based on a number of factors, including but not limited to the prevailing market rental rate of similar property located in the vicinity, the area leased and the term of the lease. Other charges under the Master Lease Agreement, which include property management fees and water and electricity fees, were arrived at after arm’s length negotiation between the parties with reference to the area of the leased properties, the water and electricity fees prescribed by the relevant governmental department and the actual usage of water and electricity.

b) *Listing Rules Implications*

According to HKFRS 16 Leases which was adopted by our Group effective from January 1, 2019, where (i) the lease term of a lease has a non-cancellable period and (ii) such period is covered by an option to extend the lease with reasonable certainty that the lessee will exercise that option or such period is covered by an option to terminate the lease with reasonable certainty that the lessee will not exercise that option, such lease will be recognized as right-of-use assets. Since our Group is reasonably certain to exercise the option to extend the leases for plants with Ningbo Linfeng under the Master Lease Agreement because our Group has made some leasehold improvements at the plants which have an estimated useful life of five years, the leases of such plants by our Group as a lessee are recognized as right-of-use assets. As such, our Company is required to set annual caps based on the total value of right-of-use assets relating to such leases to be entered into by our Group as a lessee in each year under the Master Lease Agreement. Further, according to HKFRS 16 Leases, the recognition exemption (i.e. not to recognize a lease liability and a right-of-use asset at the commencement of a lease) applies where the lease, as of its commencement date, has a lease term of 12 months or less, or where a lease of low-value assets having a value of US\$5,000 or less is concerned. As such, the leases for staff quarters under the Master Lease Agreement are regarded as short-term lease payments, and such short-term lease payments

CONTINUING CONNECTED TRANSACTIONS

and other charges under the Master Lease Agreement are recognized as expenses incurred by our Group. As such, our Company is required to set annual caps for such short-term lease payments and other charges payable by our Group in each year under the Master Lease Agreement.

For the three years ending December 31, 2022, 2023 and 2024, (i) the proposed annual caps on the year-end total value of right-of-use assets relating to the leases to be or expected to be entered into by our Group under the Master Lease Agreement are RMB7,934,000, RMB5,935,000 and RMB3,891,000, respectively, and (ii) the proposed annual caps for the maximum aggregate annual amount of short-term lease payments and other charges under the Master Lease Agreement are RMB1,405,925, RMB2,627,252 and RMB3,327,252, respectively. The respective proposed annual caps for the transactions contemplated under the Master Lease Agreement were determined with reference to (i) the existing lease contracts that our Group has entered into with Ningbo Linfeng which in particular, included a new lease our Group entered into with Ningbo Linfeng after the end of the Track Record Period in respect of new manufacturing plants to prepare for commercialization of our Bladder Cryoablation System and Endoscopic Clip for Anastomosis, (ii) the historical rental and expected fluctuation in the rental, (iii) the historical property management fees and water and electricity fees paid by us during the Track Record Period, and (iv) the estimated property management fees and water and electricity fees payable by us under the Master Lease Agreement.

The historical transactions entered into with Ningbo Linfeng in respect of lease arrangements have been, and the transactions contemplated under the Master Lease Agreement will be, entered into in the ordinary and usual course of business of our Company, on normal commercial terms or better. As each of the applicable percentage ratios in respect of the transactions contemplated under the Master Lease Agreement will, as our Company currently expects, be less than 5% on an annual basis but the total consideration on an annual basis is more than HK\$3 million, the transactions contemplated under the Master Lease Agreement would, upon [REDACTED], be subject to the reporting, announcement and annual review requirements but exempt from the circular and independent shareholders' approval requirements pursuant to Rule 14A.76 of the Listing Rules.

CONFIRMATION OF DIRECTORS

Our Directors (including independent non-executive Directors) consider that the above partially exempt continuing connected transactions have been and will be entered into in the ordinary and usual course of business of our Company, on normal commercial terms or better that are fair and reasonable and in the interest of our Company and Shareholders as a whole. The proposed annual caps in respect of the partially exempt continuing connected transactions are also fair and reasonable and in the interest of our Company and Shareholders as a whole.

CONFIRMATION OF THE JOINT SPONSORS

The Joint Sponsors have reviewed the relevant information and historical figures prepared and provided by us in relation to the partially exempt continuing connected transactions as set out above, obtained various representations and confirmations from us and made reasonable inquiries. Based on the aforementioned due diligence work, the Joint Sponsors are of the view that (i) the partially exempt continuing connected transactions as set out above have been entered into in the ordinary and usual course of business of our Group, on normal commercial terms or better that are fair and reasonable and in the interests of our Company and Shareholders as a whole; and (ii) the proposed annual caps for these partially exempt continuing connected transactions are fair and reasonable and in the interests of our Company and Shareholders as a whole.

CONTINUING CONNECTED TRANSACTIONS

WAIVER APPLICATION FOR PARTIALLY EXEMPT CONTINUING CONNECTED TRANSACTIONS

The transactions set out under “Partially Exempt Continuing Connected Transactions” in this section will constitute partially exempt continuing connected transactions under the Listing Rules upon [REDACTED], which are exempt from the circular and independent shareholders’ approval requirements but subject to the reporting, announcement and annual review requirements under Chapter 14A of the Listing Rules.

In respect of these partially exempt continuing connected transactions, we have applied for, and the Stock Exchange [has granted] us, a waiver under Rule 14A.105 of the Listing Rules from strict compliance with the announcement requirement in respect of such transactions under Chapter 14A of the Listing Rules, subject to the condition that the aggregate amounts of the partially exempt continuing connected transactions for each financial year shall not exceed the relevant amounts set forth in the respective annual caps (as stated above). Apart from the announcement requirement for which a waiver has been sought [and granted], our Group will comply with the relevant requirements under Chapter 14A of the Listing Rules.

SHARE CAPITAL

This section presents certain information regarding our share capital prior to and following the completion of the [REDACTED].

BEFORE THE [REDACTED]

As of the Latest Practicable Date, our registered share capital was RMB228,000,000 comprising 228,000,000 Unlisted Shares with a nominal value of RMB1.00 each.

UPON COMPLETION OF THE [REDACTED]

The share capital of our Company immediately after the [REDACTED] will be as follows:

Description of Shares	Number of Shares	Approximate percentage of the enlarged issued share capital after the [REDACTED]
Unlisted Shares ⁽¹⁾	[REDACTED]	[REDACTED]%
H Shares converted from Unlisted Shares ⁽²⁾	[REDACTED]	[REDACTED]%
H Shares to be issued pursuant to the [REDACTED]	[REDACTED]	[REDACTED]%
Total	[REDACTED]	100%

Notes:

- (1) The Unlisted Shares of our Company refer to [REDACTED] Unlisted Shares held by Ningbo Linfeng, [REDACTED] Unlisted Shares held by Mr. Lv, [REDACTED] Unlisted Shares held by Shanghai Shidi, [REDACTED] Unlisted Shares held by Ningbo Maishang, [REDACTED] Unlisted Shares held by Ningbo Hongyingkang, [REDACTED] Unlisted Shares held by Ningbo Kangrui, [REDACTED] Unlisted Shares held by Zhuhai Gao Ling Junheng Equity Investment L.P. (Limited Partnership) (珠海高瓴鈞恒股權投資合夥企業(有限合夥)), [REDACTED] Unlisted Shares held by Suzhou Proxima Venture Investment L.P. (Limited Partnership) (蘇州比鄰星創業投資合夥企業(有限合夥)), [REDACTED] Unlisted Shares held by TD Engineering, [REDACTED] Unlisted Shares held by Galaxy Yuanhui Investment Co., Ltd (銀河源匯投資有限公司), [REDACTED] Unlisted Shares held by Ms. SHEN Yao (申堯), [REDACTED] Unlisted Shares held by Qingdao Marine Innovation Industry Investment Fund Co., Ltd. (青島海洋創新產業投資基金有限公司), [REDACTED] Unlisted Shares held by Mr. ZHU Jun (朱軍), [REDACTED] Unlisted Shares held by Ms. YUAN Dan (袁丹) and [REDACTED] Unlisted Shares held by Mr. XU Li (徐力).
- (2) Following the completion of the [REDACTED] and according to the approval letter issued by the CSRC on October 12, 2022, [REDACTED] Unlisted Shares will be converted into H Shares on a one-for-one basis and [REDACTED] on the [REDACTED] for [REDACTED].

SHARE CAPITAL

[REDACTED] REQUIREMENTS

Rules 8.08(1)(a) and (b) of the Listing Rules require there to be an open market in the securities for which listing is sought and for a sufficient public float of an issuer’s listed securities to be maintained. This normally means that (i) at least 25% of the issuer’s total issued share capital must at all times be held by the public; and (ii) where an issuer has one class of securities or more apart from the class of securities for which listing is sought, the total securities of the issuer held by the public (on all regulated market(s) including the Stock Exchange) at the time of listing must be at least 25% of the issuer’s total issued share capital.

Based on the information in the above tables, our Company will meet the [REDACTED] requirement under the Listing Rules after the completion of the [REDACTED].

SHARE CLASSES

Upon completion of the [REDACTED], our Company would have two classes of Shares, namely Unlisted Shares and H Shares. Both Unlisted Shares and H Shares are ordinary shares in the share capital of our Company. H Shares may only be [REDACTED] and [REDACTED] in Hong Kong dollars (except for H Shares under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect, which can be traded in Renminbi) between legal and natural persons of Hong Kong, the Macau Special Administrative Region, Taiwan or any country or jurisdiction other than the PRC and qualified domestic institutional investors of the PRC. Apart from certain qualified domestic institutional investors in the PRC, as well as certain PRC qualified investors under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect, H Shares generally cannot be [REDACTED] by or [REDACTED] among legal and natural persons of the PRC. We have not approved any share issue plan other than the [REDACTED].

RANKING

Unlisted Shares and H Shares are regarded as different classes of Shares under the Articles of Association. The differences between Unlisted Shares and H Shares and the provisions on class rights, the dispatch of notices and financial reports to shareholders, dispute resolution, registration of Shares on different registers of shareholders, the method of share transfer and appointment of dividend receiving agents are set forth in the Articles of Association and summarized in Appendix V to this document. Except for the differences above, Unlisted Shares and H Shares will rank *pari passu* with each other in all other respects and, in particular, will rank equally for all dividends or distributions declared, paid or made after the date of this document. All dividends in respect of the H Shares are to be declared in Renminbi and paid by our Company in Hong Kong dollars. In addition to cash, dividends may be distributed in the form of Shares.

SHARE CAPITAL

CONVERSION OF UNLISTED SHARES INTO H SHARES

Our Unlisted Shares are unlisted Shares which are currently not listed or traded on any stock exchange.

According to stipulations by the State Council securities regulatory authority and the Articles of Association, the Unlisted Shares may be converted into H Shares. Such converted Shares may be listed or traded on an overseas stock exchange provided that the conversion and trading of such converted Shares shall only be effected after all requisite internal approval processes have been duly completed and the approval from the relevant PRC regulatory authorities (including the CSRC) and the relevant overseas stock exchange have been obtained. In addition, such conversion and trading shall in all respects comply with the regulations prescribed by the State Council securities regulatory authority and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange.

If any of the Unlisted Shares are to be converted to H Shares to be traded on the [REDACTED], such conversion requires the approval of the relevant PRC regulatory authorities, including the CSRC. Approval of the [REDACTED] is required for the [REDACTED] of such converted Shares on the [REDACTED]. Subject to fulfilling the procedures below, our Company may apply for the [REDACTED] of all or any portion of the Unlisted Shares on the [REDACTED] as H Shares before any proposed conversion so that the conversion process can be completed promptly upon notice to the [REDACTED] and delivery of shares for entry on the H Share register. As any [REDACTED] of additional Shares after our Company’s initial [REDACTED] on the [REDACTED] is ordinarily considered by the [REDACTED] to be a purely administrative matter, it does not require prior application for [REDACTED] as of the time of our Company’s initial [REDACTED] in Hong Kong. A vote by our Shareholders in separate class meetings is not required for the [REDACTED] and [REDACTED] of the converted Shares on an overseas stock exchange. Any [REDACTED] of the converted Shares on the [REDACTED] after the initial [REDACTED] is subject to prior notification by way of announcement to inform Shareholders and the public of any proposed conversion.

After all the requisite approvals have been obtained, the relevant Unlisted Shares will be withdrawn from the Unlisted Share register, and our Company will re-register such Shares on the H Share register maintained in Hong Kong and instruct the [REDACTED] to issue H Share certificates. Registration on the H Share register of our Company will be on the conditions that (i) the [REDACTED] lodges with the [REDACTED] a letter confirming the entry of the relevant H Shares on the H Share register and the due dispatch of H Share certificates; and (ii) the [REDACTED] of the H Shares to be [REDACTED] the [REDACTED] complies with the Listing Rules and the [REDACTED] and the [REDACTED] in force from time to time. Until the converted Shares are re-registered on the H Share register of our Company, such Shares would not be [REDACTED] as H Shares. For details of our existing Shareholders’ proposed conversion of Unlisted Shares into H Shares, see “History, Development and Corporate Structure—[REDACTED]” in this document.

SHARE CAPITAL

RESTRICTIONS OF SHARE TRANSFER

In accordance with the PRC Company Law, the shares issued prior to any [REDACTED] of shares by a company cannot be transferred within one year from the date on which such [REDACTED] shares are [REDACTED] and [REDACTED] on the relevant stock exchange. As such, the Shares [REDACTED] by our Company prior to the issue of H Shares will be subject to such statutory restriction on transfer within a period of one year from the [REDACTED].

Our Directors, Supervisors and members of the senior management of our Company shall declare their shareholdings in our Company and any changes in their shareholdings. Shares transferred by our Directors, Supervisors and members of the senior management each year during their term of office shall not exceed 25% of their total respective shareholdings in our Company. The Shares that the aforementioned persons held in our Company cannot be transferred within one year from the date on which the Shares are [REDACTED] and [REDACTED], nor within half a year after they leave their positions in our Company. The Articles of Association may contain other restrictions on the transfer of the Shares held by our Directors, Supervisors and members of senior management of our Company.

For details of the lock-up undertaking given by our Controlling Shareholder pursuant to Rule 10.07 of the Listing Rules, see “[REDACTED]” in this document.

SHAREHOLDERS’ GENERAL MEETINGS AND CLASS MEETINGS

For details of circumstances under which Shareholders’ general meeting and Shareholders’ class meeting are required, see “Appendix IV—Summary of Principal Legal and Regulatory Provisions” in this document.

REGISTRATION OF SHARES NOT LISTED ON AN OVERSEAS STOCK EXCHANGE

According to the Notice of Centralized Registration and Deposit of Non-overseas Listed Shares of Companies Listed on an Overseas Stock Exchange (《關於境外上市公司非境外上市股份集中登記存管有關事宜的通知》) issued by the CSRC, an overseas listed company is required to register its shares that are not listed on any overseas stock exchange with China Securities Depository and Clearing Corporation Limited within 15 business days upon its listing.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and the conversion of our Unlisted Shares to H Shares, the following persons will have an interest and/or short position in the Shares or the underlying Shares which would fall to be disclosed to us and the [REDACTED] under the provisions of [REDACTED], or, who are, directly or indirectly interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company:

LONG POSITIONS IN THE SHARES OF OUR COMPANY

Name of shareholder	Capacity / nature of interest	Class of Shares upon the completion of the [REDACTED]	Number of Shares	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the total share capital of our Company upon completion of the [REDACTED] ⁽¹⁾	Approximate percentage of shareholding in the relevant class of Shares upon completion of the [REDACTED] ⁽²⁾
Ms. Li ⁽³⁾	Interest in controlled corporations; interest held jointly with another person	Unlisted Shares	91,369,084	40.07%	[REDACTED]%	[REDACTED]%
		H Shares	41,578,172	18.24%	[REDACTED]%	[REDACTED]%
Mr. Lv ⁽³⁾	Beneficial owner; interest in a controlled corporation; interest held jointly with another person	Unlisted Shares	91,369,084	40.07%	[REDACTED]%	[REDACTED]%
		H Shares	41,578,172	18.24%	[REDACTED]%	[REDACTED]%
Ningbo Linfeng ⁽⁴⁾	Beneficial owner; interest in controlled corporations	Unlisted Shares	66,058,120	28.97%	[REDACTED]%	[REDACTED]%
		H Shares	30,730,616	13.48%	[REDACTED]%	[REDACTED]%
Shanghai Shidi ⁽⁴⁾⁽⁵⁾	Beneficial owner; interest in controlled corporations	Unlisted Shares	76,060,092	33.36%	[REDACTED]%	[REDACTED]%
		H Shares	35,017,176	15.36%	[REDACTED]%	[REDACTED]%
Shanghai Shidi Biotechnology Co., Ltd. (上海仕地生物科技有限公司) (“Shidi Biotechnology”) ⁽⁴⁾	Interest in controlled corporations	Unlisted Shares	21,519,825	9.44%	[REDACTED]%	[REDACTED]%
		H Shares	9,222,783	4.05%	[REDACTED]%	[REDACTED]%
Mr. ZHU Jun (朱軍) ⁽⁶⁾	Beneficial owner; interest in a controlled corporation	Unlisted Shares	9,721,236	4.26%	[REDACTED]%	[REDACTED]%
		H Shares	4,166,244	1.83%	[REDACTED]%	[REDACTED]%
Ningbo Maishang	Beneficial owner	Unlisted Shares	8,972,712	3.94%	[REDACTED]%	[REDACTED]%
		H Shares	3,845,448	1.69%	[REDACTED]%	[REDACTED]%
Ningbo Hongyingkang	Beneficial owner	Unlisted Shares	8,690,539	3.81%	[REDACTED]%	[REDACTED]%
		H Shares	3,724,517	1.63%	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of shareholder	Capacity / nature of interest	Class of Shares upon the completion of the [REDACTED]	Number of Shares	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the total share capital of our Company upon completion of the [REDACTED] ⁽¹⁾	Approximate percentage of shareholding in the relevant class of Shares upon completion of the [REDACTED] ⁽²⁾
Zhuhai Gao Ling Junheng Equity Investment L.P. (Limited Partnership) (珠海高瓴鈞恒股權投資 合夥企業(有限合夥)) (“Gao Ling Junheng”) ⁽⁷⁾	Beneficial owner	Unlisted Shares H Shares	13,537,272 5,801,688	5.94% 2.54%	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%
Shenzhen Gao Ling Tiancheng III Investment Co., Ltd. (深圳高瓴天成 三期投資有限公司) ⁽⁷⁾	Interest in controlled corporations	Unlisted Shares H Shares	13,537,272 5,801,688	5.94% 2.54%	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%
Ms. ZHANG Haiyan (張海燕) ⁽⁷⁾	Interest in controlled corporations	Unlisted Shares H Shares	13,537,272 5,801,688	5.94% 2.54%	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%
Shenzhen Gao Ling Muqi Equity Investment Fund L.P. (Limited Partnership) (深圳高瓴慕 祺股權投資基金合夥企 業(有限合夥)) ⁽⁷⁾	Interest in controlled corporations	Unlisted Shares H Shares	13,537,272 5,801,688	5.94% 2.54%	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%
Xiamen Gao Ling Ruiqi Equity Investment Fund L.P. (Limited Partnership) (廈門高瓴瑞 祺股權投資基金合夥企 業(有限合夥)) ⁽⁷⁾	Interest in controlled corporations	Unlisted Shares H Shares	13,537,272 5,801,688	5.94% 2.54%	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%
Suzhou Industrial Park New Phase 2 Venture Capital Enterprise (Limited Partnership) (蘇州工業園 區新建元二期創業投資 企業(有限合夥)) (“Suzhou New Phase 2 VC”) ⁽⁸⁾	Beneficial owner	H Shares	12,283,500	5.39%	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of shareholder	Capacity / nature of interest	Class of Shares upon the completion of the [REDACTED]	Number of Shares	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the total share capital of our Company upon completion of the [REDACTED] ⁽¹⁾	Approximate percentage of shareholding in the relevant class of Shares upon completion of the [REDACTED] ⁽²⁾
Suzhou YuanBio Private Equity Fund Management Partnership Enterprise (Limited Partnership) (蘇州元生私募基金管理合夥企業(有限合夥)) ⁽⁸⁾	Interest in controlled corporations	H Shares	12,283,500	5.39%	[REDACTED]%	[REDACTED]%
Suzhou Industrial Park Zhinuo Business Information Consulting Co., Ltd. (蘇州工業園區智諾商務信息諮詢有限公司) ⁽⁸⁾	Interest in controlled corporations	H Shares	12,283,500	5.39%	[REDACTED]%	[REDACTED]%
Mr. CHEN Jie (陳杰) ⁽⁸⁾	Interest in controlled corporations	H Shares	12,283,500	5.39%	[REDACTED]%	[REDACTED]%
Hangzhou Proxima Innovative Investment L.P. (Limited Partnership) (杭州比鄰星創新投資合夥企業(有限合夥)) (“Hangzhou Proxima”) ⁽⁹⁾	Beneficial owner	H Shares	8,047,944	3.53%	[REDACTED]%	[REDACTED]%
Mr. SUN Xiaolu (孫曉路) ⁽⁹⁾	Interest in controlled corporations	Unlisted Shares H Shares	5,295,368 10,317,388	2.32% 4.53%	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%
Hangzhou Proxima Innovative Investment Management L.P. (Limited Partnership) (杭州比鄰星創新投資管理合夥企業(有限合夥)) ⁽⁹⁾	Interest in controlled corporations	Unlisted Shares H Shares	5,295,368 10,317,388	2.32% 4.53%	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%
Shanghai Proxima Asset Management Co., Ltd. (上海比鄰星資產管理有限公司) ⁽⁹⁾	Interest in controlled corporations	Unlisted Shares H Shares	5,295,368 10,317,388	2.32% 4.53%	[REDACTED]% [REDACTED]%	[REDACTED]% [REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of shareholder	Capacity / nature of interest	Class of Shares upon the completion of the [REDACTED]	Number of Shares	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the total share capital of our Company upon completion of the [REDACTED] ⁽¹⁾	Approximate percentage of shareholding in the relevant class of Shares upon completion of the [REDACTED] ⁽²⁾
FutureX Investment I Company Limited ⁽¹⁰⁾	Beneficial owner	H Shares	7,963,128	3.49%	[REDACTED]%	[REDACTED]%
FutureX ICT Opportunity Fund II LP ⁽¹⁰⁾	Interest in controlled corporations	H Shares	7,963,128	3.49%	[REDACTED]%	[REDACTED]%
FutureX Innovation II Limited ⁽¹⁰⁾	Interest in controlled corporations	H Shares	7,963,128	3.49%	[REDACTED]%	[REDACTED]%
Ms. ZHANG Qian (張倩) ⁽¹⁰⁾	Interest in controlled corporations	H Shares	7,963,128	3.49%	[REDACTED]%	[REDACTED]%
Shengshan Asset Management (Shanghai) Co., Ltd. (盛山資產管理(上海)有限公司) ⁽¹¹⁾	Interest in controlled corporations	H Shares	6,072,552	2.66%	[REDACTED]%	[REDACTED]%
Mr. GAN Shixiong (甘世雄) ⁽¹¹⁾	Interest in controlled corporations	H Shares	6,072,552	2.66%	[REDACTED]%	[REDACTED]%

Notes:

- (1) The calculation is based on the total number of [REDACTED] Shares in issue immediately after completion of the [REDACTED].
- (2) The calculation is based on the total number of [REDACTED] Unlisted Shares and [REDACTED] H Shares in issue immediately after completion of the [REDACTED].
- (3) Pursuant to a concert party agreement dated April 26, 2021 entered into by Ms. Li and Mr. Lv, the Concert Parties confirmed that they have been acting in concert in exercising Shareholders’ rights pertaining to our Group (including our Company and Ningbo SensCure) since January 1, 2014, and they have agreed to continue to act in concert and reach consensus on proposals related to the daily management and operation of our Group presented to general meetings of the Shareholders of our Company for voting. Mr. Lv beneficially owns 15,308,992 Unlisted Shares and 6,560,996 H Shares of our Company. As of the Latest Practicable Date, Mr. Lv owned approximately 37.22% in Ningbo Maishang as one of its limited partners. As such, under the SFO, Mr. Lv is deemed to be interested in the 8,972,712 Unlisted Shares and 3,845,448 H Shares held by Ningbo Maishang. As of the Latest Practicable Date, Ningbo Linfeng was owned as to 65% by Shanghai Shidi which was in turn wholly owned by Ms. Li. Further, as of the Latest Practicable Date, Ms. Li controlled the executive partner of each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui, namely, Shidi Biotechnology. Shidi Biotechnology is entitled to exercise the voting power held by each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui in our Company pursuant to their respective partnership agreements. As of the Latest Practicable Date, Tongshang Linfeng Equity Investment Partnership (Limited Partnership) (寧波通商麟豐股權投資合夥企業(有限合夥)) (“**Tongshang Linfeng**”) was owned as to approximately 49.02% by Ningbo Linfeng as a limited partner. As such, under the SFO, Ms. Li is deemed to be interested in the 76,060,092 Unlisted Shares and 35,017,176 H Shares held by Shanghai Shidi, Ningbo Linfeng, Ningbo Maishang, Ningbo Hongyingkang, Ningbo Kangrui and Tongshang Linfeng.

SUBSTANTIAL SHAREHOLDERS

- (4) Ningbo Linfeng beneficially owns 44,538,295 Unlisted Shares and 19,087,841 H Shares of our Company. As of the Latest Practicable Date, the executive partner of each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui, namely, Shidi Biotechnology, is wholly owned by Ningbo Linfeng. Shidi Biotechnology is entitled to exercise the voting power held by each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui in our Company pursuant to their respective partnership agreements. As such, under the SFO, Shidi Biotechnology and Ningbo Linfeng are deemed to be interested in the 21,519,825 Unlisted Shares and 9,222,783 H Shares held by Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui. Further, as of the Latest Practicable Date, Tongshang Linfeng Equity Investment Partnership (Limited Partnership) (寧波通商麟豐股權投資合夥企業(有限合夥)) (“**Tongshang Linfeng**”) was owned as to approximately 49.02% by Ningbo Linfeng as a limited partner. As such, under the SFO, Ningbo Linfeng is also deemed to be interested in the 2,419,992 H Shares held by Tongshang Linfeng.
- (5) Shanghai Shidi beneficially owns 10,001,972 Unlisted Shares and 4,286,560 H Shares of our Company. As of the Latest Practicable Date, Ningbo Linfeng was owned as to 65% by Shanghai Shidi. As such, under the SFO, Shanghai Shidi is deemed to be interested in the 66,058,120 Unlisted Shares and 30,730,616 H Shares held by Ningbo Linfeng, Ningbo Maishang, Ningbo Hongyingkang, Ningbo Kangrui and Tongshang Linfeng.
- (6) Mr. ZHU Jun (朱軍) (“**Mr. Zhu**”), our executive Director, beneficially owns 1,030,697 Unlisted Shares and 441,727 H Shares of our Company. As of the Latest Practicable Date, Mr. Zhu owned approximately 38.77% in Ningbo Hongyingkang as one of its limited partners. As such, under the SFO, Mr. Zhu is deemed to be interested in the 8,690,539 Unlisted Shares and 3,724,517 H Shares held by Ningbo Hongyingkang.
- (7) Gao Ling Junheng is a limited partnership established in the PRC, whose general manager is Shenzhen Gao Ling Tiancheng III Investment Co., Ltd. (深圳高瓴天成三期投資有限公司), which is owned as to 55% by Ms. ZHANG Haiyan (張海燕). Further, Gao Ling Junheng is owned as to approximately 50.11% and 36.42% by its limited partners, Shenzhen Gao Ling Muqi Equity Investment Fund L.P. (Limited Partnership) (深圳高瓴慕祺股權投資基金合夥企業(有限合夥)) and Xiamen Gao Ling Ruiqi Equity Investment Fund L.P. (Limited Partnership) (廈門高瓴瑞祺股權投資基金合夥企業(有限合夥)), respectively. As such, under the SFO, Shenzhen Gao Ling Tiancheng III Investment Co., Ltd. (深圳高瓴天成三期投資有限公司), Ms. ZHANG Haiyan (張海燕), Shenzhen Gao Ling Muqi Equity Investment Fund L.P. (Limited Partnership) (深圳高瓴慕祺股權投資基金合夥企業(有限合夥)) and Xiamen Gao Ling Ruiqi Equity Investment Fund L.P. (Limited Partnership) (廈門高瓴瑞祺股權投資基金合夥企業(有限合夥)) are deemed to be interested in the 13,537,272 Unlisted Shares and 5,801,688 H Shares held by Gao Ling Junheng.
- (8) Suzhou New Phase 2 VC is a limited partnership established in the PRC, which is managed by its general partner, Suzhou YuanBio Private Equity Fund Management Partnership Enterprise (Limited Partnership) (蘇州元生私募基金管理合夥企業(有限合夥)), whose general partner is Suzhou Industrial Park Zhinuo Business Information Consulting Co., Ltd. (蘇州工業園區智諾商務信息諮詢有限公司), which is owned as to 99% by Mr. CHEN Jie (陳杰). As such, under the SFO, Suzhou YuanBio Private Equity Fund Management Partnership Enterprise (Limited Partnership) (蘇州元生私募基金管理合夥企業(有限合夥)), Suzhou Industrial Park Zhinuo Business Information Consulting Co., Ltd. (蘇州工業園區智諾商務信息諮詢有限公司) and Mr. CHEN Jie (陳杰) are deemed to be interested in the 12,283,500 H Shares held by Suzhou New Phase 2 VC.
- (9) Each of Hangzhou Proxima and Suzhou Proxima Venture Investment L.P. (Limited Partnership) (蘇州比鄰星創業投資合夥企業(有限合夥)) (“**Suzhou Proxima**”) is a limited partnership established in the PRC and is managed by its general partner, Hangzhou Proxima Innovative Investment Management L.P. (Limited Partnership) (杭州比鄰星創新投資管理合夥企業(有限合夥)), whose general partner is Shanghai Proxima Asset Management Co., Ltd. (上海比鄰星資產管理有限公司), which is owned as to 90% by Mr. SUN Xiaolu (孫曉路), our non-executive Director. As such, under the SFO, Hangzhou Proxima Innovative Investment Management L.P. (Limited Partnership) (杭州比鄰星創新投資管理合夥企業(有限合夥)), Shanghai Proxima Asset Management Co., Ltd. (上海比鄰星資產管理有限公司) and Mr. SUN Xiaolu (孫曉路) are deemed to be interested in 5,295,368 Unlisted Shares and 10,317,388 H Shares held by Hangzhou Proxima and Suzhou Proxima.
- (10) FutureX Investment I Company Limited is a limited company incorporated in Hong Kong and is wholly owned by FutureX ICT Opportunity Fund II LP, whose general partner is FutureX Innovation II Limited, which is in turn indirectly wholly owned by Ms. ZHANG Qian (張倩). As such, under the SFO, FutureX ICT Opportunity Fund II LP, FutureX Innovation II Limited and Ms. ZHANG Qian (張倩) are deemed to be interested in the 7,963,128 H Shares held by FutureX Investment I Company Limited.

SUBSTANTIAL SHAREHOLDERS

- (11) Shanghai Shengshan Xingqian Venture Capital Center (Limited Partnership) (上海盛山興錢創業投資中心(有限合夥)) (“**Shengshan Xingqian**”) is a limited partnership established in the PRC and is managed by its general partner, Shengshan Asset Management (Shanghai) Co., Ltd. (盛山資產管理(上海)有限公司) (“**Shengshan Asset Management**”). Suzhou Shengshan Huiying Venture Capital Enterprise (Limited Partnership) (蘇州盛山滙贏創業投資企業(有限合夥)) (“**Shengshan Huiying**”) is a limited partnership established in the PRC and is managed by its general partner, Suzhou Shengshan Chuanghe Venture Capital Center (Limited Partnership) (蘇州盛山創禾創業投資中心(有限合夥)) whose general partner is Shengshan Asset Management. Shengshan Asset Management is owned as to 51% by Mr. GAN Shixiong (甘世雄). As such, under the SFO, Shengshan Asset Management and Mr. GAN Shixiong (甘世雄) are deemed to be interested in the 6,072,552 H Shares held by Shengshan Xingqian and Shengshan Huiying.

Save as disclosed herein, our Directors are not aware of any persons who will, immediately following completion of the [REDACTED], have interests and/or short positions in Shares or underlying Shares which would fall to be disclosed under the provisions of [REDACTED] or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board currently consists of nine Directors, comprising two executive Directors, three non-executive Directors and four independent non-executive Directors. Pursuant to the Articles of Association, our Directors are elected and appointed by our Shareholders at a Shareholders’ meeting for a term of three years, which is renewable upon re-election and re-appointment.

The following table sets forth general information regarding our Directors:

Name	Position	Age	Date of appointment as Director	Time of joining our Group	Role and responsibilities	Relationship with other Directors, Supervisors and senior management
Mr. LI Kejian (李克儉)	Chairperson of our Board, executive Director	53	March 15, 2013	March 15, 2013	Responsible for overall management, business, and strategy of our Group and oversight of the commercial suitability and sustainability of our Group	None
Mr. ZHU Jun (朱軍)	Executive Director; general manager	48	January 5, 2021	May 24, 2019	Responsible for the daily operations of our Group	None
Mr. LV Shiwen (呂世文)	Non-executive Director	53	July 8, 2014	July 8, 2014	Responsible for decision-making in respect of major matters such as overall strategies	None
Mr. SUN Xiaolu (孫曉路)	Non-executive Director	47	November 19, 2018	November 19, 2018	Responsible for decision-making in respect of major matters such as overall strategies	None
Mr. ZHAO Chunsheng (趙春生)	Non-executive Director	50	June 15, 2021	June 15, 2021	Responsible for decision-making in respect of major matters such as overall strategies	None
Dr. GAO Dayong (高大勇)	Independent non-executive Director	63	December 2, 2021 (effective from the [REDACTED])	December 2, 2021	Responsible for providing independent advice and judgment to our Board	None
Mr. LIANG Hsien Tse Joseph (梁顯治)	Independent non-executive Director	68	December 2, 2021 (effective from the [REDACTED])	December 2, 2021	Responsible for providing independent advice and judgment to our Board	None
Dr. QIN Zheng (覃正)	Independent non-executive Director	64	December 2, 2021 (effective from the [REDACTED])	December 2, 2021	Responsible for providing independent advice and judgment to our Board	None
Dr. HU Henan (胡赫男)	Independent non-executive Director	34	November 5, 2022 (effective from the [REDACTED])	November 5, 2022	Responsible for providing independent advice and judgment to our Board	None

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

The following sets forth the biographies of our Directors:

Executive Directors

Mr. LI Kejian (李克儉), aged 53, joined our Group in March 2013 and has served as the chairperson of our Board and a Director since then. He was re-designated as an executive Director on December 28, 2021. He is responsible for overall management, business, and strategy of our Group and oversight of the commercial suitability and sustainability of our Group.

Mr. Li has more than 11 years of experience in the investment and medical device industries. From September 1990 to December 2006, Mr. Li was a technician at Hanchuan Machine Tool Co., Ltd. (漢川機床有限責任公司), a company principally engaged in the R&D and manufacturing of machine tools, machine tool components, and high-tech electromechanical products. Since November 2010, he has been a director of Beijing Boruilai Technology Investment Co., Ltd (北京博瑞萊科技投資有限公司) (“**Beijing Boruilai**”), a company principally engaged in project investment with a focus on power and electrical equipment, energy and environmental protection sectors, where he has participated in investment decisions. Since May 2014, he has served as the deputy general manager of Shanghai Shidi, one of our Controlling Shareholders, where he has been primarily responsible for the company’s administration and human resources management, as well as participating in the company’s investment decisions.

Mr. Li graduated in electrical engineering from State-Operated Hanchuan Machine Tool and Technician School (國營漢川機床廠技工學校) in Hanzhong in September 1990.

Mr. Li is the brother of Ms. Li, one of our Controlling Shareholders upon [REDACTED].

Mr. ZHU Jun (朱軍), aged 48, joined our Group in May 2019 as a director and the chief executive officer of Ningbo SensCure and has served as the general manager of our Company since October 2020. He was appointed as a Director in January 2021 and was re-designated as an executive Director on December 28, 2021. He is primarily responsible for the daily operations of our Group. He is currently a director of our subsidiaries, Ningbo SensCure, Beijifeng Biotechnology (Shanghai) Co., Ltd. (北極豐生物科技(上海)有限公司) (“**Beijifeng Biotechnology**”) and Huifeng Biotechnology (Shanghai) Co., Ltd. (輝豐生物科技(上海)有限公司) (“**Huifeng Biotechnology**”).

Mr. Zhu has more than 19 years of experience in the medical industry. From July 1997 to August 2001, he was a resident doctor at Affiliated Hospital of Nantong University (南通大學附屬醫院), primarily responsible for clinical diagnoses and treatments. From July 2004 to June 2017, he was a deputy general manager at Erbe China Ltd. (愛爾博(上海)醫療器械有限公司), a company principally engaged in promotion and sale of medical devices, where he was primarily responsible for nationwide marketing and sales, scientific research, and trainings. From February 2018 to September 2020, Mr. Zhu was an investment partner at Hangzhou Proxima Innovative Investment L.P. (Limited Partnership) (杭州比鄰星創新投資合夥企業(有限合夥)), a company principally engaged in investment in medical fields, where he was involved in research and analyses of medical devices.

Mr. Zhu graduated in clinical medicine from Nanjing Medical University (南京醫科大學) in Nanjing in July 1997. He further obtained his master’s degree in clinical medicine from the Shanghai Medical College of Fudan University (復旦大學上海醫學院) in Shanghai in June 2004.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Non-executive Directors

Mr. LV Shiwen (呂世文), aged 53, has joined our Group since July 2014 as a Director and was re-designated as a non-executive Director on December 28, 2021. He is responsible for decision-making in respect of major matters such as overall strategies. He is also currently a director of Ningbo SensCure.

Mr. Lv has more than 20 years of experience in the medical device industry, especially in the R&D and production of medical devices. From July 1993 to April 1998, Mr. Lv was the deputy director of the research department and the management department of Shanghai Navigation Instrument General Factory (上海航海儀器總廠), a company specializing in marine, communication and navigation equipment, where he was primarily responsible for the R&D of navigation instrument technologies and quality management of the production department. From May 1998 to February 2000, he was a quality manager at Shanghai CIMC Generating Set Co., Ltd. (上海中集內燃機發電設備有限公司), a company principally engaged in the production of special internal combustion power generation equipment and diesel water pump units, where he was primarily responsible for quality management of the production department. From May 2000 to November 2001, Mr. Lv served as a manager of the quality control department and production department of MicroPort Medical (Shanghai) Co., Ltd. (微創醫療器械(上海)有限公司), a company principally engaged in the R&D, manufacturing and sales of cardiovascular interventional medical devices and a wholly-owned subsidiary of MicroPort Scientific Corporation (a company listed on the Stock Exchange; stock code: 853). From December 2001 to December 2002, he was the director of operations at Weike Medical Devices (Suzhou) Co., Ltd. (維科醫療器械(蘇州)有限公司), a company principally engaged in the R&D, manufacturing and sales of cardiovascular interventional medical devices, where he was primarily responsible for the R&D, quality control, and production management. Mr. Lv then served as the vice general manager of Lifetech Scientific (Shenzhen) Co., Ltd. (先健科技(深圳)有限公司), a company principally engaged in the R&D, manufacturing and sales of cardiovascular interventional medical devices and a wholly-owned subsidiary of LifeTech Scientific Corporation (a company listed on the Stock Exchange; stock code: 1302) from January 2003 to February 2009. From March 2009 to December 2011, Mr. Lv served as the general manager of Beijing Puhui Biomedical Engineering Co., Ltd. (北京市普惠生物醫學工程有限公司), a company principally engaged in the development, manufacturing and sales of biological valves.

Besides, Mr. Lv also holds directorships and senior management positions in certain close associates of our Controlling Shareholders (other than our Group). Since January 2013, Mr. Lv has successively served as the chief technology officer, a director and the chief executive officer of Jenscare Scientific Co., Ltd. (寧波健世科技股份有限公司) (“**Jenscare**”), a company principally engaged in the development of interventional products for the treatment of structural heart diseases. He is currently an executive director, the chairman of the board of directors, the chief executive officer and the chief technology officer of Jenscare, primarily responsible for the overall management of business operation, strategy and corporate development of the company and its subsidiaries. Since October 2014, he has also been an executive director of Ningbo Dixiang Venture Capital Co., Ltd. (寧波迪翔創業投資有限公司) (formerly known as Ningbo Dixiang Medical Technology Co., Ltd. (寧波迪翔醫療科技有限公司)) (“**Ningbo Dixiang**”), an investment holding company with a focus on the life sciences and healthcare industries. Further, since July 2018, he has been a non-executive director of Ningbo Hicren Biotechnology Co., Ltd. (寧波華科潤生物科技有限公司) (“**Hicren Biotechnology**”), a company principally engaged in the R&D, manufacturing and sales of medical devices used for vertebroplasty.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Lv obtained his bachelor’s degree in machinery manufacturing and equipment from Harbin Engineering University (哈爾濱工程大學) (formerly known as Harbin Shipbuilding Engineering Institute (哈爾濱船舶工程學院) in Harbin in July 1993. Mr. Lv is currently a member of Zhejiang Pharmaceutical Society Medical Device Expert Committee (浙江省藥學會醫療器械專家委員會) and a mentor of the Center for China Cardiovascular Innovations (中國心血管醫生創新學院).

Mr. SUN Xiaolu (孫曉路), aged 47, has joined our Group since November 2018 as a Director and was re-designated as a non-executive Director on December 28, 2021. He is primarily responsible for decision-making in respect of major matters such as overall strategies.

Mr. Sun has more than 14 years of experience in financial management. From July 2002 to August 2005, Mr. Sun worked at Philips (China) Investment Co., Ltd. (飛利浦(中國)投資有限公司), a company specializing in medical equipment during which he once served as a senior scientist at its Shanghai branch. From May 2007 to October 2015, he was a partner at DT Capital Investment & Consulting (Shanghai) Co., Ltd. (德同豐嘉(上海)私募基金管理有限公司) (formerly known as DT Capital Management (Shanghai) Co., Ltd. (德同投資諮詢(上海)有限公司)), a company principally engaged in venture capital investment, where he was primarily responsible for venture capital investments. Since October 2015, Mr. Sun has been the founder and a representative for the executive partner of Hangzhou Proxima Innovative Investment Management L.P. (Limited Partnership) (杭州比鄰星創新投資管理合夥企業(有限合夥)), a company principally engaged in venture capital investment, where he was primarily responsible for venture capital investments. Since October 2018, he has also been a representative for the executive partner of Suzhou Proxima Venture Investment L.P. (Limited Partnership) (蘇州比鄰星創業投資合夥企業(有限合夥)), a company principally engaged in venture capital investment, where he was primarily responsible for venture capital investments.

Mr. Sun obtained his bachelor’s degree in applied electronic technology from Zhejiang University (浙江大學) in Hangzhou in June 1997. He obtained his master’s degree in electronic science and technology from Zhejiang University (浙江大學) in Hangzhou in March 2000. Further, he obtained his master’s degree in business administration from The Hong Kong University of Science and Technology (香港科技大學) in Hong Kong in November 2007.

Mr. ZHAO Chunsheng (趙春生), aged 50, has joined our Group since June 2021 as a Director and was re-designated as a non-executive Director on December 28, 2021. He is primarily responsible for decision-making in respect of major matters such as overall strategies.

Mr. Zhao has more than 22 years of experience in the medical device industry. From April 1999 to July 2020, he was the deputy general manager and general manager at Shanghai Medical Instrument (Group) Co., Ltd. (上海醫療器械(集團)有限公司), a company specializing in X-ray, surgical instruments, disinfection equipment and sanitary materials, where he was primarily responsible for formulation of strategies and operational management of the company. From June 2009 to June 2012, Mr. Zhao served as a director of Beijing Wandong Medical Technology Co., Ltd. (北京萬東醫療科技股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600055) and principally engaged in the R&D and manufacturing of imaging medical devices, where he was primarily responsible for formulating strategies for the company.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Besides, Mr. Zhao also holds directorships and senior management positions in Ningbo Linfeng, one of our Controlling Shareholders, and certain close associates of our Controlling Shareholders (other than our Group). Mr. Zhao has been an executive director of Ningbo Naruinode Medical Technology Co., Ltd. (寧波納睿諾德醫療科技有限公司) (“**Ningbo Naruinode**”) (a company principally engaged in the R&D, manufacturing and sales of radiation imaging devices such as static computerized tomography (CT)) since December 2020, Dalian Qikexing Medical Instrument Co., Ltd. (大連七顆星醫療器械有限公司) (“**Dalian Qikexing**”) (a company principally engaged in the R&D, manufacturing and sales of medical devices used in neurosurgical procedures) since March 2021, Ningbo Huifeng Biotechnology Co., Ltd. (寧波慧豐生物科技有限公司) (“**Ningbo Huifeng**”) (a company principally engaged in the R&D, manufacturing and sales of medical devices used in neurosurgical procedures) since June 2021 and Shanghai Pannuoxi Medical Technology Co., Ltd. (上海潘諾西醫療科技有限公司) (“**Shanghai Pannuoxi**”) (a company principally engaged in the R&D, manufacturing and sales of medical modeling products and personalized implant materials) since November 2021. Since October 2021, he has been the general manager of Ningbo Linfeng, where he has been primarily responsible for operational management. Since January 2022, he has been a non-executive director and the board chairman of Ningbo Dize Biotechnology Co., Ltd. (寧波迪澤生物科技有限公司) (“**Ningbo Dize**”), a company principally engaged in the R&D, manufacturing and sales of passive medical devices used in treating arteriosclerosis associated with coronary heart diseases.

Mr. Zhao obtained his master’s degree in vehicle engineering and inspection from Jilin University of Technology (吉林工業大學) in Jilin in March 1999. He also obtained his master’s degree in business management from Shanghai Jiao Tong University (上海交通大學) in Shanghai in March 2003. Mr. Zhao has also been certified as an engineer by Shanghai Pharmaceutical Group Co., Ltd. (上海醫藥(集團)有限公司) since December 2002.

Independent non-executive Directors

Dr. GAO Dayong (高大勇), aged 63, was appointed as our independent non-executive Director on December 2, 2021 with his appointment taking effect upon [REDACTED]. He is responsible for providing independent advice and judgment to our Board.

Dr. Gao has more than 23 years of experience in teaching and scientific research. He was a senior research scientist at Cryobiology Research Institute of the Methodist Hospital of Indiana, primarily responsible for participating in and leading scientific research, as well as development of new technologies and applications. Dr. Gao was a tenured full professor from January 1998 to June 2004 and has been the Baxter Healthcare Chair of Engineering since July 2004 at the Department of Mechanical Engineering and Center for Biomedical Engineering at the University of Kentucky, primarily responsible for teaching, scientific research, and technology transformation. He has also been the tenured full professor of the Department of Mechanical Engineering and Department of Bioengineering since September 2004 and the ORIGINCELL Endowed Professor since July 2019 at the University of Washington, primarily responsible for teaching, scientific research and technology transformation.

Dr. Gao obtained his bachelor’s degree in modern mechanics from the University of Science and Technology of China (中國科學技術大學) in Hefei in February 1982. He further obtained his doctor’s degree in mechanical engineering and biomedical engineering from Concordia University in Montreal in May 1991.

Mr. LIANG Hsien Tse Joseph (梁顯治), aged 68, was appointed as our independent non-executive Director on December 2, 2021 with his appointment taking effect upon [REDACTED]. He is responsible for providing independent advice and judgment to our Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Liang has more than 14 years of experience in teaching and financial management. From August 2001 to August 2003, he was the financial controller of Skyworth Digital Holdings Ltd (創維數碼控股有限公司), a company listed on the Stock Exchange (stock code: 751) principally engaged in the manufacturing and sale of TV sets, DVDs and related products. Since February 2009, he has been an associate professor at Beijing Normal University-Hong Kong Baptist University United International College (北京師範大學-香港浸會大學聯合國際學院). From October 2009 to September 2011, he was the managing director of financial planning and development at Beijing Normal University-Hong Kong Baptist University United International College (北京師範大學-香港浸會大學聯合國際學院). From October 2011 to November 2013, he worked at Total Wireless Solutions (Macao Commercial Offshore) Limited (明美製品(澳門離岸商業服務)有限公司), where he was responsible for financial matters of the company, and he served as an executive vice president of the finance department from October 2011 to July 2013.

Besides, since October 2011, Mr. Liang has been an independent non-executive director of LifeTech Scientific Corporation (先健科技公司), a company listed on the Stock Exchange (stock code: 1302) and principally engaged in the manufacturing and marketing of minimally invasive interventional medical devices for cardiovascular and peripheral vascular diseases and disorders. Since February 2013, he has been an independent non-executive director of North Asia Strategic Holdings Ltd (北亞策略控股有限公司), a company listed on the Stock Exchange (stock code: 8080) and principally engaged in investments in high-tech product related businesses.

Mr. Liang obtained a diploma in business management licensing from Hong Kong Baptist College (香港浸會學院) in Hong Kong in December 1977. He obtained his master's degree in professional accounting from the University of Texas at Austin (美國德克薩斯大學奧斯丁學院) in Austin in June 1981. He further obtained his bachelor's degree in language and translation through long distance learning courses from The Open University of Hong Kong (香港公開大學) in Hong Kong in December 2007. Mr. Liang is currently a fellow of the Association of Chartered Certified Accountants (ACCA) (特許公認會計師公會) (formerly known as the Chartered Association of Certified Accountants), an associate of the Hong Kong Institute of Certified Public Accountants (香港會計師公會) (formerly known as the Hong Kong Society of Accountants), and a fellow member of the Texas Society of Certified Public Accountants.

Dr. QIN Zheng (覃正), aged 64, was appointed as our independent non-executive Director on December 2, 2021 with his appointment taking effect upon [REDACTED]. He is responsible for providing independent advice and judgment to our Board.

Dr. Qin has years of experience in teaching and academic research in areas including enterprise management and risk management. Dr. Qin was a doctoral adviser and professor at the School of Management of Xi'an Jiaotong University (西安交通大學) in Shaanxi. He was also a doctoral adviser and professor at the School of Information Management and Engineering of the Shanghai University of Finance and Economics (上海財經大學). He is also the founding vice principal of and currently a doctoral adviser and professor of the Southern University of Science and Technology (南方科技大學). Further, Dr. Qin has also taken up various research projects and published various journals covering areas such as enterprise management and risk management.

Dr. Qin obtained his master's degree in engineering from Xidian University (西安電子科技大學) in Shaanxi in March 1991. He further obtained his doctor's degree in mechanical manufacturing from Xidian University (西安電子科技大學) in July 1994.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. HU Henan (胡赫男), aged 34, was appointed as our independent non-executive Director on November 5, 2022 with her appointment taking effect upon [REDACTED]. She is responsible for providing independent advice and judgment to our Board.

Dr. Hu has more than five years of experience in law and teaching. Since December 2014, she has been a supervisor of Guangzhou Yunsu Technology Co., Ltd. (廣州雲溯科技有限公司), a company principally engaged in provision of software and information technology services. From August 2016 to January 2017, she was an assistant professor at Xiamen University (廈門大學), where she was primarily responsible for teaching and research. Since July 2017, Dr. Hu has been a lecturer at South China University of Technology (華南理工大學), where she has been primarily responsible for teaching and research. Since November 2018, she has been a supervisor of Guangzhou Cloud Stack Technology Co., Ltd. (廣州雲棧科技有限公司), a company principally engaged in provision of software and information technology services.

Dr. Hu obtained her bachelor’s degree in law from the China University of Political Science and Law (中國政法大學) in Beijing in July 2009. She further obtained her master’s degree in law from the University of Hong Kong (香港大學) in Hong Kong in November 2010 and her doctor’s degree in law from the University of Hong Kong (香港大學) in Hong Kong in December 2016. She also obtained her legal profession qualification (法律職業資格) from the Ministry of Justice of the PRC (中華人民共和國司法部) in March 2010.

OUR DIRECTORS’ INTERESTS IN OTHER BUSINESSES

Our Group’s core business operations focus on minimally-invasive interventional cryotherapy. Apart from minimally-invasive interventional cryotherapy, our product pipeline also includes certain non-cryotherapy products in the categories of magnetic rings, digestive endoscopic anastomosis medical devices, single hole laparoscopic surgical approach system and related accessories, lung puncture localization, balloon dilatation catheters for endoscopic use and atrial fibrillation pulsed field ablation systems (together with minimally-invasive interventional cryotherapy, the “**Core Operations**”).

Apart from our Core Operations, Mr. LI Kejian, the chairperson of our Board and our executive Director, held approximately 23.80% of equity interests in Beijing Boruilai as of the Latest Practicable Date and is currently a director of Beijing Boruilai. Beijing Boruilai is a limited liability company established in the PRC on January 22, 2008, and is principally engaged in project investment with a focus on power and electrical equipment, energy and environmental protection sectors. Given the differences between (i) the business nature of Beijing Boruilai and the entities in which it holds equity interests and (ii) that of our Company, our Company is of the view that there is no direct or indirect competition between Beijing Boruilai and our Company.

Further, apart from our Core Operations, as of the Latest Practicable Date, Mr. Lv, our non-executive Director, was able to exercise voting rights of approximately 50.53% in Jenscare together with Ms. Li as concert parties with regard to Jenscare. He is also currently an executive director, the chairman of the board of directors, the chief executive officer and the chief technology officer of Jenscare. Jenscare (its predecessor being Ningbo Jenscare Biotechnology Co., Ltd. (寧波健世生物科技有限公司), a limited liability company established in the PRC on November 8, 2011) is a joint stock company incorporated in the PRC with limited liability on March 23, 2021, and is principally engaged in the development of interventional products for the treatment of structural heart diseases. To the best knowledge of our Company, Jenscare has developed a series of treatment solutions targeting different

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

types of structural heart diseases, including tricuspid valve diseases, aortic valve diseases, mitral valve diseases and heart failure. Mr. Lv was also able to exercise voting rights of approximately 12.19% in Hicren Biotechnology as of the Latest Practicable Date and is currently a non-executive director of Hicren Biotechnology. Hicren Biotechnology is a limited liability company established in the PRC on September 28, 2011 and is principally engaged in the R&D, manufacturing and sales of medical devices used for vertebroplasty. Besides, Mr. Lv held 98% equity interests in Ningbo Dixiang as of the Latest Practicable Date and is currently an executive director of Ningbo Dixiang. Ningbo Dixiang is a limited liability company established in the PRC on October 16, 2014 and is principally engaged in investments with a focus on the life sciences and healthcare industries. Given the differences between the products involved in our Core Operations and those of Jencare and Hicren Biotechnology (including their respective indications and clinical applications and the difference in business nature between Ningbo Dixiang and our Company), our Company is of the view that there is no direct or indirect competition between the aforementioned companies and our Company. Further, Mr. Lv’s role in our Group is non-executive in nature that he will not be involved in the daily management of our Group’s business.

Besides, apart from our Core Operations, Mr. ZHAO Chunsheng, our non-executive Director, holds directorship in Ningbo Naruinode (in which he also held approximately 18.60% of equity interests as of the Latest Practicable Date), Dalian Qikexing, Ningbo Huifeng (in which he also held 30% of equity interests as of the Latest Practicable Date), Shanghai Pannuoxi and Ningbo Dize. For further details relating to the principal business activities, see “— Board of Directors — Non-executive Directors” in this section. Given the differences between the products involved in our Core Operations and those of the aforementioned companies, our Company is of the view that there is no direct or indirect competition between the aforementioned companies and our Company. Further, Mr. Zhao’s role in our Group is non-executive in nature that he will not be involved in the daily management of our Group’s business.

None of our Directors has any interest in any business, apart from the business operated by members of our Group, that competes or is likely to compete, directly and indirectly, with the business of our Group and would require disclosure pursuant to Rule 8.10 of the Listing Rules.

SUPERVISORS

The following table set forth general information regarding our Supervisors:

Name	Position	Age	Date of appointment as Supervisor	Time of joining our Group	Role and responsibilities	Relationship with Directors, other Supervisors and senior management
Ms. LI Cuiqin (李翠琴)	Chairperson of our Board of Supervisors	29	November 19, 2018	August 15, 2018	Supervising our Board and Management	None
Mr. ZHU Haorong (朱浩榮)	Supervisor	41	June 17, 2020	June 17, 2020	Supervising our Board and Management	None
Mr. QIU Junkang (邱軍康)	Supervisor	44	November 19, 2018	April 7, 2013	Supervising our Board and Management	None

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The PRC Company Law requires a joint stock company with limited liability to establish a supervisory committee. Our Board of Supervisors currently consists of three members. Pursuant to our Articles of Association, at least one-third of our Supervisors must be employees' representatives elected by our employees. Except for the employees' representative Supervisors, the other Supervisors are elected and appointed by our Shareholders at a Shareholders' meeting for a term of three years, which is renewable upon re-election and re-appointment.

The following sets forth the biographies of our Supervisors:

Ms. LI Cuiqin (李翠琴), aged 29, joined our Group in August 2018 as the chief accountant and has served as a deputy manager of the management department of our Company since September 2019. In this capacity, she is primarily responsible for financial matters of our Company. She has been our employees' representative Supervisor since November 2018.

Ms. Li has more than five years of experience in finance. Prior to joining our Group, from September 2015 to June 2017, Ms. Li was an accountant for supplies at Elec-Tech International Co., Ltd. (廣東德豪潤達電氣股份有限公司), a company specializing in home appliances, where she was primarily responsible for financial matters.

Ms. Li obtained her bachelor's degree in logistics management from Hubei University of Education (湖北第二師範學院) in Wuhan in June 2015.

Mr. ZHU Haorong (朱浩榮), aged 41, joined our Group in June 2020 and has been our shareholders' representative Supervisor since then.

Mr. Zhu has approximately 19 years of experience in research, project management and business management. From August 2002 to June 2010, Mr. Zhu was an engineer at the East-China Research Institute of Computer Technology (中國電子科技集團公司第三十二研究所). From July 2010 to September 2012, he was a project manager at Shanghai Hugang Jinmao Accounting Co., Ltd. (上海滬港金茂會計師事務所有限公司), a company principally engaged in construction engineering consultancy services, accounting, auditing and asset evaluation. From August 2012 to August 2013, he was a project manager at Tianjin Qiaobo Investment Consulting Management Co., Ltd. (天津喬博投資諮詢管理有限公司), a company principally engaged in project investment consultancy services and business management and planning. Since August 2013, he has been the general manager at Suzhou Qiaojing Investment Management Consulting Co., Ltd. (蘇州喬景投資管理諮詢有限公司), a company principally engaged in investment management and consultancy services. Since June 2013, he has been a director and the general manager at Suzhou Qiaojing Oriental Investment Management Consulting Co., Ltd. (蘇州喬景東方投資管理諮詢有限公司), a company principally engaged in investment management and consultancy services. Since December 2014, he has been the chairman of the board of directors at Nantong Qiaojie Investment Management Co., Ltd. (南通喬杰投資管理有限公司), a company principally engaged in investment management and consultancy services. Since June 2016, he has been the chairman of the board of directors at Nantong Tianzhu Qiaojing Investment Management Co., Ltd. (南通天助喬景投資管理有限公司), a company principally engaged in investment management and consultancy services.

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Mr. Zhu obtained his bachelor’s degree in computer networks from Fudan University (復旦大學) in Shanghai in July 2006. He also obtained his master’s degree in software and domain engineering from Shanghai Jiao Tong University (上海交通大學) in Shanghai in June 2010. He is currently certified as a registered accountant by the Chinese Institute of Certificated Public Accountants (中國註冊會計師).

Mr. QIU Junkang (邱軍康), aged 44, joined our Group in April 2013 and has been a driver and an administrative assistant of our Company, primarily responsible for administrative matters of our Company and carrying out various responsibilities delegated by the management department. He has been our employees’ representative Supervisor since November 2018.

Save as disclosed in this document, each of our Directors and Supervisors confirms with respect to himself or herself, to the best of his or her knowledge, information and belief, that he or she (1) did not hold other long positions or short positions in the Shares, underlying Shares, debentures of our Company or any associated corporation (within the meaning of Part XV of the SFO) as of the Latest Practicable Date; (2) had no other relationship with any Directors, Supervisors, senior management or substantial shareholders of our Company as of the Latest Practicable Date; (3) did not hold any other directorships in the three years prior to the Latest Practicable Date in any public companies of which the securities are listed on any securities market in Hong Kong and/or overseas; and (4) there are no other matters concerning the appointment of our Directors and Supervisors that need to be brought to the attention of our Shareholders and the Stock Exchange or shall be disclosed pursuant to Rule 13.51(2)(h) to (v) of the Listing Rules as of the Latest Practicable Date.

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SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management of our business. The table below sets out certain information in respect of the senior management of our Group.

Name	Position	Age	Date of appointment as senior management	Time of joining our Group	Role and responsibilities	Relationship with Directors, Supervisors and other senior management
Mr. ZHU Jun (朱軍)	General manager	47	October 1, 2020	May 24, 2019	Responsible for the daily operations of our Group	None
Mr. DIAO Yuepeng (刁月鵬)	Deputy vice president	38	September 9, 2013	September 9, 2013	Responsible for our Company's product development and management	Brother-in-law of Dr. ZHAO Kuiwen
Mr. LIU Wei (劉偉)	Chief financial officer; Board secretary	32	October 12, 2020	October 12, 2020	Responsible for financial planning of our Group, investor relations and providing support to our Board	None
Mr. Thach Buu DUONG	Deputy general manager	54	March 15, 2013	March 15, 2013	Responsible for overseeing the operations of Cryofocus America Inc., our wholly-owned subsidiary	None
Mr. LIU Yulong (劉玉龍)	Vice general manager	46	September 17, 2018	September 17, 2018	Responsible for medical, clinical, and market development of our Group	None
Dr. ZHAO Kuiwen (趙奎文)	Technical director, R&D manager	39	March 1, 2019	September 1, 2017	Responsible for the R&D activities of our Group	Brother-in-law of Mr. DIAO Yuepeng
Dr. QU Jihong (瞿紀洪)	Chief medical officer	59	March 1, 2022	March 1, 2022	Responsible for formulating strategies in respect of matters including product application, technology deployment, entry into overseas markets and introduction of international innovative products	None
Mr. CHEN Zhimin (陳智敏)	Executive vice president of Ningbo SensCure	38	January 3, 2017	May 26, 2014	Responsible for the daily operations and overall management of certain of our subsidiaries	None

Mr. ZHU Jun (朱軍) is our executive Director and general manager. For details, see “—Board of Directors—Executive Directors” in this section.

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Mr. DIAO Yuepeng (刁月鵬), aged 38, joined our Group in September 2013 and has successively served as an engineer in the R&D department and as a deputy vice president since then, primarily responsible for our Company’s product development and management. Mr. Diao is currently a director and the general manager of our subsidiaries, Beijifeng Biotechnology, Huifeng Biotechnology, Ningbo Beijifeng Biotechnology Co., Ltd. (寧波北極豐生物科技有限公司) and Ningbo Huifeng Biotechnology Co., Ltd. (寧波輝豐生物科技有限公司). He is primarily responsible for the daily operations and strategy execution of the aforementioned subsidiaries.

Mr. Diao has more than 12 years of experience in the medical device industries. Prior to joining our Group, from June 2007 to June 2009, he was an automation control engineer at Shanghai Tauto Biotech Co., Ltd. (上海同田生物技術有限公司), a company principally engaged in the R&D of biomedicine, and the production and sales of plant intermediates and instruments, where he was primarily responsible for the R&D of scientific instruments. From May 2011 to January 2013 and from April 2013 to September 2013, he worked at AccuTarget MediPharma (Shanghai) Co., Ltd. (上海導向醫療系統有限公司), a company principally engaged in the R&D and production of medical devices, provision of technical consultation and after-sales technical services. From January 2013 to April 2013, he was a manager of the technology department at DH (Shanghai) Medica Tec Co., Ltd. (上海道恒醫療科技股份有限公司, formerly known as DH (Shanghai) Medica Device Co., Ltd. (上海道恒醫療器械有限公司)), a company principally engaged in medical technology development, technical consultation and services, technology transfer, and the import and export of goods and technologies.

Mr. Diao obtained his bachelor’s degree in electromechanical technology education from Shanghai Normal University (上海師範大學) in Shanghai in July 2006. He further obtained his master’s degree in software engineering from the University of Science and Technology of China (中國科學技術大學) in Anhui in June 2016.

Mr. LIU Wei (劉偉), aged 32, has joined our Group as our chief financial officer and Board secretary since October 2020. He is primarily responsible for financial planning of our Group, investor relations and providing support to our Board. Mr. Liu is also currently a director of our subsidiaries, Beijifeng Biotechnology and Huifeng Biotechnology.

Mr. Liu has approximately eight years of experience in audits. Prior to joining our Group, from October 2012 to September 2020, he worked as an audit project manager at the Shanghai branch of Ernst & Young Hua Ming LLP (安永華明會計師事務所(特殊普通合伙)), where he was primarily responsible for financial audits of listed companies and multinational corporations.

Mr. Liu obtained his bachelor’s degree in international accounting from Shanghai Lixin University of Accounting and Finance (上海立信會計金融學院) (previously known as Shanghai Lixin University of Commerce (上海立信會計學院)) in Shanghai in July 2012. He is currently a non-practicing member of the Chinese Institute of Certificated Public Accountants (中國註冊會計師協會).

Mr. Thach Buu DUONG, aged 54, joined our Group in March 2013. Between March 2013 and September 2020, he successively served as a director of R&D and a general manager of our Company. He is currently the deputy general manager of our Company and is primarily responsible for overseeing the operations of Cryofocus America Inc., our wholly-owned subsidiary. He is also currently a director of Cryofocus America Inc.

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Mr. Duong has more than 24 years of experience in engineering. Prior to joining our Group, from December 1992 to August 1996, he successively served as a design engineer and a project engineer at Able Corporation. From August 1996 to June 1998, he was a design engineer at Parker Hannifin Corporation (formerly known as Parker Appliance Company), a company listed on the New York Stock Exchange (stock symbol: PH) and principally engaged in the design and manufacturing of flight control systems. From July 1998 to December 2000, he was a project engineer at Robertshaw Controls Company, a company principally engaged in the design and manufacturing of controls for commercial and home appliances. From December 2000 to July 2001, he was a senior mechanical engineer at Newport Corporation, a company principally engaged in the design and manufacturing of fiber optic laser welders and a wholly-owned subsidiary of MKS Instruments, Inc., which is listed on the NASDAQ Stock Exchange (stock symbol: MKSI). From September 2001 to February 2010, he was a manager at the mechanical engineering department at Endocare Inc, a company specializing in cryoablation for tumors. From July 2010 to February 2012, he was a mechanical engineering department manager at Nearfield Systems Inc., a company principally engaged in the design and manufacturing of antenna measurement systems and software.

Mr. Duong obtained his bachelor of science in mechanical engineering from California State University of Long Beach in California in December 1992. He has also obtained his professional engineer license in mechanical engineering from the State Board of Registration for Professional Engineers and Land Surveyors in the State of California since February 1997.

Mr. LIU Yulong (劉玉龍), aged 46, has joined our Group as a vice general manager of our Company since September 2018. He is primarily responsible for medical, clinical and market development of our Group.

Mr. Liu has more than 17 years of experience in the pharmaceutical and medical device industries. Prior to joining our Group, from March 1999 to June 2000, he was a medical representative at Anhui Anke Biotechnology (Group) Co., Ltd. (安徽安科生物工程(集團)股份有限公司), a company principally engaged in the R&D, manufacturing and sales of biopharmaceutical products. From January 2004 to February 2006, he was a sales representative at Boehringer Ingelheim Shanghai Pharmaceuticals Co., Ltd. (上海勃林格殷格翰藥業有限公司), a company principally engaged in the R&D, manufacturing and sales of pharmaceutical drugs. From February 2006 to March 2017, he was a sales manager at Medtronic (Shanghai) Management Co., Ltd. (美敦力(上海)管理有限公司), a company principally engaged in the R&D, manufacturing and sales of medical instruments. From March 2018 to August 2018, he was the general manager of LY Photoelectric Technology Co., Ltd. (江蘇龍元光電科技有限公司), a company principally engaged in the manufacturing and export of photovoltaic technologies, where he was primarily responsible for project execution.

Mr. Liu obtained his bachelor's degree in biotechnology from South China Agricultural University (華南農業大學) in Guangzhou in July 1999.

Dr. ZHAO Kuiwen (趙奎文), aged 39, joined our Group in September 2017 as an R&D engineering supervisor, and has served as a technical director and R&D manager of our Company since March 2019. He is primarily responsible for the R&D activities of our Group.

Prior to joining our Group, from September 2015 to September 2017, Dr. Zhao worked as a post-doctoral research fellow at Shanghai Jiao Tong University (上海交通大學), primarily responsible for carrying out post-doctoral research.

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Dr. Zhao obtained his bachelor's degree in thermal energy and kinetic engineering from Shandong University of Science and Technology (山東科技大學) in Shandong in June 2006 and his master's degree in refrigeration and cryogenic engineering from the University of Shanghai for Science and Technology (上海理工大學) in Shanghai in March 2009. He further obtained his doctor's degree in engineering thermophysics from Shanghai Jiao Tong University (上海交通大學) in Shanghai in September 2015. Dr. Zhao has been a member of the Interventional Medicine Engineering Professional Committee (介入醫學工程專業委員會委員) of the Shanghai Society of Biomedical Engineering (上海市生物醫學工程學會) since September 2020.

Dr. QU Jihong (瞿紀洪), aged 59, has joined our Group as our chief medical officer since March 2022. He is primarily responsible for formulating strategies in respect of matters including product application, technology deployment, entry into overseas markets and introduction of international innovative products.

Dr. Qu has years of experience in research in areas including cardiac electrophysiology and heart diseases and the medical device industry. Prior to joining our Group, he was a research assistant at the Department of Physiology and Biophysics of the University of Sherbrooke, primarily responsible for participating in cardiac electrophysiology research projects and assisting in the management of preclinical research laboratories, and a postdoctoral scientist at Columbia University, primarily responsible for leading and conducting research projects relating to treatment of heart diseases through emerging biotechnologies, including stem cell and gene therapy technologies. Dr. Qu further worked at Guidant Corporation, a company principally engaged in the design, development, manufacturing, and sales of medical devices for treatment of vascular diseases, where he was primarily responsible for research projects on the application of biotechnology to medical devices and innovative therapies with the use of biotechnology. From December 2014 to November 2017, Dr. Qu was the director of clinical affairs at Abbott Medical (Shanghai) Co., Ltd. (formerly known as St. Jude Medical (Shanghai) Co., Ltd.), a company principally engaged in the design, development, manufacturing, and sales of medical devices for treatment of heart diseases, where he was primarily responsible for formulation of strategies on and execution of clinical affairs in Asia. From December 2017 to March 2019, he was a vice president of clinical and regulatory registration affairs at Peijia Medical Limited (沛嘉醫療有限公司), a company listed on the Stock Exchange (stock code: 9996) and principally engaged in the research and development of transcatheter valve therapeutic and neurointerventional medical devices, where he was primarily responsible for regulatory registration affairs. From April 2019 to June 2020, he was a vice president of medical, clinical and regulatory affairs at Boston Scientific Corporation, a company listed on the New York Stock Exchange (stock symbol: BSX) and principally engaged in the manufacturing and sales of medical devices used in interventional medical specialties, where he was involved in medical, clinical and regulatory affairs. From October 2020 to February 2022, he was the chief medical officer at Genesis Medtech Group (健適醫療科技集團), a company principally engaged in the R&D, manufacturing and sales of surgical and vascular interventional medical devices, where he was primarily responsible for formulating strategies on medical applications and technology deployment.

Dr. Qu obtained his bachelor's degree in biomedical engineering from Shanghai Jiao Tong University in Shanghai (上海交通大學) in July 1986 and his master's degree in biomedical engineering from the Shanghai Medical College of Fudan University (復旦大學上海醫學院) (formerly known as Shanghai Medical University (上海醫科大學)) in Shanghai in July 1989. He obtained his doctor's degree in science from University of Sherbrooke in Quebec in December 1996. Further, Dr. Qu obtained his master's degree in business administration from the Carlson School of Management of the University of Minnesota in Minneapolis in July 2008.

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Mr. CHEN Zhimin (陳智敏), aged 38, joined our Group in May 2014. Since May 2014, he has successively held various positions in our Group, including an R&D engineer, R&D manager, R&D supervisor and R&D director, and is currently an executive vice president of Ningbo SensCure, our wholly-owned subsidiary. He is also currently a director and the general manager of our subsidiaries, Shanghai SensCure Biotechnology Co., Ltd. (上海勝杰康生物科技有限公司) and Ningbo Shengjielong Medical Equipment Co., Ltd. (寧波勝杰隆醫療器材有限公司). He is primarily responsible for the daily operations and overall management of the aforementioned subsidiaries.

Mr. Chen has more than 12 years of experience in engineering. Prior to joining our Group, from July 2008 to June 2009, he was an R&D engineer at Shenzhen Sullair Asia Industrial Co., Ltd. (深圳壽力亞洲實業有限公司), a company principally engaged in the manufacturing and sales of air compressors, vacuum pumps and related products, where he was primarily responsible for the R&D, assembly, testing and manufacturing of air compressor equipment, prototypes and related parts. From January 2010 to May 2014, he was an R&D engineer at Ningbo Pango Machinery Industries Ltd. (寧波磐吉奧機械工業有限公司), a company principally engaged in the manufacturing and sales of car parts, where he was primarily responsible for the new project development, as well as formulation and improvement of processes.

Mr. Chen obtained his bachelor’s degree in mechanical design, manufacturing, and automation from Huazhong University of Science and Technology (華中科技大學) in Wuhan in June 2006. He further obtained his master’s degree in mechanical design and theory from Huazhong University of Science and Technology (華中科技大學) in Wuhan in June 2008.

JOINT COMPANY SECRETARIES

Mr. LIU Wei (劉偉) was appointed as a joint company secretary of our Company on December 28, 2021. Mr. Liu is also a member of senior management of our Company. See “—Senior Management” in this section for his biographical details.

Ms. LEUNG Wai Yan (梁慧欣), was appointed as a joint company secretary of our Company on December 28, 2021. Ms. Leung currently serves as a manager of corporate services of Vistra Corporate Services (HK) Limited. She has over 14 years of experience in providing company secretarial services and compliance services to listed companies and private companies.

Ms. Leung has been an associate member of The Hong Kong Chartered Governance Institute (formerly known as The Hong Kong Institute of Chartered Secretaries) and an associate member of The Chartered Governance Institute (formerly known as the Institute of Chartered Secretaries and Administrators) in the UK since October 2009.

Ms. Leung obtained her bachelor’s degree in business (administrative management) from the University of South Australia in April 2004.

BOARD COMMITTEES

Our Board delegates certain responsibilities to various Board committees. In accordance with the relevant PRC laws and regulations, the Articles and the Listing Rules, we have established our audit committee, remuneration committee and nomination committee.

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Audit Committee

We have established an audit committee with terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph D.3 of the Corporate Governance Code and Corporate Governance Report as set out in Appendix 14 to the Listing Rules. The audit committee consists of Mr. LIANG Hsien Tse Joseph (梁顯治), Mr. ZHAO Chunsheng (趙春生) and Dr. QIN Zheng (覃正), with Mr. LIANG Hsien Tse Joseph (梁顯治) being the chairperson of the committee.

The primary functions of the audit committee are to assist our Board in providing an independent view of our financial reporting process, internal control and risk management system, overseeing the audit process and performing other duties and responsibilities as assigned by our Board, which includes amongst other things:

- proposing to our Board the appointment and replacement of external audit firms;
- supervising the implementation of our internal audit system;
- liaising between our internal audit department and external auditors;
- reviewing our financial information and related disclosures; and
- other duties conferred by our Board.

Remuneration Committee

We have established a remuneration committee with terms of reference in compliance with paragraph E.1 of the Corporate Governance Code and Corporate Governance Report as set out in Appendix 14 to the Listing Rules. The remuneration committee consists of Dr. QIN Zheng (覃正), Mr. LIANG Hsien Tse Joseph (梁顯治), and Mr. LI Kejian (李克儉), with Dr. QIN Zheng (覃正) being the chairperson of the committee.

The primary functions of the remuneration committee are to develop remuneration policies of our Directors, evaluate the performance, make recommendations on the remuneration packages of our Directors and senior management and evaluate and make recommendations on employee benefit arrangements, which includes amongst other things:

- establishing, reviewing and making recommendations to our Directors on our policy and structure concerning remuneration of our Directors and senior management;
- determining the terms of the specific remuneration package of each Director and members of senior management;
- reviewing and approving performance-based remuneration by reference to corporate goals and objectives resolved by our Directors from time to time; and
- other duties conferred by our Board.

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Nomination Committee

We have established a nomination committee with terms of reference in compliance with paragraph B.3 of the Corporate Governance Code and Corporate Governance Report as set out in Appendix 14 to the Listing Rules. The nomination committee consists of Mr. LI Kejian (李克儉), Dr. QIN Zheng (覃正) and Dr. HU Henan (胡赫男), with Mr. LI Kejian (李克儉) being the chairperson of the committee.

The primary function of the nomination committee is to make recommendations to our Board in relation to the appointment and removal of Directors which includes, amongst other things:

- reviewing the structure, size and composition of our Board on a regular basis and making recommendations to our Board regarding any proposed changes;
- identifying, selecting or making recommendations to our Board on the selection of individuals nominated for directorships;
- assessing the independence of our independent non-executive Directors;
- making recommendations to our Board on relevant matters relating to the appointment, re-appointment and removal of our Directors; and
- other duties conferred by our Board.

CORPORATE GOVERNANCE

Board Diversity

We seek to achieve board diversity through the consideration of a number of factors, including but not limited to gender, age, cultural and educational background, ethnicity, professional experience, skills, knowledge and length of service. We have adopted a board diversity policy (the “**Board Diversity Policy**”) to enhance the effectiveness of our Board and to maintain a high standard of corporate governance. Pursuant to the Board Diversity Policy, in reviewing and assessing suitable candidates to serve as a Director of the Company, our nomination committee will consider a range of diversity perspectives with reference to our Company’s business model and specific needs, including but not limited to gender, age, cultural and educational background and professional experience and knowledge. Furthermore, our nomination committee is responsible for reviewing the diversity of our Board, reviewing the Board Diversity Policy from time to time, developing and reviewing measurable objectives for implementing the Board Diversity Policy, and monitoring the progress on achieving these measurable objectives in order to ensure that the Board Diversity Policy remains effective.

Our Directors have a balanced mix of knowledge and skills, including but not limited to overall business management, finance and accounting, R&D, law and investment. They obtained degrees in various majors including clinical medicine, machinery manufacturing and equipment, applied electronic technology, electronic science and technology, business administration, law, engineering, modern mechanics and professional accounting. Further, as of the date of this document, our Board has a relatively wide range of ages ranging from 34 years old to 68 years old. Our Company has reviewed the membership, structure and composition of our Board, and is of the opinion that the structure of our Board is reasonable, and the experience and skills of the Directors in various aspects and fields can enable our Company to maintain a high standard of operation.

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Besides, our Company will take opportunities to promote gender diversity at all levels of our Company, including but not limited to our Board and the senior management levels. We will encourage our Board members to recommend female director candidates and take other actions to help achieve greater board diversity, for example, inviting some of our outstanding female staff at the middle to senior level to attend and observe our Board meetings. This will also allow our Board to understand more about these potential female candidates before they are nominated to our Board and provide opportunities for potential female candidates to prepare themselves for discharging a Director's duties. We will also continue to ensure that there is gender diversity when recruiting staff at the middle to senior level so that our Company will have a pipeline of female senior management and potential successors to our Board. As such, we are of the view that our Board will be offered chances to identify competent female staff at the middle to senior level to be nominated as a Director in the future with a pipeline of female candidates.

We believe that such merit-based selection process with reference to our diversity policy and the nature of our business will be in the best interests of our Company and our Shareholders as a whole.

Corporate Governance Code

Our Directors recognize the importance of incorporating elements of good corporate governance in the management structures and internal control procedures of our Group so as to achieve effective accountability.

Our Company has adopted the code provisions stated in the Corporate Governance Code. Our Company is committed to the view that our Board should include a balanced composition of executive directors and independent non-executive directors so that there is a strong independent element on our Board, which can effectively exercise independent judgment.

EMOLUMENT OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

We offer our executive Directors, employees' representative Supervisors and senior management members, who are also employees of our Company, emoluments in the form of salaries, allowances and benefits in kind, performance related bonuses, equity-settled share award expense and pension scheme contributions. Our independent non-executive Directors receive emoluments based on their responsibilities (including being members or chairpersons of Board committees).

For the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022, the aggregate amounts of emoluments paid by our Company to our Directors and Supervisors were RMB852,000 (including RMB15,000 equity-settled share award expense), RMB8,333,000 (including RMB5,219,000 equity-settled share award expense) and RMB8,522,000 (including RMB6,493,000 equity-settled share award expense), respectively.

For the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022, the aggregate amounts of emoluments paid by our Company to the five highest paid individuals were RMB7,716,000 (including RMB2,589,000 equity-settled share award expense), RMB15,420,000 (including RMB9,282,000 equity-settled share award expense) and RMB13,201,000 (including RMB8,768,000 equity-settled share award expense), respectively. During the Track Record Period, no remuneration was paid by our Company to, or receivable by, our Directors, Supervisors or the five highest paid individuals as an inducement to join or upon joining our Company or as a compensation for loss of office in connection with the management of the affairs of our Company or any subsidiary.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

During the Track Record Period, none of our Directors and Supervisors waived or agreed to waive any emolument. Except as disclosed above, no other payments have been paid, or are payable, by our Company or our subsidiaries to our Directors, Supervisors or the five highest paid individuals during the Track Record Period.

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract, (ii) a confidentiality agreement and (iii) a non-competition agreement with our senior management members and other key personnel. Below sets forth the key terms of these contracts we normally enter into with our senior management and other key personnel.

Confidentiality

- *Confidentiality obligations.* The employee shall, during the course of employment with our Group and thereafter, keep in confidence all confidential information (including but not limited to technical secrets, trade secrets and client information) which belongs to our Group. Without our Group's consent, the employee shall not leak, disclose, publish, announce, issue, teach, transfer or otherwise make available to any third party (including employees who are not privy to such confidential information) any such confidential information in any manner and shall not use such confidential information apart from discharging his/her duties as an employee of our Group. During the term of employment, the employee will be paid monthly as the compensation for the confidentiality obligation.

Ownership of Intellectual Work Products and Business Secrets

- *Acknowledgement:* The employee acknowledges and agrees that our Group shall own all intellectual work products (including but not limited to inventions and copyrights) and trade secrets he or she produces, including but not limited to those produced (i) during the course of discharging his/her duties as an employee of our Group; or (ii) mainly using the resources, technology, information or data of our Group during the course of his/her employment.

Non-competition

- *Non-competition obligations during employment term.* During the term of his/her employment with our Group, except with our Group's consent, the employee shall not (i) be employed in any forms by, become a partner in, or acquire an equity interest of over 5% in any other entity that manufactures products of the same type as our Group does or that is engaged in the same type of business as our Group and may constitute a competitive relationship with our Group, (ii) utilize our Group's resources to create business opportunities for himself/herself, (iii) misappropriate the business opportunities provided by the Group to others for himself/herself, or (iv) conduct a transaction on behalf of our Group, or accept a commission related to such transaction, without prior approval of our Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

- *Non-competition obligations following termination of employment relationship.* Within two years after termination of the employment relationship between the employee and our Group, the employee shall not (i) be employed in any forms by, become a partner in, or acquire an equity interest of over 5% in any other entity that manufactures products of the same type as our Group does or that is engaged in the same type of business as our Group and may constitute a competitive relationship with our Group, (ii) utilize our Group's resources to create business opportunities for himself/herself, (iii) misappropriate the business opportunities provided by the Group to others for himself/herself, or (iv) conduct a transaction on behalf of our Group, or accept a commission related to such transaction, without prior approval of our Board.
- *Compensation paid during the term of non-competition.* During the term of non-competition, the employee will be paid monthly as the compensation for the two years' non-competition obligation following the termination of the employment relationship.

Compensation for Breaches of Covenants

- If the employee breaches any obligation under the confidentiality and non-competition agreements, our Group shall be entitled to terminate the employment relationship with the employee immediately without prior notice and recover from the employee any economic losses incurred as a result of such breach by the employee and reasonable expenses incurred by our Group as a result of investigating such breach by the employee.

COMPLIANCE ADVISER

We have appointed Maxa Capital Limited as our compliance adviser pursuant to Rules 3A.19 and 19A.05 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, the compliance adviser will advise us on the following circumstances:

- a) before the publication of any announcements, circulars or financial reports required by regulatory authorities or applicable laws;
- b) where a transaction, which might constitute a notifiable or connected transaction under the Listing Rules, is contemplated, including share issues and securities repurchases;
- c) where we propose to use the [REDACTED] of the [REDACTED] in a manner different from that detailed in this document or where our business activities, developments or results deviate from any forecast, estimate or other information in this document; and
- d) where the [REDACTED] makes an inquiry of us regarding any unusual movement in the [REDACTED] or [REDACTED] or any other issues under Rule 13.10 of the Listing Rules.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Pursuant to Rule 19A.06 of the Listing Rules, Maxa Capital Limited will, in a timely manner, inform us of any amendment or supplement to the Listing Rules that are announced by the Stock Exchange. Maxa Capital Limited will also inform us of any amendment or supplement to applicable laws and guidelines.

The term of the appointment will commence on the [REDACTED] and end on the date on which we distribute the annual report of the first full financial year commencing after the [REDACTED] pursuant to the Rule 13.46 of the Listing Rules.

FINANCIAL INFORMATION

You should read the following discussion and analysis in conjunction with our consolidated financial statements included in “Appendix I—Accountants’ Report” to this document, together with the accompanying notes. Our consolidated financial information has been prepared in accordance with HKFRSs, which may differ in material aspects from generally accepted accounting principles in other jurisdictions. You should read the entire Accountants’ Report and not merely rely on the information contained in this section.

The following discussion and analysis contain forward-looking statements that reflect the current views with respect to future events and financial performance. These statements are based on assumptions and analysis made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate under the circumstances. However, whether the actual outcome and developments will meet our expectations and predictions depends on a number of risks and uncertainties over which we do not have control. For details, please refer to “Forward-looking Statements” and “Risk Factors” in this document.

OVERVIEW

Founded in 2013, we are a medical device company in China with a main focus on the field of minimally-invasive interventional cryotherapy. We have two Core Products, the Bladder Cryoablation System (膀胱冷凍消融系統) and the Endoscopic Clip for Anastomosis (內鏡吻合夾). The Bladder Cryoablation System is a cryotherapy device designed for the treatment of bladder cancer approved for commercialization in China. The Endoscopic Clip for Anastomosis is an anastomotic device for closure of soft tissue in digestive tract, which is one of over-the-scope clips (“**OTS Clips**”) approved for commercialization in China. We have developed a comprehensive product portfolio mainly targeting the treatment of urinary, cardiovascular, respiratory and digestive diseases. Four of our pipeline products, including two Core Products, the Atrial Fibrillation Cryoablation System (心臟冷凍消融系統) and the Cryofocus Renal Denervation System (Cryofocus 冷凍消融系統) which are still in an early stage, were recognized as “innovative medical devices” by the NMPA or its provincial counterparts. Our Core Products, the Bladder Cryoablation System and the Endoscopic Clip for Anastomosis, have demonstrated good efficacy and safety profiles in their respective clinical trials. We believe our competitive advantages, technologies and product pipeline have established high entry barriers difficult for our competitors to surpass.

As of the Latest Practicable Date, we had two Core Products, 15 other product candidates in various stages of development, as well as six additional commercialized medical consumables. During the Track Record Period, our revenue amounted to RMB9.1 million, RMB22.4 million and RMB16.4 million, respectively, for 2020, 2021 and the eight months ended August 31, 2022. A majority of our revenue was attributable to the sales of the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform during the Track Record Period.

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We expect to incur an increased amount of operating expenses in the near future as we further our preclinical research for, continue the clinical development of, seek regulatory approval for and manufacturing of, our product candidates, launch our pipeline products, and hire additional personnel to operate our business. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a public company. We expect that our financial performance will fluctuate from period to period due to the development status of our product candidates, regulatory approval timeline and commercialization of our product candidates after approval.

BASIS OF PREPARATION

Our Company was established in Shanghai, the PRC on March 15, 2013 as a limited liability company. On July 21, 2021, the Company was converted into a joint stock company with limited liability. For details, see “History, Development and Corporate Structure—Corporate Development” in this document.

The historical financial information has been prepared in accordance with Hong Kong Financial Reporting Standards (“HKFRSs”) (which include all Hong Kong Financial Reporting Standards, Hong Kong Accounting Standards (“HKASs”) and Interpretations) issued by the HKICPA and accounting principles generally accepted in Hong Kong. We have adopted all applicable new and revised HKFRSs effective for the accounting period commencing from January 1, 2022, together with the relevant transitional provisions.

The historical financial information has been prepared under the historical cost convention except for certain financial instruments which have been measured at fair value at the year end of 2020 and 2021 and the eight months end of August 31, 2022.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our Ability to Successfully Develop our Product Candidates and Commercialize our Products

Our business and results of operations depend on our ability to successfully advance the development of our pipeline product candidates and commercialize our registered products. As of the Latest Practicable Date, we had two Core Products, 15 other product candidates in various stages of development and six additional commercialized products. Particularly, for our Bladder Cryoablation System, one of our Core Products, we have successfully completed a multi-center clinical trial on 218 subjects, which was designed to evaluate the safety and efficacy of cryoablation using our Bladder Cryoablation System as an adjuvant therapy with transurethral resection to treat bladder tumor. We submitted registration application, including the clinical trial results as a key part of the registration application, with the NMPA in May 2021. We received the NMPA approval for the Bladder Cryoablation System in June 2022. For more information on the development status of our pipeline product candidates, see “Business—Our Products and Product Candidates—Our Core Products” in this document. Whether our product candidates can demonstrate favorable safety and efficacy clinical trial results, and whether we can obtain the requisite regulatory approvals for our product candidates in time, are crucial for our business and results of operations.

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Our results of operations also depend on our ability to commercialize our product candidates upon approval. The commercial success of our products depends upon the degree of market acceptance each of such products achieves, particularly among hospitals and physicians. Physicians’ and hospitals’ receptiveness to our products in turn depends on, among others, our ability to convince them as to the distinctive characteristics, advantages, safety and cost effectiveness of our products as compared to traditional surgical products and our competitors’ products. If our products are not widely accepted by physicians and hospitals, we may not be able to recover the significant investments we made in developing our product candidates.

Growth and Competitive Landscape of the Cryotherapy Device Market in China

We believe that our financial performance and future growth are dependent on the overall growth of the cryotherapy device market. In China, the markets for cryotherapy devices targeting: (i) NOTES, and (ii) vascular interventional therapy are both at its emerging stages. With the escalating prevalence of cardiovascular and respiratory diseases and urinary and digestive diseases, enhanced patient health awareness, favorable government policies, increased patient affordability, and improved clinical practice of physicians, the cryotherapy device market in China has experienced rapid growth. We believe that by leveraging our competitive advantages, comprehensive product portfolio, as well as strong research and development capabilities, we are well positioned to capture the significant growth potential of markets for cryotherapy devices targeting: (i) NOTES, and (ii) vascular interventional therapy.

Research and Development Expenses and Selling and Distribution Expenses

The development of medical devices requires significant investment of resources over a prolonged period of time, and we intend to continue making sustained investments in this area. We have devoted significant resources on research and development activities and our pipeline of product candidates has been steadily advancing and expanding. In 2020, 2021 and the eight months ended August 31, 2022, our total research and development expenses amounted to RMB42.3 million, RMB89.8 million and RMB35.8 million, respectively.

We intend to continue to advance the development of our product candidates, and as a result, the research and development expenses are expected to continue to be a major component in our operating expenses.

Particularly, we intend to continue to advance our clinical programs for our product candidates. In 2020, 2021 and the eight months ended August 31, 2022, our clinical trial fees for research and development activities amounted to RMB10.8 million, RMB5.0 million and RMB2.3 million, respectively. Clinical product development involves a lengthy and expensive process with an uncertain outcome. The amount of investment required for clinical product development depends on a variety of factors, including the location of the clinical trials, the complexity for the requirements on conducting clinical trials of the product candidates, the number of patients required for such clinical trials, and any additional requirements imposed by competent government authorities to our clinical trials, among others. For more details of risks relating to the development of our product candidates, see “Risk Factors—Risks Relating to Our Products and Product Candidates—Risks Relating to the Development of Our Product Candidates” in this document.

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Furthermore, with the continuing expansion of our business and development of product candidates, we may require further funding through public or private equity offerings, debt financing and other sources. Any changes in our ability to fund our operations and to continue with our research and development of product candidates will affect our cash flow and results of operation.

Government Healthcare Spending, Medical Insurance Coverage and Pricing Policies

We expect that the market acceptance and sales volume of our products and product candidates (assuming that relevant regulatory approvals are obtained and such product candidates are successfully commercialized) will depend in part on the level of government spending on healthcare and the coverage of our products and product candidates under government medical insurance schemes. In line with the overall growth in the healthcare service industry in China, the PRC government has promulgated a series of policies in the last several years aimed at encouraging healthcare infrastructure development and improving patients' accessibility to healthcare services. In particular, growth in population coverage and funding for public medical insurance programs have significantly improved patients' ability to pay for medical treatment, resulting in considerable growth in both patient enrollment and average spending. The inclusion of our products in the governmental insurance coverage would significantly increase the demand for such products, and would therefore have a positive impact on the sales volume of our products and our financial performance. However, there are uncertainties as to whether the government will continue to increase its healthcare spending, and whether our products can be included in the governmental insurance coverage, and different provinces may have different practices for the reimbursement of our products.

PRC regulations and medical insurance plans also exert significant influence over the pricing of medical devices, for example, by imposing reimbursement caps, which could affect patients' access to our products as well as our profitability. If the competent government authorities issue any pricing guidance or exercise any control measures on the tendering process of any of our products, either at the national or provincial level, our profitability and results of operations may be adversely affected.

SIGNIFICANT ACCOUNTING POLICIES AND ESTIMATES

We have identified certain accounting policies that are significant to the preparation of our consolidated financial statements. Some of our accounting policies involve subjective assumptions and estimates, as well as complex judgments relating to accounting items. Estimates and judgments are continually re-evaluated and are based on historical experience and other factors, including industry practices and expectations of future events that we believe to be reasonable under the circumstances. We have not changed our assumptions or estimates in the past and have not noticed any material errors regarding our assumptions or estimates. Under current circumstances, we do not expect that our assumptions or estimates are likely to change significantly in the future. When reviewing our consolidated financial statements, you should consider (i) our critical accounting policies, (ii) the judgments and other uncertainties affecting the application of such policies, and (iii) the sensitivity of reported results to changes in conditions and assumptions.

We set forth below those accounting policies that we believe are of critical importance to us or involve the most significant estimates and judgments used in the preparation of our consolidated financial statements. Our significant accounting policies and estimates, which are important for an understanding of our financial condition and results of operations, are set forth in detail in notes 2 and 3 to the Accountants' Report set out in Appendix I to this document.

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Significant Accounting Policies

Revenue Recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which we will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between us and the customer at contract inception. When the contract contains a financing component which provides us with a significant financial benefit for more than one year, revenue recognized under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in HKFRS 15.

Sales of medical consumables

Revenue from the sale of medical consumables is recognized at the point in time when control of the asset is transferred to the customers, generally on delivery of the medical devices.

Revenue from other sources

Rental income is recognized on a time proportion basis over the lease terms.

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Fair Value Measurement

We measure unlisted financial instruments at fair value at the end of each of the reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be

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accessible by us. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

We use valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly

Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognized in the financial statements on a recurring basis, we determine whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the reporting period.

Property, Plant and Equipment and Depreciation

Property, plant and equipment, other than construction in progress are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalized in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, we recognize such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Office equipment	19%
Motor vehicles	24%
Plant and machinery	5% to 19%
Leasehold improvements	20% to 33%

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Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at the end of each of the reporting period.

An item of property, plant and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognized in the statement of profit or loss in the year the asset is derecognized is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents leasehold improvements under construction and equipment under installation, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction during the period of construction. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Research and Development Costs

All research costs are charged to the statement of profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Share-based Payments

We operate a employee incentive scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of our operations. Our employees (including directors) receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments ("**equity-settled transactions**").

The cost of equity-settled transactions with employees for share grants is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 27 to the Accountants' Report as set out in Appendix I to this document.

The cost of equity-settled transactions is recognized in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each of the relevant periods until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognized as of the beginning and end of that period.

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Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of our best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognized. Where grants include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled grant are modified, as a minimum an expense is recognized as if the terms had not been modified, if the original terms of the grant are met. In addition, an expense is recognized for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled grant is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the grant is recognized immediately. This includes any award where non-vesting conditions within the control of either of us or the employee are not met. However, if a new award is substituted for the cancelled grant, and is designated as a replacement award on the date that it is granted, the cancelled and new grants are treated as if they were a modification of the original grant, as described in the previous paragraph.

Significant Accounting Judgements and Estimates

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgement in applying our accounting policies.

Estimates and judgements are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

Research and Development Costs

All research costs are charged to profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred. Determining the amounts of development costs to be capitalized requires the use of judgements and estimation.

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Recognition of Income Tax and Deferred Tax Assets

Determining income tax provision involves judgment on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatments of such transactions are reconsidered periodically to take into account all changes in tax legislation. Deferred tax assets are recognized in respect of deductible temporary differences and unused tax losses.

As those deferred tax assets can only be recognized to the extent that it is probable that future taxable profits will be available against which the deductible temporary differences and the losses can be utilized, management's judgment is required to assess the probability of future taxable profits. Management's assessment is revised as necessary and additional deferred tax assets are recognized if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

Impairment of Non-financial Assets

We assess whether there are any indicators of impairment for all non-financial assets at the end of each of the relevant periods. Non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present values of those cash flows.

Share-based Payments

We have set up the share compensation plan for the Company's directors and our employees. Estimating fair value for share-based payment transactions requires defemination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires determination of the most appropriate inputs to the valuation model including the volatility, risk-free interest rate and exercise multiple and making assumptions about them. For the measure for the fair value of equity-settled transactions with employees at the grant date, we use a binomial model.

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DESCRIPTION OF SELECTED COMPONENTS OF STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the periods indicated:

	Year Ended December 31,		Eight Months Ended August 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Revenue	9,054	22,426	12,061	16,431
Cost of Sales	(4,414)	(6,881)	(4,146)	(5,225)
Gross profits	4,640	15,545	7,915	11,206
Other income and gains	5,283	4,405	2,598	6,230
Research and development expenses	(42,307)	(89,827)	(71,647)	(35,751)
Administrative expenses	(124,049)	(50,753)	(28,343)	(40,547)
Selling and distribution expenses	(2,849)	(4,806)	(2,693)	(2,141)
Other expenses	(8)	(686)	(73)	(70)
Finance costs	(43)	(375)	(193)	(349)
Loss before tax	(159,333)	(126,497)	(92,436)	(61,422)
Income tax expenses	-	-	-	-
Loss for the year/period	(159,333)	(126,497)	(92,436)	(61,422)
Attributable to:				
Owners of the parent	(137,085)	(101,873)	(68,930)	(57,944)
Non-controlling interests	(22,248)	(24,624)	(23,506)	(3,478)
	(159,333)	(126,497)	(92,436)	(61,422)

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Revenue

During the Track Record Period, all of our revenue was generated from the sales of our medical consumables, which were broadly classified into the following product categories: the Pulmonary Nodule Localization Needle, the Laparoscopic Single Port Multi-Channel Access Platform, and other medical consumables. The following table sets forth a breakdown of our revenue by product categories for the periods indicated:

	Year Ended December 31,				Eight Months Ended August 31,			
	2020		2021		2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
	<i>(unaudited)</i>							
Pulmonary Nodule Localization Needle	5,294	58.5	17,077	76.1	8,347	69.2	13,142	80.0
Laparoscopic Single Port Multi-Channel Access Platform	3,237	35.8	4,637	20.7	3,203	26.6	2,864	17.4
Others ⁽¹⁾	523	5.7	712	3.2	511	4.2	425	2.6
Total	9,054	100.0	22,426	100.0	12,061	100.0	16,431	100.0

Note:

- (1) Include the Wound Retractor, the Ureteral Dilatation Balloon Catheter, the Laparoscopic Biopsy Bag and the Laparoscopic Surgical Instrument.

The following table sets forth the sales volume and average selling price of the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform for the periods indicated:

	Year Ended December 31,				Eight Months Ended August 31,			
	2020		2021		2021		2022	
	Sales Volume	Average Selling Price ⁽¹⁾	Sales Volume	Average Selling Price ⁽¹⁾	Sales Volume	Average Selling Price ⁽¹⁾	Sales Volume	Average Selling Price ⁽¹⁾
	<i>(unit)</i>	<i>(RMB)</i>	<i>(unit)</i>	<i>(RMB)</i>	<i>(unit)</i>	<i>(RMB)</i>	<i>(unit)</i>	<i>(RMB)</i>
	<i>(unaudited)</i>							
Pulmonary Nodule Localization Needle	19,923	265.7	61,236	278.9	29,192	285.9	44,238	297.1
Laparoscopic Single Port Multi-Channel Access Platform	5,743	563.6	8,214	564.5	5,628	569.1	5,199	550.9

Note:

- (1) Average selling price equals revenue generated from the sales of the relevant product during a year divided by the sales volume of such product during the same year.

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During the Track Record Period, around 99.7% of our total revenue in 2020, 2021 and the eight months ended August 31, 2022 was generated in Mainland China, with around 0.3% generated from overseas countries/areas.

Cost of Sales

During the Track Record Period, the cost of sales was related to the sales of our medical consumables. The cost of sales primarily consisted of (i) costs of raw materials and consumables used; (ii) employee benefits expenses; (iii) depreciation expenses; and (iv) testing fees. The following table sets forth a breakdown of our cost of sales in absolute amounts and as percentages of the total cost of sales for the periods indicated:

	Year Ended December 31,				Eight Months Ended August 31,			
	2020		2021		2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
	<i>(unaudited)</i>							
Costs of raw materials and consumables used	2,331	52.8	4,358	63.3	2,404	58.0	3,385	64.8
Employee benefits expenses	1,048	23.7	1,432	20.8	1,132	27.3	1,295	24.8
Depreciation expenses	181	4.1	174	2.5	148	3.6	92	1.8
Testing fees	177	4.0	190	2.8	78	1.9	59	1.1
Others	677	15.4	727	10.6	384	9.2	394	7.5
Total	4,414	100.0	6,881	100.0	4,146	100.0	5,225	100.0

Costs of raw materials and consumables used primarily consisted of costs of raw materials and consumables including metals and plastics used to manufacture our commercialized products. Employee benefits expenses under cost of sales primarily included the salaries and welfare, for employees involved in the manufacturing of our commercialized products. Depreciation expenses was mainly related to depreciation of manufacturing plants and equipment. Testing fees mainly consisted of expenses incurred for certain testing of our commercialized products. Others mainly consisted of costs related to training provided to our production workers, as well as repair and maintenance costs for our manufacturing plants and equipment.

Gross Profit and Gross Profit Margin

During the Track Record Period, our gross profit represents our revenue less our cost of sales. Our gross profit margin represents our gross profit as a percentage of our revenue. Our gross profit amounted to RMB4.6 million, RMB15.5 million and RMB11.2 million in 2020, 2021 and the eight months ended August 31, 2022, respectively, while our gross profit margin reached 51.2%, 69.3% and 68.2% during the same period.

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The following table sets forth a breakdown of our gross profit and gross profit margin of the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform for the periods indicated:

	Year Ended December 31,				Eight Months Ended August 31,			
	2020		2021		2021		2022	
	Gross profit	Gross profit margin	Gross profit	Gross profit margin	Gross profit	Gross profit margin	Gross profit	Gross profit margin
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Pulmonary Nodule Localization								
Needle	3,666	69.3	13,625	79.8	6,732	80.7	10,344	78.7
Laparoscopic Single Port								
Multi-Channel Access Platform	1,325	40.9	2,302	49.6	1,448	45.2	1,059	37.0

(unaudited)

Our total gross profit and gross profit margin is primarily affected by the respective gross profit and gross profit margin of the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform. We made huge amount of investment in manufacturing equipment and other related fixed assets initially. As we continued to increase our productivity of the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform and optimize our manufacturing efficiency, the revenue of such products increased while the unit costs of production decreased, thus the respective gross profit and gross profit margin of such two main products gradually increased.

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Other Income and Gains

During the Track Record Period, our other income primarily consisted of (i) investment income from the redemption of our purchased wealth management products; (ii) government grants, mainly representing various types of incentives and subsidies received from the local governments, such as subsidies for research and development activities and funds for talents; and (iii) bank interest income. Our other gains primarily consisted of gains on financial assets at fair value through profit or loss, mainly including price fluctuations of our purchased wealth management products. The following table sets forth a breakdown of our other income and gains for the periods indicated:

	Year Ended December 31,				Eight Months Ended August 31,			
	2020		2021		2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
	<i>(unaudited)</i>							
Other income								
Investment income	1,252	23.7	2,704	61.4	1,383	53.2	445	7.1
Government grants	3,649	69.1	1,295	29.4	633	24.4	3,515	56.4
Bank interest income	36	0.7	280	6.4	125	4.8	359	5.8
Others	41	0.7	126	2.9	9	0.3	21	0.3
	<u>4,978</u>	<u>94.2</u>	<u>4,405</u>	<u>100.0</u>	<u>2,150</u>	<u>82.8</u>	<u>4,340</u>	<u>69.7</u>
Other Gains								
Fair value gains, net:								
Financial assets at fair value through								
profit or loss	305	5.8	-	-	397	15.3	13	0.2
Foreign exchange differences, net	-	-	-	-	51	2.0	1,877	30.1
	<u>305</u>	<u>5.8</u>	<u>-</u>	<u>-</u>	<u>448</u>	<u>17.3</u>	<u>1,890</u>	<u>30.3</u>
Total	<u>5,283</u>	<u>100.0</u>	<u>4,405</u>	<u>100.0</u>	<u>2,598</u>	<u>100.0</u>	<u>6,230</u>	<u>100.0</u>

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Research and Development Expenses

During the Track Record Period, our research and development expenses primarily consisted of (i) staff costs for our research and development personnel; (ii) cost of materials and consumables used; (iii) share-based payments; (iv) clinical trial fees, including payment to hospitals, CROs, SMOs, and other service providers in connection with our research and development activities; and (v) expenditures in proprietary technologies. The following table sets forth a breakdown of our research and development expenses for the periods indicated:

	Year Ended December 31,				Eight Months Ended August 31,			
	2020		2021		2021		2022	
	RMB'000	%	RMB'000	%	RMB'000	%	RMB'000	%
	<i>(unaudited)</i>							
Expenditures in proprietary technologies	-	-	50,973	56.7	50,973	71.1	-	-
Staff cost	12,740	30.1	18,295	20.4	9,242	12.9	18,478	51.7
Cost of materials and consumables used	9,261	21.9	7,118	7.9	3,967	5.5	8,561	23.9
Share-based payments	4,539	10.7	4,933	5.5	3,492	4.9	2,985	8.3
Clinical trial fees	10,799	25.5	4,963	5.5	1,959	2.7	2,327	6.5
Depreciation and amortization	527	1.2	393	0.4	252	0.4	397	1.1
Others ⁽¹⁾	4,441	10.5	3,152	3.6	1,762	2.5	3,003	8.4
Total	42,307	100.0	89,827	100.0	71,647	100.0	35,751	100.0

Note:

- (1) Primarily include intellectual property and CE certification expenses, business travel and transportation expenses incurred by our research and development staff, animal experiment expenses and product design expenses.

Mr. DIAO Yuepeng developed certain proprietary technologies by himself, outside of his normal working hours and without utilizing any resources of the Company. After evaluating the potential value of the relevant technologies and the synergies they would bring to the Company if combined with the Company’s existing technologies, the Company determined to acquire such technologies from Mr. DIAO for the purpose to use such proprietary technologies in the future research and development of its product candidates. After amiable discussions between the parties, Mr. DIAO transferred the relevant self-developed proprietary technologies to the Group. Such transfers of technologies were completed in the form of capital contributions to two subsidiaries of the Company. Specifically, in April 2021, Mr. DIAO subscribed for RMB11.8 million of the registered capital of Beijifeng Biotechnology (Shanghai) Co., Ltd. (“**Beijifeng**”), by transferring the “cryoablation-related technology using nitrous oxide or carbon dioxide as cryogenic source (利用笑氣或二氧化碳作為能量源的冷凍技術)” he developed to Beijifeng; in addition, in April 2021, Mr. DIAO subscribed for RMB39.2 million of the registered capital of Huifeng Biotechnology (Shanghai) Co., Ltd. (“**Huifeng**”), by transferring the “pulsed field ablation technology for the treatment of atrial fibrillation (應用於房顫的脈衝電場消融 (PFA) 技術)” he developed to Huifeng. Mr. DIAO also agreed that all the relevant intellectual property rights (including any patents to be registered in the future in relation to such proprietary technologies) would be solely owned by the Group (with Mr. DIAO serving as the first inventor). After the transfer, the Group owns the proprietary technologies exclusively, which are not subject to any third party claims. The aggregate

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consideration of RMB51.0 million in acquiring the proprietary technologies from Mr. DIAO, i.e. the expenditures in proprietary technologies, were classified as research and development expenses. For more details, see “History, Development and Corporate Structure—Our Subsidiaries” and Note 28(a) to the Accountants’ Report in Appendix I to this document.

Pursuant to HKAS 38.21, an intangible asset shall be recognized if, and only if (a) it is probable that the expected future economic benefits that are attributable to the asset will flow to the entity and; and (b) the cost of the asset can be measured reliably. The Group acquired such proprietary technologies from Mr. DIAO for the purpose to use such proprietary technologies in the future research and development of its product candidates. In addition, the Group will incur additional R&D expenses to conduct clinical trials and obtain related registrations before the commercialization of the product candidates. Therefore, the proprietary technologies could not meet the criteria of HKAS 38.21(a), and thus were recognized as R&D expenses when transferred from Mr. DIAO.

The research and development expenditures incurred for our Core Products, were RMB8.4 million, RMB5.2 million and RMB3.8 million in 2020, 2021 and the eight months ended August 31, 2022, respectively.

Administrative Expenses

During the Track Record Period, our administrative expenses primarily consisted of (i) staff costs for our administrative personnel; (ii) share-based payments primarily for our administrative personnel; (iii) professional service fees, which were primarily for related training and advises in relation to corporate administration and the [REDACTED]; and (iv) depreciation and amortization. The following table sets forth a breakdown of our administrative expenses for the periods indicated:

	Year Ended December 31,				Eight Months Ended August 31,			
	2020		2021		2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
	<i>(unaudited)</i>							
Staff costs	10,384	8.4	18,117	35.7	9,900	34.9	15,879	39.2
Professional service fees	2,740	2.2	14,229	28.0	4,271	15.1	7,704	19.0
Share-based payments	107,412	86.6	11,407	22.5	9,327	32.9	10,099	24.9
Depreciation and amortization	1,784	1.4	2,555	5.0	1,707	6.0	3,484	8.6
Others ⁽¹⁾	1,729	1.4	4,445	8.8	3,138	11.1	3,381	8.3
Total	124,049	100.0	50,753	100.0	28,343	100.0	40,547	100.0

Note:

(1) Primarily include business travel expenses, hospitality expenses, office expenses, rent and utilities expenses.

During the Track Record Period, the share-based payments in administrative expenses mainly included options granted to our employees and directors. However, in 2020, there were several transfers of shares and an equity subscription in relatively low prices compared to the fair value of such equity as determined by the appraiser, and the shortfall between the consideration of such equity and the fair value of such equity was recorded as share-based payments as well.

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To be specific, on September 8, 2020, Ningbo Mukang transferred registered capital of RMB990,716 in Ningbo SensCure to Ningbo Linfeng at a consideration of RMB990,716, which was lower than the fair value of such equity as determined by the appraiser, and thus the shortfall was recorded in share-based payments of RMB27.7 million.

On November 23, 2020, Ningbo Kangrui transferred registered capital in Ningbo SensCure of: (i) RMB549,750 to Ningbo Linfeng at a consideration of RMB1,023,503; and (ii) RMB150,000 to Mr. ZHU Jun at a consideration of RMB279,255. On the same day, Ningbo Mukang transferred registered capital in Ningbo SensCure of RMB150,000 to Mr. ZHU Jun at a consideration of RMB279,255. Such transfers of registered capital in Ningbo SensCure were made in prices lower than the fair value of such equity as determined by the appraiser, thus the shortfall was recorded as share-based payments of RMB23.0 million in aggregate. For more information, please refer to the paragraphs headed “History, Development and Corporate Structure—Reorganization—Incorporation of Ningbo SensCure and Early Shareholding Changes—Equity Transfers in 2020” in this document.

On December 25, 2020, Ningbo Hongyingkang, one of our ESOP Platforms, subscribed for the increased registered capital in the Company of RMB3,242,681 at a consideration of RMB16,213,405. Such subscription was made in a price lower than the fair value of such equity as determined by the appraiser, thus was recorded as equity-based payments of RMB52.6 million. For more information, please refer to the paragraphs headed “History, Development and Corporate Structure—Corporate Development—Capital Increase pursuant to the Equity Swap and Subscription by Ningbo Hongyingkang” in this document.

In particular, the emoluments paid by the Company to our Directors and Supervisors in 2020 and 2021 were included in staff costs and share-based payments under administrative expenses. The increase in the aggregate amount of emoluments paid to Directors and Supervisors from RMB852,000 (including RMB15,000 equity-settled share award expense) in 2020 to RMB8,333,000 (including RMB5,219,000 equity-settled share award expense) in 2021 was primarily because the Company granted equity-settled share award expense of approximately RMB5.2 million to some of our key personnel, and paid higher salaries, bonuses, allowances and benefits to new management member who joined the senior management team in October 2020. For more details of emoluments of Directors and Supervisors, please see “Directors, Supervisors and Senior Management—Emolument of Directors, Supervisors and Senior Management” in this document and Note 8 to the Accountants’ Report in Appendix I to this document.

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Selling and Distribution Expenses

During the Track Record Period, our selling and distribution expenses mainly consisted of (i) staff costs, primarily including salaries, bonus and welfare for sales and marketing personnel; (ii) share-based payments primarily for our selling and distribution personnel; (iii) market development expenses, primarily including expenses in connection with our sales and marketing activities; and (iv) business travel expenses. The following table sets forth a breakdown of our selling and distribution expenses for the periods indicated:

	Year Ended December 31,				Eight Months Ended August 31,			
	2020		2021		2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
					<i>(unaudited)</i>			
Staff costs	1,864	65.4	2,380	49.5	1,082	40.2	1,353	63.2
Share-based payments	314	11.0	1,481	30.8	1,063	39.5	461	21.5
Market development expenses	223	7.8	309	6.4	205	7.6	93	4.3
Business travel expenses	268	9.4	263	5.5	174	6.5	145	6.8
Others ⁽¹⁾	180	6.3	373	7.8	169	6.2	89	4.2
Total	2,849	100.0	4,806	100.0	2,693	100.0	2,141	100.0

Note:

(1) Primarily include office expenses, conference expenses, hospitality expenses, and depreciation and amortization.

Other Expenses

During the Track Record Period, our other expenses mainly consisted of foreign exchange losses. Foreign exchange losses mainly represented the losses from the change in exchange rate between USD and RMB due to our cash balance in USD. Our other expenses amounted to RMB8.0 thousand, RMB686.0 thousand and RMB70.0 thousand in 2020, 2021 and the eight months ended August 31, 2022, respectively.

Finance Costs

During the Track Record Period, our finance costs consisted of interest on lease liabilities. Our finance costs amounted to RMB43.0 thousand, RMB375.0 thousand and RMB349.0 thousand in 2020, 2021 and the eight months ended August 31, 2022, respectively.

Income Tax Expenses

Our principal applicable taxes and tax rates are set forth as follows:

Mainland China

Pursuant to the Corporate Income Tax Law of the PRC (the “CIT Law”), the Company and our PRC subsidiaries are subject to a standard corporate income tax rate of 25% on taxable income, except that Ningbo SensCure was qualified as a “High and New Technology Enterprise” to enjoy a preferential

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income tax rate of 15% during the Track Record Period. The related tax authorities review the “High and New Technology Enterprise” status every three years. Ningbo SensCure continues to qualify as a “High Technology Enterprise” for the next three years since 2021.

No provision for Mainland China income tax has been provided for pursuant to the CIT Law and the respective regulations, as our Group’s PRC entities have no estimated assessable profits.

United States

Among our subsidiaries, Cryofocus America, Inc. was incorporated in California, the U.S. and was subject to statutory U.S. federal corporate income tax at a rate of 21% during the Track Record Period. It is also subject to the state income tax in California during the Track Record Period. No provision for federal corporate income tax and the state income tax has been provided as the subsidiary has no estimated assessable profits.

We did not record any income tax expense during the Track Record Period. Our Directors confirm that during the Track Record Period, we had made all the required tax filings and had paid all outstanding tax liabilities with the relevant tax authorities in the relevant jurisdictions and we are not aware of any outstanding or potential disputes with such tax authorities.

Loss for the Year/Period

As a result of the foregoing, in 2020, 2021 and the eight months ended August 31, 2022, our net losses amounted to RMB159.3 million, RMB126.5 million and RMB61.4 million, respectively.

PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

Eight Months Ended August 31, 2022 Compared to Eight Months Ended August 31, 2021

Revenue

Our revenue increased from RMB12.1 million for the eight months ended August 31, 2021 to RMB16.4 million for the eight months ended August 31, 2022, mainly driven by the increase in the sales of the Pulmonary Nodule Localization Needle.

Cost of Sales

Our cost of sales increased from RMB4.1 million for the eight months ended August 31, 2021 to RMB5.2 million for the eight months ended August 31, 2022, which was generally in line with the increase in the sales of our commercialized products in 2022.

Gross Profit and Gross Profit Margin

As a result of the foregoing, our overall gross profit increased from RMB7.9 million for the eight months ended August 31, 2021 to RMB11.2 million the eight months ended August 31, 2022. Our overall gross profit margin remained relatively stable at 65.6% for the eight months ended August 31, 2021 and 68.2% for the eight months ended August 31, 2022.

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Other Income and Gains

Our other income and gains significantly increased from RMB2.6 million for the eight months ended August 31, 2021 to RMB6.2 million for the eight months ended August 31, 2022, primarily due to (i) an increase in government grants received from local governments of RMB2.9 million; and (ii) an increase in net foreign exchange differences of RMB1.9 million resulted from the appreciation of the U.S. dollar against RMB, which is our functional and reporting currency, partially offset by a decrease in investment income of RMB0.9 million because we did not redeem any wealth management products for the eight months ended August 31, 2022.

Research and Development Expenses

Our research and development expenses significantly decreased from RMB71.6 million for the eight months ended August 31, 2021 to RMB35.8 million for the eight months ended August 31, 2022, mainly resulted from a decrease in expenditures in proprietary technologies of RMB51.0 million as such expenditures in proprietary technologies of RMB51.0 million were one-off expenses in 2021, partially offset by an increase in staff cost of RMB9.2 million resulted from the increased number of R&D personnel in line with our recruitment plan for 2022.

Administrative Expenses

Our administrative expenses increased from RMB28.3 million for the eight months ended August 31, 2021 to RMB40.5 million for the eight months ended August 31, 2022, primarily due to (i) an increase in staff costs of RMB6.0 million driven by the increased average salaries and the number of administrative personnel; and (ii) an increase in professional service fees of RMB[REDACTED] paid to the professional parties of the [REDACTED].

Selling and Distribution Expenses

Our selling and distribution expenses decreased from RMB2.7 million for the eight months ended August 31, 2021 to RMB2.1 million for the eight months ended August 31, 2022, primarily due to a decrease in share-based payments of RMB0.6 million mainly caused by the vesting of some options granted to our selling and distribution personnel.

Other Expenses

Our other expenses remained relatively stable at RMB73.0 thousand for the eight months ended August 31, 2021 and RMB71.0 thousand for the eight months ended August 31, 2022.

Finance Costs

Our finance costs increased from RMB0.2 million for the eight months ended August 31, 2021 to RMB0.3 million for the eight months ended August 31, 2022, which mainly resulted from the new long-term leases of offices for our subsidiaries.

Loss for the Period

As a result of the foregoing, our loss for the period decreased from RMB92.4 million for the eight months ended August 31, 2021 to RMB61.4 million for the eight months ended August 31, 2022.

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Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

Revenue

Our revenue significantly increased from RMB9.1 million for the year ended December 31, 2020 to RMB22.4 million for the year ended December 31, 2021, mainly driven by the increase in the sales volume of the Pulmonary Nodule Localization Needle from 19,923 units in 2020 to 61,236 units in 2021 and the increase in the average selling price of the Pulmonary Nodule Localization Needle from RMB265.7 per unit in 2020 to RMB278.9 per unit in 2021, as a result of the increased procurement by existing customers.

The respective unit price of the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform remained relatively stable for the years ended December 31, 2020 and 2021.

Cost of Sales

Our cost of sales increased from RMB4.4 million for the year ended December 31, 2020 to RMB6.9 million for the year ended December 31, 2021, which was generally in line with the increase in the sales of our commercialized products in 2021.

Gross Profit and Gross Profit Margin

As a result of the foregoing, our overall gross profit increased from RMB4.6 million for the year ended December 31, 2020 to RMB15.5 million for the year ended December 31, 2021, and our overall gross profit margin increased from 51.2% to 69.3% during the same periods primarily driven by the increase in revenue of the Pulmonary Nodule Localization Needle and the Laparoscopic Single Port Multi-Channel Access Platform. The increase in our overall gross profit margin was mainly resulted from (i) an increase in gross profit margin of the Pulmonary Nodule Localization Needle from 69.3% for the year ended December 31, 2020 to 79.8% for the year ended December 31, 2021; and (ii) an increase in gross profit margin of the Laparoscopic Single Port Multi-Channel Access Platform from 40.9% for the year ended December 31, 2020 to 49.6% for the year ended December 31, 2021, primarily because we made great amount of investment in equipment and other fixed assets during the initial stage of our commercialization of such products, as the sales volume of such products increased at later stage, the fixed costs per unit decreased. Thus, the gross profit margin increased accordingly.

Other Income and Gains

Our other income and gains decreased from RMB5.3 million for the year ended December 31, 2020 to RMB4.4 million for the year ended December 31, 2021, primarily due to the net effect of a decrease in government grants of RMB2.4 million because the Company received significant amount of one-off subsidies from local government for the Company’s equity financing activities in 2020, which did not occur in 2021, and an increase in investment income of RMB1.5 million resulted from the redemption of wealth management products.

Research and Development Expenses

Our research and development expenses significantly increased from RMB42.3 million for the year ended December 31, 2020 to RMB89.8 million for the year ended December 31, 2021, primarily because

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we purchased two proprietary technologies, namely, “cryoablation-related technology using nitrous oxide or carbon dioxide as cryogenic source (利用笑氣或二氧化碳作為能量源的冷凍技術)” and “pulsed field ablation technology for the treatment of atrial fibrillation (應用於房顫的脈衝電場消融 (PFA) 技術)” from Mr. DIAO in consideration of RMB51.0 million in aggregation for the purpose to use such proprietary technologies in the future research and development of our product candidates, which purchase amount was classified as research and development expenses. Such transfers of technologies were completed in the form of capital contributions to two subsidiaries of the Company. For more information, please refer to “—Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income—Research and Development Expenses” in this section.

Administrative Expenses

Our administrative expenses significantly decreased from RMB124.0 million for the year ended December 31, 2020 to RMB50.8 million for the year ended December 31, 2021, primarily due to a decrease in share-based payments of RMB96.0 million. The shareholders of Ningbo SensCure made several share transfers to one of the Controlling Shareholders of the Company and an executive director of the Company in 2020 in relative low prices as compared to the fair value as determined by the appraiser. The shortfall between the consideration and the fair value was recorded as share-based payments. For more information, please refer to the paragraphs headed “—Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income—Administrative Expenses” in this section. Such decrease was partially offset by an increase in staff costs of RMB7.7 million mainly as a result of the expansion of our management and administrative team in line with our business development, and an increase in professional service fees of RMB[REDACTED] associated with the [REDACTED].

Selling and Distribution Expenses

Our selling and distribution expenses increased from RMB2.8 million for the year ended December 31, 2020 to RMB4.8 million for the year ended December 31, 2021, primarily due to an increase in the share-based payments of RMB1.2 million made to our selling and distribution personnel.

Other Expenses

Our other expenses increased from RMB8.0 thousand for the year ended December 31, 2020 to RMB686.0 thousand for the year ended December 31, 2021, primarily due to the fluctuations in exchange rate between RMB, our functional currency, and U.S. dollar.

Finance Costs

Our finance costs increased from RMB43.0 thousand for the year ended December 31, 2020 to RMB375.0 thousand for the year ended December 31, 2021, mainly resulted from the new long-term leases of offices for our subsidiaries.

Loss for the Year

As a result of the foregoing, our loss for the year decreased from RMB159.3 million for the year ended December 31, 2020 to RMB126.5 million for the same period in 2021.

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DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The table below sets forth selected information from our consolidated statements of financial position as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31, 2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Total non-current assets	23,378	42,306	41,229
Total current assets	50,980	189,387	138,046
Total assets	74,358	231,693	179,275
Total non-current liabilities	588	6,406	6,701
Total current liabilities	23,488	28,289	23,308
Net current assets	27,492	161,098	114,738
Total liabilities	24,076	34,695	30,009
Net assets	50,282	196,998	149,266
Share capital/Paid-in capital	50,802	228,000	228,000
Reserves	(520)	(57,351)	(101,605)
Non-controlling interests	–	26,349	22,871
Total equity	50,282	196,998	149,266

We recorded net assets of RMB197.0 million as of December 31, 2021, compared to net assets of RMB50.3 million as of December 31, 2020, mainly attributable to the net effect of: (i) the loss for the year of RMB126.5 million; (ii) capital contribution by our shareholders of RMB204.4 million; (iii) capital contribution from Mr. DIAO Yuepeng, a shareholder of two of our subsidiaries, of RMB51.0 million; and (iv) equity-settled share award expense of RMB17.8 million.

Our net assets decreased from RMB197.0 million as of December 31, 2021 to RMB149.3 million as of August 31, 2022, mainly attributable to the net effect of: (i) the loss for the period of RMB61.4 million; and (ii) equity-settled share award expense of RMB13.5 million.

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Current Assets and Liabilities

The table below sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,		As of	As of
	2020	2021	August 31,	October 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(unaudited)</i>
Current assets				
Inventories	8,103	11,696	15,757	18,221
Prepayments, other receivables and other assets	9,870	19,824	30,580	35,646
Financial assets at fair value through profit or loss	25,521	–	4,013	–
Cash and cash equivalents	7,486	157,867	87,696	73,991
Total current assets	50,980	189,387	138,046	127,858
Current liabilities				
Trade payables	185	314	1,758	2,117
Other payables and accruals	16,544	23,699	16,650	23,926
Lease liabilities	450	2,595	3,127	3,809
Contract liabilities	6,309	1,681	1,773	1,641
Total current liabilities	23,488	28,289	23,308	31,493
Net current assets	27,492	161,098	114,738	96,365

We recorded net current assets of RMB161.1 million as of December 31, 2021, compared to net current assets of RMB27.5 million as of December 31, 2020, mainly attributable to capital contribution by our shareholders of RMB204.4 million. Our net current assets decreased to RMB114.7 million as of August 31, 2022, mainly due to loss for the period of RMB61.4 million.

FINANCIAL INFORMATION

Property, Plant and Equipment

During the Track Record Period, our property, plant and equipment primarily consisted of (i) plant and machinery; (ii) construction in progress; (iii) leasehold improvements; (iv) office equipment; and (v) motor vehicles. The following table sets forth a breakdown of our property, plant and equipment as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>2022</i>
			<i>RMB'000</i>
Plant and machinery	18,381	17,787	18,329
Leasehold improvements	585	5,223	4,298
Construction in progress	–	3,265	3,119
Office equipment	428	2,220	2,580
Motor vehicles	414	621	494
Total	19,808	29,116	28,820

Our property, plant and equipment increased from RMB19.8 million as of December 31, 2020 to RMB29.1 million as of December 31, 2021, which was mainly attributable to (i) an increase in leasehold improvements of RMB4.6 million mainly due to the renovation of our laboratories and factories in 2021; (ii) an increase in construction in progress of RMB3.3 million due to the renovations of our owned properties in Shanghai and leased property in Ningbo; and (iii) an increase in office equipment of RMB1.8 million due to the procurement of new office equipment. Our property, plant and equipment remained relatively stable at RMB28.8 million as of August 31, 2022.

Right-of-use Assets

Our right-of-use assets are primarily related to our leased properties used in our operations during the Track Record Period. Our right-of-use assets significantly increased from RMB0.3 million as of December 31, 2020 to RMB9.0 million as of December 31, 2021 mainly due to the extension of current leases of dormitories in Shanghai for the amount of RMB0.3 million and manufacturing facilities in Ningbo for the amount of RMB1.9 million, and new leases of offices in Shanghai for the amount of RMB6.7 million. Our right-of-use assets decreased to RMB6.9 million as of August 31, 2022, primarily due to the depreciation and amortization of the existing right-of-use assets.

Other Intangible Assets

Our other intangible assets mainly consisted of software. Our other intangible assets remained nil as of December 31, 2020, and increased to RMB59.0 thousand as of December 31, 2021, primarily due to the purchase of software. Our other intangible assets remained relatively stable at RMB47.0 thousand as of August 31, 2022.

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Other Non-Current Assets

During the Track Record Period, our other non-current assets consisted of prepayments for insurance and value-added tax recoverable. Value-added tax recoverable mainly represented our value-added tax (VAT) input tax credit that can be refunded by the competent authority. Our VAT input tax credit is resulted from the difference between our VAT input tax (arising from our purchase of services, raw materials and other consumables) and our VAT output tax (arising from revenue). The following table sets forth a breakdown of our other non-current assets as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments for long-term assets	–	–	120
Prepayments for insurance	244	102	131
Value-added tax recoverable	3,062	4,052	5,181
Total	3,306	4,154	5,432

Our other non-current assets increased from RMB3.3 million as of December 31, 2020 to RMB4.2 million as of December 31, 2021, primarily due to an increase in value-added tax recoverable of RMB1.0 million mainly resulted from increased procurement of research and development consumables, manufacturing equipment and office equipment, as well as our office renovations. Our other non-current assets further increased to RMB5.4 million as of August 31, 2022, primarily due to an increase in value-added tax recoverable of RMB1.1 million which mainly resulted from the increased procurement of research and development consumables and devices and office equipment.

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Inventories

During the Track Record Period, our inventories consisted of (i) raw materials; (ii) work in progress; (iii) finished goods; and (iv) goods shipped in transit. The following table sets forth a breakdown of our inventories as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31, 2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	6,365	10,298	13,101
Work in progress	304	749	1,691
Finished goods	1,452	745	965
Goods shipped in transit	101	51	17
Subtotal	8,222	11,843	15,774
Less: Provision for inventories	119	147	17
Total	8,103	11,696	15,757

Our inventories increased from RMB8.1 million as of December 31, 2020 to RMB11.7 million as of December 31, 2021, which was primarily the net effect of an increase in raw materials of RMB3.9 million mainly for the preparation of massive manufacturing of our cryoablation systems after commercialization, and a decrease in finished goods of RMB0.7 million mainly resulted from an increase in our sales of our commercialized products. Our inventories further increased to RMB15.8 million as of August 31, 2022. In addition, in anticipation of the impact of the COVID-19 pandemic, we strategically procured more raw materials for our research and development and manufacturing activities to control the potential shortage of raw materials. Our Directors confirm that our inventory control system and policies have been effective and we did not experience any material shortage in supply or overstock of inventory during the Track Record Period and up to the Latest Practicable Date. For more details, please refer to the paragraphs headed “Business—Inventory Management” in this document.

As of the Latest Practicable Date, RMB5.9 million, representing 37.3% of the RMB15.8 million inventories as of August 31, 2022, was subsequently utilized. In relation to the unutilized inventories as of the Latest Practicable Date, in the opinion of our Directors, there was no material recoverability issues with such outstanding inventories and the inventory provision was made sufficient, considering that (i) the low subsequent utilization of raw materials was mostly because we strategically increased the reserve of raw materials in response to the recurrence of the COVID-19 pandemic; and (ii) the subsequent sales of finished goods are much faster since 2021.

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The table below sets forth our inventory, raw material and finished goods turnover days for the periods indicated:

	Year Ended December 31,		Eight Months
			Ended
	2020	2021	August 31, 2022
Inventory turnover days ⁽¹⁾	200	262	240
Raw material turnover days ⁽²⁾	148	217	202
Finished goods turnover days ⁽³⁾	118	58	39

Notes:

- (1) Inventory turnover days for a year/period is the arithmetic mean of the beginning and ending balances of inventories for the relevant year/period divided by the sum of cost of sales and material costs for R&D for the relevant year/period multiplied by 365 for 2020 and 2021 and 240 for the eight months ended August 31, 2022.
- (2) Average raw materials turnover days for a year/period is the arithmetic mean of the beginning and ending balances of raw materials for the relevant year/period divided by the sum of cost of sales and material costs for R&D for the relevant year/period and multiplied by 365 for 2020 and 2021 and 240 for the eight months ended August 31, 2022.
- (3) Average finished goods turnover days for a year/period is the arithmetic mean of the beginning and ending balances of finished goods for the relevant year/period divided by the sum of cost of sales for the relevant year/period and multiplied by 365 for 2020 and 2021 and 240 for the eight months ended August 31, 2022.

Our overall inventory turnover days were 200 days, 262 days and 240 days in 2020 and 2021 and the eight months ended August 31, 2022, respectively. Our raw materials turnover days were 148 days, 217 days and 202 days in 2020 and 2021 and the eight months ended August 31, 2022, respectively. Our finished goods turnover days were 118 days, 58 days and 39 days in 2020 and 2021 and the eight months ended August 31, 2022, respectively. The relatively longer total inventory turnover days and raw material turnover days were mainly because (i) a substantial portion of our inventory and raw materials were in relation to our pipeline product candidates which were not yet commercialized, and (ii) we strategically increased the reserve of raw materials in response to the recurrence of the COVID-19 pandemic, to minimize the risks that we might run short of raw materials. During the Track Record Period, our finished goods turnover days gradually reduced, as the sales of our commercialized products increased.

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Prepayments, Other Receivables and Other Assets

During the Track Record Period, our prepayments, other receivables and other assets primarily consisted of (i) amounts due from related parties; (ii) prepayment to suppliers; (iii) employee reserve fund; (iv) [REDACTED]; and (v) deposits. The following table sets forth a breakdown of our prepayments and other receivables as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31, 2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Prepayment to suppliers [REDACTED]	8,907 [REDACTED]	9,207 [REDACTED]	15,935 [REDACTED]
Deposits	223	1,429	1,986
Employee reserve fund	286	769	1,283
Amounts due from related parties	380	250	341
Others	102	1,447	1,566
Subtotal	9,898	19,970	30,795
Impairment loss for other receivables	(28)	(146)	(215)
Total	9,870	19,824	30,580

Our prepayments, other receivables and other assets increased from RMB9.9 million as of December 31, 2020 to RMB19.8 million as of December 31, 2021, primarily due to (i) an increase in [REDACTED] of RMB[REDACTED] resulted from the engagement with professional parties for our [REDACTED], including RMB[REDACTED] paid to legal counsels and accountants, and RMB[REDACTED] paid to other professional parties; (ii) an increase in others of RMB1.3 million mainly resulted from increased prepayments for research and development activities for Cryo-RDN System; and (iii) an increase in prepayment to suppliers of RMB0.3 million mainly resulted from procurement of raw materials. Our prepayments, other receivables and other assets increased to RMB30.6 million as of August 31, 2022, primarily due to (i) an increase in prepayment to suppliers of RMB6.7 million mainly resulted from procurement of raw materials, molds and equipment; and (ii) an increase in capitalized [REDACTED] of RMB[REDACTED] associated with the [REDACTED].

For more details about amounts due from related parties, please refer to the paragraphs headed “—Related Party Transactions” in this section.

FINANCIAL INFORMATION

Financial Assets at Fair Value Through Profit or Loss

During the Track Record Period, our financial assets at fair value through profit or loss represented wealth management products issued by banks in Mainland China. Such wealth management products comprised short-term and low-risk wealth management products with a term less than a year or wealth management products that were redeemable at anytime, issued by Bank of Ningbo, Industrial and Commercial Bank of China, Agricultural Bank of China, China Merchants Bank and Shanghai Pudong Development Bank. The expected but not guaranteed rates of return range from 1.5% to 4.1% per year. In accordance with our risk management and investment strategy, we managed and evaluated the performance of these investments on a fair value basis and therefore these investments are designated as financial assets at fair value through profit or loss as of December 31, 2020 and 2021 and August 31, 2022. Our financial assets at fair value through profit or loss decreased from RMB25.5 million as of December 31, 2020 to nil as of December 31, 2021, due to the redemption of all wealth management products in 2021. Our financial assets at fair value through profit or loss increased to RMB4.0 million as of August 31, 2022 as we purchased wealth management products from Bank of Ningbo in 2022.

We purchase wealth management products as a supplemental means to improve utilization of our cash on hand on a short-term basis. We believe that making such investments is in the best interest of the Company, and we can make better use of our cash by utilizing low-risk wealth management products, to enhance our income without interfering with our business operations or capital expenditures. We have established a set of risk management and capital preservation investment policy, and have implemented a series of internal control measures regarding our investment in wealth management products. These policies and measures include:

- prior to making an investment, we ensure that there remains sufficient working capital for our business needs, operating activities, research and development and capital expenditures even after purchasing such wealth management products;
- our investment decisions are made on a case-by-case basis and after due and careful consideration of a number of factors, such as the duration of the investment and the expected returns;
- we only purchase low-risk wealth management products issued by qualified financial institutions, and in any given period, we make investments in products provided by multiple issuers to mitigate concentration risks;
- our finance department, subject to the review and approval of our management, is responsible for the overall execution of our investments, including risk assessment; and
- after making an investment, we closely monitor its performance and fair value on a regular basis to ensure that the purpose of such investment is to preserve capital and liquidity until free cash is used in our primary business and operation.

Our investment in wealth management products after the [REDACTED] will be subject to the compliance with Chapter 14 of the Listing Rules.

FINANCIAL INFORMATION

Cash and Cash Equivalents

During the Track Record Period, our cash and cash equivalents were denominated in Renminbi and USD. The following table sets forth a breakdown of our cash and cash equivalents as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Cash and bank balances	7,486	157,867	87,696
Denominated in:			
RMB	7,163	125,270	71,627
USD	323	32,597	16,069
Cash and cash equivalents	7,486	157,867	87,696

Our cash and cash equivalents significantly increased from RMB7.5 million as of December 31, 2020 to RMB157.9 million as of December 31, 2021, primarily due to the receipt of proceeds from our series B financing. Our cash and cash equivalents decreased to RMB87.7 million as of August 31, 2022, primarily due to our cash expenditures incurred for our operating activities.

Trade Payables

During the Track Record Period, our trade payables consisted of trade payables to our suppliers. Our trade payables are non-interest-bearing and are normally settled within one month. Our trade payables remained relatively stable at RMB0.2 million as of December 31, 2020 and RMB0.3 million as of December 31, 2021. Our trade payables increased significantly from RMB0.3 million as of December 31, 2021 to RMB1.8 million as of August 31, 2022, primarily due to our increased procurement of raw materials.

The following table sets forth an aging analysis of our trade payables as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Within one year	185	314	1,758

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The table below sets forth our trade payables turnover days for the periods indicated:

	Year Ended December 31,		Eight Months Ended
	2020	2021	August 31, 2022
	2020	2021	2022
Trade payables turnover days ⁽¹⁾	4	7	17

Note:

- (1) Trade payables turnover days for a year/period is the arithmetic mean of the beginning and ending balances of trade payables for the relevant year/period divided by the sum of cost of sales and the total material costs for R&D for the relevant year/period multiplied by 365 for 2020 and 2021 and 240 for the eight months ended August 31, 2022.

As of the Latest Practicable Date, approximately RMB0.3 million, representing 16.7% of the RMB1.8 million trade payables as of August 31, 2022, was subsequently settled.

Other Payables and Accruals

During the Track Record Period, our other payables and accruals primarily consisted of (i) accrued expenses; (ii) payroll and welfare payable; (iii) other taxes and surcharges payable; (iv) government grants payable; and (v) amounts due to related parties. Our other payables and accruals increased from RMB16.5 million as of December 31, 2020 to RMB23.7 million as of December 31, 2021, primarily due to (i) an increase in accrued expenses of RMB3.0 million due to the withholding of [REDACTED]; and (ii) an increase in payroll and welfare payable of RMB3.9 million due to the increased number of employees and increased annual bonuses paid to the employees. Our other payables and accruals decreased to RMB16.7 million as of August 31, 2022 primarily due to (i) a decrease in accrued expenses of RMB5.6 million mainly because we accrued much less [REDACTED] for the eight months in 2022 as compared to 2021; and (ii) a decrease in payroll and welfare payable of RMB1.6 million resulted from settlement of large amount of annual bonus payables in 2022.

	As of December 31,		As of
	2020	2021	August 31, 2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Payroll and welfare payable	7,098	10,961	9,364
Accrued expenses	7,092	10,104	4,492
Other taxes and surcharges payable	1,256	1,408	1,317
Government grants payable	960	960	960
Amounts due to related parties	81	63	135
Other payables	57	203	382
Total	16,544	23,699	16,650

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Other payables and accruals are unsecured, non-interest-bearing and repayable on demand. The carrying amounts of financial liabilities included in other payables and accruals as of the end of each of the Track Record Period approximated to their fair values due to their short-term maturities.

For more details about amounts due to related parties, please refer to the paragraphs headed “—Related Party Transactions” in this section.

Contract Liabilities

During the Track Record Period, contract liabilities represented the obligations to deliver medical consumables sold to the customers, for which products the Group had received consideration. The contract liabilities decreased from RMB6.3 million in 2020 to RMB1.7 million in 2021, due to the duly delivery of medical consumables to the customers. Our contract liabilities increased to RMB1.8 million as of August 31, 2022, mainly due to increased sales of our commercialized products in 2022.

As of the Latest Practicable Date, approximately RMB1.1 million, representing 61.1% of the RMB1.8 million contract liabilities as of August 31, 2022, was subsequently recognized as revenue.

Deferred Income

During the Track Record Period, deferred income were government grants we received from the local government as subsidies for compensating our future research and development activities for certain product development projects. Such subsidies were recognized as deferred income upon receipt. As we gradually spend such subsidies for the advancement of the targeted projects, the spent portion will be amortized and recognized as other income. When the project is completed and acceptance requirements are met, the residuals (if any) will be recognized as other income as well. Our deferred income decreased from RMB0.5 million as of December 31, 2020 to nil as of December 31, 2021, primarily because the targeted projects were completed and the subsidies were fully utilized for the projects in 2021. Our deferred income increased to RMB2.0 million as of August 31, 2022 as we received government grants from local government for new research and development projects in 2022.

LIQUIDITY AND CAPITAL RESOURCES

Working Capital

Our primary uses of cash relate to the research and development of our product candidates and capital expenditures. During the Track Record Period, we primarily funded our working capital requirements through capital contributions from our shareholders and private equity financing. We monitor and maintain a level of cash and cash equivalents which we deem to be adequate to finance our business operations and mitigate the effects of fluctuations in cash flows. Our net cash used in operating activities was RMB34.2 million, RMB62.5 million and RMB60.0 million for the years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022, respectively. As our business develops and expands, we expect to generate net cash from our operating activities, through the sales revenue of our future commercialized products. Going forward, we believe our liquidity requirements will be satisfied by using funds from a combination of our cash and cash equivalents at hand, the net cash generated from our operating activities, and net [REDACTED] from the [REDACTED]. As of August 31, 2022, we had cash and cash equivalents of RMB87.7 million.

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Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents, future operating cash flows in respective periods, and the estimated net [REDACTED] from the [REDACTED], we have sufficient working capital to cover at least 125% of our costs and expenses, including research and development expenses, administrative expenses, distribution costs, finance costs and other expenses (including any production costs), for at least the next 12 months from the date of this document.

Our cash burn rate refers to our average monthly (i) net cash used in operating activities; (ii) capital expenditures; and (iii) lease payments. Assuming that the average cash burn rate going forward will be approximately 2.5 times the level in 2021, we estimate that our cash and cash equivalents as of August 31, 2022, will be able to maintain our financial viability for approximately [REDACTED] or, if we also take into account the estimated net [REDACTED] (based on the [REDACTED]) of HK\$[REDACTED] per [REDACTED] from the [REDACTED], for at least [REDACTED].

Cash Flows

The following table sets forth our cash flows for the periods indicated:

	Year Ended December 31,		Eight Months Ended August 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Cash outflow from operating activities before movements in working capital	(45,385)	(54,733)	(26,504)	(45,270)
Changes in working capital	11,186	(7,758)	(7,376)	(14,699)
Net cash flows used in operating activities	(34,199)	(62,491)	(33,880)	(59,969)
Net cash flows (used in)/generated from investing activities	27,009	15,653	(107,616)	(6,385)
Net cash flows (used in)/generated from financing activities	(608)	197,747	202,370	(5,839)
Net (decrease)/increase in cash and cash equivalents	(7,798)	150,909	60,874	(72,193)
Cash and cash equivalents at beginning of the year/period	15,381	7,486	7,486	157,867
Effect of foreign exchange rate changes	(97)	(528)	83	2,022
Cash and cash equivalents at end of the year/period	<u>7,486</u>	<u>157,867</u>	<u>68,443</u>	<u>87,696</u>

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Net Cash Flows Used in Operating Activities

For the eight months ended August 31, 2022, our net cash used in operating activities was RMB60.0 million, which was primarily attributable to our loss before tax of RMB61.4 million. Negative adjustments for non-cash and non-operating items primarily included equity-settled share award expense of RMB13.5 million and depreciation of property, plant and equipment of RMB2.9 million. The amount was then adjusted positively by changes in working capital, primarily including (i) an increase in prepayments, other receivables and other assets of RMB9.0 million; (ii) an increase in inventories of RMB3.9 million; and (iii) a decrease in other payables and accruals of RMB5.3 million.

In 2021, our net cash used in operating activities was RMB62.5 million, which was primarily attributable to our loss before tax of RMB126.5 million. Negative adjustments for non-cash and non-operating items primarily included equity-settled share award expense of RMB17.8 million and expenditures in proprietary technologies of RMB51.0 million. The amount was then adjusted positively by changes in working capital, primarily included (i) an increase in inventories of RMB3.6 million; (ii) an increase in prepayments, other receivables and other assets of RMB3.6 million; and (iii) a decrease in contract liabilities of RMB4.6 million.

In 2020, our net cash used in operating activities was RMB34.2 million, which was primarily attributable to our loss before tax of RMB159.3 million. Negative adjustments for non-cash and non-operating items primarily included equity-settled share award expense of RMB112.3 million. The amount was then adjusted negatively by changes in working capital, primarily included an increase in other payables and accruals of RMB8.8 million.

We expect our net operating cash outflows position to improve concurrently with our profitability, mainly through (i) expediting the registration and commercialization of our Core Products; (ii) further increasing our sales of commercialized products, by, for example, expanding our sales and marketing team and engaging more distributors to cover more end customers; and (iii) further improving our operational efficiency to enhance our working capital position by reviewing regularly and updating our liquidity and funding policies to ensure that it is aligned with our business plan and financial position, and preparing cash flow and funding summaries on a regular basis to monitor our cash flow.

Net Cash Flows (Used in)/From Investing Activities

For the eight months ended August 31, 2022, our net cash used in investing activities was RMB6.4 million, which is the net effect of (i) purchase of financial assets at fair value through profit or loss of RMB213.9 million; and (ii) purchases of items of property, plant and equipment of RMB2.8 million, partially offset by proceeds from disposal of financial assets at fair value through profit or loss of RMB209.9 million.

In 2021, our net cash from investing activities was RMB15.7 million, which is mainly resulted from proceeds from disposal of financial assets at fair value through profit or loss of RMB742.8 million, partially offset by (i) the purchase of financial assets at fair value through profit or loss of RMB717.9 million; and (ii) purchase of items of property, plant and equipment of RMB12.4 million.

In 2020, our net cash from investing activities was RMB27.0 million, which is the net effect of proceeds from disposal of financial assets at fair value through profit or loss of RMB139.0 million, partially offset by purchase of financial assets at fair value through profit or loss of RMB112.0 million.

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Net Cash Flows (Used in)/From Financing Activities

For the eight months ended August 31, 2022, our net cash used in financing activities was RMB5.8 million, which primarily resulted from the payment of lease liabilities of RMB1.2 million and the payment of the capitalized [REDACTED] of RMB[REDACTED].

In, 2021, our net cash generated from financing activities was RMB197.7 million, primarily as a result of the receipt of proceeds from issue of shares of RMB204.4 million.

In 2020, our net cash used in financing activities was RMB0.6 million, primarily due to the lease liabilities of RMB0.6 million.

CASH OPERATING COSTS

The following table sets forth key information relating to our cash operating costs for the periods indicated:

	Year Ended		Eight Months Ended	
	December 31,		August 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
R&D costs				
<i>R&D costs for our Core Product</i>				
– Clinical trial expenses	1,614	1,921	1,549	569
– Direct inputs ⁽¹⁾	1,732	473	232	929
– Staff costs	1,230	2,084	1,388	2,261
– Others	948	736	448	153
<i>R&D costs for our other product candidates</i>				
– Clinical trial expenses	5,494	6,125	4,120	5,820
– Direct inputs ⁽¹⁾	9,470	7,810	3,435	8,676
– Staff costs	7,810	16,863	11,478	16,609
– Others	2,303	1,632	1,032	1,219
Workforce employment costs⁽²⁾	10,042	16,073	10,758	22,700
Product marketing costs	674	942	550	337
Direct production costs	2,755	4,618	2,603	3,834
Non-income taxes, royalties and other governmental charges	–	–	–	–
Administrative expense	10,682	24,232	11,138	19,162
Contingency allowance	–	–	–	–
Total	<u>54,752</u>	<u>83,509</u>	<u>48,731</u>	<u>82,269</u>

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Notes:

- (1) Direct inputs represent raw materials and utility expenses (such as water and electricity) for the advancement of our research and development activities.
- (2) Workforce employment costs represent total non-research and development personnel costs mainly including salaries and benefits.

INDEBTEDNESS

The following table sets forth the components of our indebtedness as of the dates indicated:

	As of December 31,		As of	As of
	2020	2021	August 31,	October 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(unaudited)</i>
Lease liabilities				
Current	450	2,595	3,127	3,809
Non-current	127	6,406	4,701	8,382
Total	577	9,001	7,828	12,191

The Company incurred no borrowings during the Track Record Period. The Company had no unutilized banking facilities in the Track Record Period and up to the Latest Practicable Date.

Lease Liabilities

As of December 31, 2020 and 2021, August 31, 2022, and October 31, 2022 we recorded lease liabilities of RMB0.6 million, RMB9.0 million, RMB7.8 million and RMB12.2 million, respectively, which were primarily in relation to the properties we leased for our office premises, manufacturing, research and development. We recognized lease liabilities with respect to all leases, except for short-term leases and leases of low value assets.

Our Directors confirm that there have been no material defaults in our payment of trade or non-trade payables, or breaches of covenants of our indebtedness during the Track Record Period and up to the date of this document.

We did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of October 31, 2022. Since October 31, 2022 and up to the Latest Practicable Date, there had not been any material adverse changes to our indebtedness.

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CAPITAL EXPENDITURE

We regularly incur capital expenditures to expand and enhance our research and development facilities, establish our manufacturing capacities and increase our operating efficiency. Our capital expenditures primarily consisted of expenditures on machinery, office equipment, as well as leasehold improvements during the Track Record Period. Historically, we have funded our capital expenditures mainly through capital contributions by our shareholders and equity financing. The following table sets forth our capital expenditures for the periods indicated:

	Year Ended December 31,		Eight Months Ended August 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Purchases of items of property, plant and equipment	1,515	12,436	8,041	2,830
Total	1,515	12,436	8,041	2,830

We expect to incur capital expenditures in the next five years primarily for purchase of equipment and the construction of our manufacturing facilities. We may adjust our capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

CONTRACTUAL OBLIGATIONS

Commitments

We had the following commitments as of the dates indicated:

	As of December 31,		As of August 31,
	2020	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Contracted, but not provided for:			
Plant and machinery	–	1,094	772
	–	1,094	772

CONTINGENT LIABILITIES

As of December 31, 2020 and 2021 and August 31, 2022, we did not have any contingent liabilities. As of the Latest Practicable Date, there had been no material changes or arrangements to our contingent liabilities.

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OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

KEY FINANCIAL RATIOS

The table below sets forth our key financial ratios as of the dates indicated:

	As of December 31,		As of
	2020	2021	August 31,
			2022
Current ratio ⁽¹⁾	2.2	6.7	5.9
Quick ratio ⁽²⁾	1.8	6.3	5.2

Notes:

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories and divided by current liabilities as of the same date.

Our current ratio significantly increased from 2.2 as of December 31, 2020 to 6.7 as of December 31, 2021, mainly attributable to an increase in cash and cash equivalents of RMB150.4 million. Our current ratio decreased to 5.9 as of August 31, 2022, which was primarily due to a decrease in our cash and cash equivalents and an increase in our lease liabilities as current liabilities.

Our quick ratio was 1.8, 6.3 and 5.2 times as of December 31, 2020 and 2021 and August 31, 2022, which was mainly in line with the movement of current asset ratio as discussed above.

RELATED PARTY TRANSACTIONS

During the Track Record Period, we had the following transactions with the following related parties that had material transaction amounts or balances with us. We are able to obtain alternative financings if and when needed. As such, there is no financial reliance on our related parties.

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Transactions with Related Parties

	Year Ended December 31,		Eight Months Ended August 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Expenditures in proprietary technologies ⁽¹⁾	–	50,973	50,973	–
Advances of payroll from related parties	137	–	–	–
Advances of payroll to related parties	138	16	–	–
Advances of tax to a related party	7	–	–	–
Advances of a utility bill to a related party	456	486	260	635
Purchases of products	199	471	286	928
Purchases of service	110	363	134	402
Total	1,047	52,309	51,653	1,965

Note:

- (1) In April 2021, we and Mr. DIAO Yuepeng jointly established Beijifeng Biotechnology (Shanghai) Co., Ltd. (北極豐生物科技(上海)有限公司) and Huifeng Biotechnology (Shanghai) Co., Ltd. (輝豐生物科技(上海)有限公司). Mr. DIAO separately made capital contributions to these two subsidiaries in the form of proprietary technologies for a total amount of RMB51.0 million. For more details, see “History, Development and Corporate Structure—Our Subsidiaries” in this document and Note 28(a) to the Accountants’ Report in Appendix I to this document.

For more details of the related party transactions, see Note 30 to the Accountants’ Report in Appendix I to this document.

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Outstanding Balances with Related Parties

	As of December 31,		As of
	2020	2021	August 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments, other receivables and other assets:			
Due from related parties:			
Shanghai Jianshi Bio-tech Co., Ltd. —			
trade and non-trade	136	110	110
TD Engineering — trade	137	64	152
Ningbo Trando 3D Medical Technology Co., Ltd			
— trade	—	59	59
Ningbo Linstant Polymer Materials Co., Ltd. — trade	18	17	17
Jenscare Scientific Co., Ltd. — trade	89	—	—
Ningbo Shidi Medical Technology Co., Ltd. — trade	—	—	3
	380	250	341
	380	250	341
Other payables and accruals:			
Due to related parties:			
Ningbo Linfeng Biotechnology Co., Ltd. — trade and non-trade	60	56	121
Shanghai Jianshi Bio-tech Co., Ltd. — trade	7	7	7
Ningbo Diochange Medical Technology Co., Ltd.			
— non-trade	13	—	—
Jenscare Scientific Co., Ltd. — non-trade	1	—	—
Ningbo Hangzhou Bay New District Muhe Property Co., Ltd. — trade	—	—	7
	81	63	135
	81	63	135

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Amounts due from Shanghai Jianshi Bio-tech Co., Ltd. (“**Shanghai Jianshi**”) in 2020 were rent receivables as Shanghai Jianshi rented offices from us in 2020, and other receivables due to advances of payroll and annual bonus we made to Shanghai Jianshi’s employees. The receivables of payroll and annual bonus were fully settled by 2020, and the balance of rent receivables were carried over to 2021. The amounts due from Ningbo Linstant Polymer Materials Co., Ltd., TD Engineering, and Ningbo Trando 3D Medical Technology Co., Ltd. were prepayments for the procurement of raw materials. The amounts due from Jenscare Scientific Co., Ltd. (“**Jenscare Scientific**”) were rent receivables as Jenscare Scientific rented offices from us. Amounts due from Ningbo Shidi Medical Technology Co., Ltd. in 2022 were prepayments we made for its sterilization services to us.

Ningbo SensCure rents properties from Ningbo Linfeng Biotechnology Co., Ltd. (“**Ningbo Linfeng**”). The outstanding rent payables due to Ningbo Linfeng are trade balances. In addition, as long as Ningbo SencCure rents the properties for its business operations, it continues to utilize water and electricity on such properties. As such, Ningbo SensCure incurs utility (water and electricity) payables every month, and it generally settles such utility payables in the middle of the next month when it receives utility bills. Since such utility payables are collected by Ningbo Linfeng for administrative convenience to be paid to the local administrative authorities, such outstanding balances are recognized as non-trade balances. As of December 31, 2020 and 2021, and August 31, 2022, the utility payables due to Ningbo Linfeng were RMB32,800, RMB56,000 and RMB121,000, respectively. Considering that such non-trade balances due to Ningbo Linfeng are not outstanding loans, guarantees, or transactions related to the Group’s financing or funding, but are relatively small amounts of utility payables that Ningbo Linfeng collects for administrative convenience to be paid to the local administrative authorities, which are usually settled within the next month, our Directors believe that the utility payables due to Ningbo Linfeng are not expected to give rise to any implications under the Listing Rules as to financial independence. For more information about the financial independence of our Group from our Controlling Shareholders, please refer to “Relationship With Our Controlling Shareholders — Independence From Our Controlling Shareholders — Financial Independence.” The amounts due to Shanghai Jianshi Bio-tech Co., Ltd. were services fee payables for animation design. The amounts due to Ningbo Hangzhou Bay New District Muhe Property Co., Ltd. were property management fee payables.

As confirmed by our Directors, except for utility payables due to Ningbo Linfeng, all outstanding non-trade balances with related parties (including non-trade balance of amounts due from Shanghai Jianshi Bio-tech Co., Ltd.) will be fully settled before the [REDACTED], and the Company does not plan to have additional non-trade related party transactions in the future.

Our Directors are of the view that the related party transactions discussed above and set out in Note 30 to the Accountants’ Report set out in Appendix I to this document were conducted in the ordinary and usual course of business and on normal commercial terms between the relevant parties. Our Directors further confirm that all material related party transactions during the Track Record Period were conducted on an arm’s length basis, and would not distort our results of operations or make our historical results over the Track Record Period not reflective of our expectations for our future performance.

RISK DISCLOSURE

Foreign Currency Risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rate. Fluctuations in exchange rate between RMB and USD may affect our financial condition and results of operations.

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The following table demonstrates the sensitivity at the end of the reporting period to a reasonably possible change in foreign currency exchange rate, with all other variables held constant, of our loss before tax (due to changes in the fair value of forward currency contracts) and our equity:

	Increase/ (decrease) in rate of foreign currency	Increase/ (decrease) in loss before tax	Increase/ (decrease) in equity
	<i>%</i>	<i>RMB'000</i>	<i>RMB'000</i>
December 31, 2020			
If RMB weakens against USD	5	7	7
If RMB strengthens against USD	(5)	(7)	(7)
December 31, 2021			
If RMB weakens against USD	5	1,624	1,624
If RMB strengthens against USD	(5)	(1,624)	(1,624)
August 31, 2022			
If RMB weakens against USD	5	791	791
If RMB strengthens against USD	(5)	(791)	(791)

Credit Risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in our financial losses. Our credit risk is primarily attributable to other financial assets, which comprise cash and bank balances, financial assets included in prepayments, other receivables and other assets. Our exposure to credit risk arising from cash and cash equivalents is limited because we trade only with recognized and creditworthy third parties. It is our policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and our exposure to bad debts is not significant.

Liquidity Risk

We monitor and maintain a level of cash and cash equivalents which we deem to be adequate by our management to finance the operations and mitigate the effects of fluctuations in cash flows.

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DIVIDEND

No dividend have been declared or paid by the Company during the Track Record Period. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our board of directors and subject to our Articles of Association and the PRC Company Law, and will depend on a number of factors, including the successful commercialization of our products as well as our earnings, capital requirements, overall financial condition and contractual restrictions. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. As confirmed by our PRC Legal Adviser, any future net profit that we make will have to be applied to make up for our historically accumulated losses in accordance with the PRC laws, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above.

DISTRIBUTABLE RESERVES

As of August 31, 2022, we did not have any distributable reserves.

[REDACTED]

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IMPACT OF THE COVID-19 OUTBREAK

Since the first quarter of 2020, the outbreak of COVID-19 has materially and adversely affected the global economy. In response, during the period from January 2020 to April 2020, China had imposed widespread lockdowns, closure of work places and restrictions on mobility and travel to contain the spread of the virus. The government lockdown and other restrictive measures had resulted in reduced mobility of our employees, such as reduced marketing activities, reduced business travels and working remotely during early phases of COVID-19 outbreak. During the COVID-19 outbreak, affected by containment measures put in place by local governments in reaction to COVID-19 pandemic across the nation, we experienced some delays in the patient enrollment and data entry for our clinical trials for AF Cryoablation System for approximately six months from January 2020 to June 2020. However, since April 2020, most of the Chinese cities had gradually eased or lifted domestic travel restrictions and resumed normal social activities, work and production. There has not been any material disruption of our ongoing clinical trials. We had resumed full and normal operations since April 2020. The COVID-19 pandemic has not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in the clinical trials.

However, since November 2021, new COVID-19 variants have been identified in many countries, including China, among which, Omicron and Delta are found to be aggressive, and highly transmissible. Certain areas across China, such as Xi'an, Chengdu and Shijiazhuang, had suffered from regional outbreaks of COVID-19 variants including Delta and Omicron. Such outbreak spread across the nation for the period from March 2022 to May 2022. In response, local governments in such affected areas imposed various restrictions on business and social activities, including city lockdowns, restrictions on travel and other emergency quarantines. We have one clinical trial center for AF Cryoablation System in Xi'an and one clinical trial center for feasibility clinical trials for COPD Cryospray System and Esophageal Cryospray System in Shanghai. Due to the enhanced containment measures in Xi'an from December 2021 to January 2022, we experienced delays in the issuance of final clinical trial report for the clinical trial of the AF Cryoablation System during such period. In May 2022, we obtained such final clinical trial report within the original timetable. In July 2022, we submitted the registration application for such product candidate with the NMPA, and currently expect to obtain the NMPA approval in or around the second quarter of 2023. Due to the enhanced containment measures in Shanghai from March 2022 to May 2022, we experienced delays in patient enrollment for feasibility clinical trials for COPD Cryospray System and Esophageal Cryospray System and for confirmatory clinical trial for Cryo-RDN System during such period. Such delays were temporary as we gradually resumed normal operations since June 2022 and the clinical trials of COPD Cryospray System, Esophageal Cryospray System and Cryo-RDN System can still be finished according to their respective original timetable.

In addition, the manufacturing facility in Ningbo experienced difficulties in the procurement of raw materials from Shanghai from March 2022 to May 2022. However, such difficulties in procuring raw materials in Shanghai were moderate and have been further reduced since the reopening of Shanghai in June. In view of such difficulties, the Company has secured replacement for such raw materials in other cities. The production activities of our manufacturing facility in Shanghai was temporarily suspended due to the lockdown measures in Shanghai from March 2022 to May 2022, however, such influences of the suspension were limited since the manufacturing facility in Shanghai provides raw materials and prototype machines for the feature improvement activities of AF Cryoablation System (delayed due to the lockdown measures) and Cryo-RDN System (also suspended due to the lockdown measures), and it does not produce any commercialized products of the Company. It has resumed operation since the reopening of Shanghai in June. Although the logistics and distribution in some cities, such as Beijing and Shanghai,

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in China were affected by the pandemic from March 2022 to May 2022, delay in distribution of the Company’s products was rare, and there was no material impact of COVID-19 outbreak and its recurrence on the Company’s sales of commercialized products to hospitals or through distributors. As of the Latest Practicable Date, we did not see material impact of COVID-19 outbreak on our Company’s operations in its target markets. We cannot guarantee you that COVID-19 pandemic will not further escalate or have a material adverse effect on our results of operations, financial position or prospects. For more details, see “Risk Factors—Key Risks Relating to our Business, Business Operations, Intellectual Property Rights and Financial Prospects—Our business, results of operations and financial position could be adversely affected by the ongoing COVID-19 pandemic” in this document.

UNAUDITED [REDACTED] STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited [REDACTED] adjusted consolidated net tangible assets of the Group prepared in accordance with Rule 4.29 of the Listing Rules and with reference to Accounting Guideline 7 Preparation of [REDACTED] Financial Information for inclusion in Investment Circulars issued by the Hong Kong Institute of Certified Public Accountants for illustration purposes only, and is set out here to illustrate the effect of the [REDACTED] on the consolidated net tangible assets of the Group attributable to owners of the parent as if the [REDACTED] had taken place on August 31, 2022.

The unaudited [REDACTED] statement of adjusted consolidated net tangible assets of the Group has been prepared for illustrative purpose only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of our Group to owners of the parent had the [REDACTED] been completed as of August 31, 2022 or at any future dates.

Audited consolidated net tangible assets of the Group attributable to owners of the Company as of August 31, 2022	Estimated net [REDACTED] from the [REDACTED]	Unaudited [REDACTED] adjusted consolidated net tangible assets as of August 31, 2022	Unaudited [REDACTED] adjusted consolidated net tangible assets per Share as of August 31, 2022	
<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB</i>	<i>HK\$</i>
<i>(Note 1)</i>	<i>(Note 2)</i>		<i>(Note 3)</i>	<i>(Note 4)</i>

Based on an [REDACTED]
of HK\$[REDACTED]
per Share

126,348	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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Notes:

1. The consolidated net tangible assets of the Group attributable to owners of the Company as of August 31, 2022 is based on audited consolidated net tangible assets of the Group attributable to owners of the Company as of August 31, 2022 of RMB126,395,000 set out in the Accountants’ Report in Appendix I to this document, after deducting other intangible assets of RMB47,000.
2. The estimated net [REDACTED] from the [REDACTED] are based on the [REDACTED] of HK\$[REDACTED] per [REDACTED] after deduction of the [REDACTED] fees and other related expenses payable by the Company.
3. The unaudited [REDACTED] adjusted consolidated net tangible assets per Share is calculated based on [REDACTED] Shares in issue immediately following the completion of the [REDACTED].

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4. For the purpose of this unaudited [REDACTED] statement of adjusted net tangible assets, the balances stated in RMB are converted into HK\$ at the rate of RMB1.00 to HK\$1.0952.
5. No adjustment has been made to the unaudited [REDACTED] adjusted consolidated net tangible assets to reflect any trading results or other transactions of the Group entered into subsequent to August 31, 2022.

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that other than as disclosed under “Recent Developments and No Material Adverse Change” in the “Summary” section in this document, there had been no material adverse change in our business, financial condition and results of operations since August 31, 2022, being the latest balance sheet date of our consolidated financial statements in the Accountants’ Report set out in Appendix I to this document, and up to the date of this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, as of the Latest Practicable Date, there was no circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS AND PROSPECTS

See “Business—Our Strategies” in this document for a detailed description of our future plans.

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED], after deducting [REDACTED] commissions, fees and estimated expenses payable by us in connection with the [REDACTED], at the [REDACTED] of HK\$[REDACTED] per Share.

We currently intend to apply these net [REDACTED] for the following purposes:

- (1) [73.9]%, or approximately HK\$[REDACTED], will be allocated to our Core Products, namely the Bladder Cryoablation System and the Endoscopic Clip for Anastomosis, including:
 - (a) [58.2]%, or approximately HK\$[REDACTED], will be used to fund R&D activities, commercial launch (including sales and marketing) and manufacturing of the Bladder Cryoablation System. Specifically, we expect that:
 - (i) [56.9]%, or approximately HK\$[REDACTED], will be used to fund the R&D work for the Bladder Cryoablation System. We received the NMPA approval in June 2022. With respect to our further R&D activities on the Bladder Cryoablation System, we intend to allocate [14.4]% of the net [REDACTED], or approximately HK\$[REDACTED], for implementing development projects to optimize features and refine design details of the Bladder Cryoablation System, such as interface upgrade and product structure improvement; [28.3]% of the net [REDACTED], or approximately HK\$[REDACTED], for conducting post-launch clinical studies and three- to five-year follow-ups for a sizable pool of patients who use the Bladder Cryoablation System to monitor the real-world clinical data and further evaluate its safety and efficacy, and expanding the indication of the Bladder Cryoablation System. Specifically, we plan to finalize the clinical trial protocol in 2023, complete the enrollment of 600 to 800 patients in approximately 20 cities by 2027, and complete all follow-ups by 2028; we intend to expand the indication of the Bladder Cryoablation System, for which expansion, we expect to finalize the preliminary protocol and select the CRO from 2023 to 2025, complete patient enrollment and follow-up visits from 2026 to 2029, and obtain the approval for commercialization in China around 2030; and [14.2]% of the net [REDACTED], or approximately HK\$[REDACTED], for applying for CE Mark registration of the Bladder Cryoablation System, as well as the expansion of our R&D and clinical trial teams to support subsequent R&D activities on the Bladder Cryoablation System. For further details of our planned post-launch studies and CE Mark registration application, see “Business—Our Products and Product Candidates—Our Core Products—1. Bladder Cryoablation System—Further Development Plan” in this document;

FUTURE PLANS AND USE OF [REDACTED]

- (ii) [0.4]%, or approximately HK\$[REDACTED], will be used for planned commercial launch (including sales and marketing) of the Bladder Cryoablation System. In particular, we intend to allocate [0.2]% of the net [REDACTED], or approximately HK\$[REDACTED], for conducting sales and marketing activities, such as product demonstrations and physician trainings, as well as sponsoring and attending more industry conferences; and [0.2]% of the net [REDACTED], or approximately HK\$[REDACTED], for establishing sales channels for our future sales of the Bladder Cryoablation System, as well as the expansion of our sales team for the Bladder Cryoablation System since the fourth quarter of 2022; and
 - (iii) [0.9]%, or approximately HK\$[REDACTED], will be used for the expansion of our manufacturing capacity for the Bladder Cryoablation System, which mainly includes upgrading our manufacturing facilities from the fourth quarter of 2022 to the fourth quarter of 2024 and purchasing new machineries and equipment, as well as hiring, retaining and training production personnel for the manufacturing of the Bladder Cryoablation System from the third quarter of 2023; and
- (b) [15.7]%, or approximately HK\$[REDACTED], will be used to fund R&D activities, commercial launch (including sales and marketing) and manufacturing of the Endoscopic Clip for Anastomosis. Specifically, we expect that:
- (i) [15.1]%, or approximately HK\$[REDACTED], will be used to fund the R&D work for the Endoscopic Clip for Anastomosis. We received the Zhejiang MPA approval in August 2022 and commercialized it in October 2022. With respect to our further R&D activities on the Endoscopic Clip for Anastomosis, we intend to allocate [3.9]% of the net [REDACTED], or approximately HK\$[REDACTED], for funding continuous development projects regarding potential improvements to its features and design details, such as product structure improvement; [8.3]% of the net [REDACTED], or approximately HK\$[REDACTED], for conducting post-launch clinical studies and one- to two-year follow-ups to further evaluate its safety and efficacy. Specifically, we plan to finalize the clinical trial protocol in 2023, complete the enrollment of 200 to 500 patients in approximately ten cities by 2026, and complete all follow-ups by 2027; and [2.9]% of the net [REDACTED], or approximately HK\$[REDACTED], for its CE Mark registration application, as well as the expansion of our R&D and clinical trial teams to support subsequent R&D activities on the Endoscopic Clip for Anastomosis. For further details of our planned post-launch studies and CE Mark registration application, see “Business—Our Products and Product Candidates—Our Core Products—2. Endoscopic Clip for Anastomosis—Further Development Plan” in this document;
 - (ii) [0.2]%, or approximately HK\$[REDACTED], will be used for planned commercial launch (including sales and marketing) of the Endoscopic Clip for Anastomosis. Specifically, we intend to allocate [0.1]% of the net [REDACTED], or approximately HK\$[REDACTED], for conducting sales and marketing activities, such as product demonstrations, providing trainings to physicians and participating in academic conferences; and [0.1]% of the net [REDACTED], or approximately HK\$[REDACTED], for establishing sales

FUTURE PLANS AND USE OF [REDACTED]

channels for our future sales of the Endoscopic Clip for Anastomosis, as well as the expansion of our sales team for the Endoscopic Clip for Anastomosis from the fourth quarter of 2022; and

- (iii) [0.4]%, or approximately HK\$[REDACTED] will be used for the expansion of our manufacturing capacity for the Endoscopic Clip for Anastomosis, which mainly includes upgrading our manufacturing facilities from the fourth quarter of 2022 to the fourth quarter of 2024 and purchasing new machineries and equipment, as well as hiring, retaining and training production personnel for the manufacturing of the Endoscopic Clip for Anastomosis from the third quarter of 2023; and
- (2) [6.1]%, or approximately HK\$[REDACTED], will be allocated to the R&D activities, planned commercial launch and manufacturing of our AF Cryoablation System. Specifically,
- (a) [5.4]%, or approximately HK\$[REDACTED], will be used to fund the R&D work for the AF Cryoablation System. We have completed a multi-center clinical trial and submitted registration application to the NMPA, and we expect to receive the NMPA approval in or around the second quarter of 2023. With respect to our further R&D activities on the AF Cryoablation System, we intend to allocate [2.7]% of the net [REDACTED], or approximately HK\$[REDACTED], for carrying out continuous development projects regarding potential improvements to various features of the AF Cryoablation System; [1.3]% of the net [REDACTED], or approximately HK\$[REDACTED], for conducting post-launch clinical studies and follow-ups to further evaluate its safety and efficacy, and expanding the indication of the AF Cryoablation System; and [1.4]% of the net [REDACTED], or approximately HK\$[REDACTED], for its CE Mark registration application, as well as the expansion of our R&D and clinical trial teams to support subsequent R&D activities on the AF Cryoablation System;
 - (b) [0.2]%, or approximately HK\$[REDACTED], will be used for commercial launch (including sales and marketing) of the AF Cryoablation System. Specifically, we intend to allocate [0.1]% of the net [REDACTED], or approximately HK\$[REDACTED], for conducting sales and marketing activities, such as product demonstrations, providing trainings to physicians and participating in academic conferences; and [0.1]% of the net [REDACTED], or approximately HK\$[REDACTED], for establishing sales channels for our future sales of the AF Cryoablation System, as well as the expansion of our sales team for the AF Cryoablation System from the fourth quarter of 2022; and
 - (c) [0.5]%, or approximately HK\$[REDACTED], will be used for the expansion of our manufacturing capacity for the AF Cryoablation System, which mainly includes upgrading our manufacturing facilities from the fourth quarter of 2022 to the fourth quarter of 2024, purchasing new machineries and recruiting and training production personnel from the third quarter of 2023; and

FUTURE PLANS AND USE OF [REDACTED]

- (3) [20.0]%, or approximately HK\$[REDACTED], will be allocated to the R&D activities, registration filings, and planned commercial launch and manufacturing of the remaining 14 product candidates in our current product pipeline. We expect that:
- (a) [5.0]%, or approximately HK\$[REDACTED], will be used to fund the ongoing and planned R&D activities including clinical trials of our cryoablation product candidates for vascular interventional therapy, including our Cryofocus Renal Denervation System and Pulmonary Hypertension Cryoablation System;
 - (b) [10.3]%, or approximately HK\$[REDACTED], will be used to fund the ongoing and planned R&D activities including clinical trials of our cryoablation product candidates for NOTES, such as our COPD Cryospray System, Asthma Cryoablation System, Gastric Cryoablation System and Esophageal Cryospray System;
 - (c) [3.7]%, or approximately HK\$[REDACTED], will be used to fund the ongoing and planned R&D activities including clinical trials of our non-cryoablation product candidates and other product candidates, including our Atrial Fibrillation Pulsed Field Ablation System and Anti-Gastroesophageal Reflux System; and
 - (d) [1.0]%, or approximately HK\$[REDACTED], will be allocated to the fund the planned registration, commercial launch (including marketing and sales) and the expansion of manufacturing capacities for our product pipeline. In particular, we intend to expand manufacturing capacities by upgrading our manufacturing facilities and purchasing new machineries and equipment, as well as hiring, retaining and training production personnel. We also plan to improve our sales and marketing capacities by hiring additional experienced sales managers and local sales personnel to build specialized and dedicated sales team, stepping up academic promotion of these products and enhancing our support and training to distributors.

To the extent that the net [REDACTED] are not immediately applied to the above purposes and to the extent permitted by the relevant law and regulations, we may hold such funds in short-term deposits with licensed banks or authorized financial institutions. We will issue an appropriate announcement if there is any material change to the above proposed use of [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

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HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF CRYOFOCUS MEDTECH (SHANGHAI) CO., LTD., CITIGROUP GLOBAL MARKETS ASIA LIMITED AND HUATAI FINANCIAL HOLDINGS (HONG KONG) LIMITED

Introduction

We report on the historical financial information of Cryofocus Medtech (Shanghai) Co., Ltd. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-4 to I-72, which comprises the consolidated statements of profit or loss, the consolidated statements of comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows of the Group for the year ended 31 December 2020 and 2021, and the eight months ended 31 August 2022 (the “Relevant Periods”), the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2020 and 2021 and 31 August 2022, and a summary of significant accounting policies and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages I-4 to I-72 forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated 24 October 2022 (the “Document”) in connection with the initial [REDACTED] of the shares of the Company on the [REDACTED] (the “[REDACTED]”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively, in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

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ACCOUNTANTS' REPORT

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants' report, a true and fair view of the financial position of the Group and the Company as at 31 December 2020 and 2021 and 31 August 2022 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively.

Review of interim comparative financial information

We have reviewed the interim comparative financial information of the Group which comprises the consolidated statement of profit or loss, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the eight months ended 31 August 2021 and other explanatory information (the "Interim Comparative Financial Information"). The directors of the Company are responsible for the preparation and presentation of the Interim Comparative Financial Information in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively. Our responsibility is to express a conclusion on the Interim Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Interim Comparative Financial Information, for the purposes of the accountants' report, is not prepared, in all material respects, in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively.

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to note 11 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

Ernst & Young

Certified Public Accountants

Hong Kong

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by the HKICPA (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	Notes	Year ended 31 December		Eight months ended 31 August	
		2020	2021	2021	2022
		RMB’000	RMB’000	RMB’000 (unaudited)	RMB’000
Revenue	5	9,054	22,426	12,061	16,431
Cost of sales		(4,414)	(6,881)	(4,146)	(5,225)
Gross profit		4,640	15,545	7,915	11,206
Other income and gains	5	5,283	4,405	2,598	6,230
Research and development expenses		(42,307)	(89,827)	(71,647)	(35,751)
Administrative expenses		(124,049)	(50,753)	(28,343)	(40,547)
Selling and distribution expenses		(2,849)	(4,806)	(2,693)	(2,141)
Other expenses		(8)	(686)	(73)	(70)
Finance costs	7	(43)	(375)	(193)	(349)
LOSS BEFORE TAX	6	(159,333)	(126,497)	(92,436)	(61,422)
Income tax expenses	10	—	—	—	—
LOSS FOR THE YEAR/PERIOD		<u>(159,333)</u>	<u>(126,497)</u>	<u>(92,436)</u>	<u>(61,422)</u>
Attributable to:					
Owners of the parent		(137,085)	(101,873)	(68,930)	(57,944)
Non-controlling interests		(22,248)	(24,624)	(23,506)	(3,478)
		<u>(159,333)</u>	<u>(126,497)</u>	<u>(92,436)</u>	<u>(61,422)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT					
Basic and diluted					
For loss for the year/period	12	<u>RMB(0.70)</u>	<u>RMB(0.45)</u>	<u>RMB(0.31)</u>	<u>RMB(0.25)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i> (unaudited)	<i>RMB’000</i>
LOSS FOR THE YEAR/PERIOD	<u>(159,333)</u>	<u>(126,497)</u>	<u>(92,436)</u>	<u>(61,422)</u>
OTHER COMPREHENSIVE (LOSS)/INCOME				
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	<u>(110)</u>	<u>39</u>	<u>32</u>	<u>146</u>
OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE YEAR/PERIOD, NET OF TAX	<u>(110)</u>	<u>39</u>	<u>32</u>	<u>146</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR/PERIOD	<u>(159,443)</u>	<u>(126,458)</u>	<u>(92,404)</u>	<u>(61,276)</u>
Attributable to:				
Owners of the parent	<u>(137,195)</u>	<u>(101,834)</u>	<u>(68,898)</u>	<u>(57,798)</u>
Non-controlling interests	<u>(22,248)</u>	<u>(24,624)</u>	<u>(23,506)</u>	<u>(3,478)</u>
	<u>(159,443)</u>	<u>(126,458)</u>	<u>(92,404)</u>	<u>(61,276)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

		As at 31 December		As at 31 August
	<i>Notes</i>	2020	2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
NON-CURRENT ASSETS				
Property, plant and equipment	13	19,808	29,116	28,820
Right-of-use assets	14	264	8,977	6,930
Other intangible assets		–	59	47
Other non-current assets	16	3,306	4,154	5,432
Total non-current assets		23,378	42,306	41,229
CURRENT ASSETS				
Inventories	17	8,103	11,696	15,757
Prepayments, other receivables and other assets	19	9,870	19,824	30,580
Financial assets at fair value through profit or loss	20	25,521	–	4,013
Cash and cash equivalents	21	7,486	157,867	87,696
Total current assets		50,980	189,387	138,046
CURRENT LIABILITIES				
Trade payables	22	185	314	1,758
Other payables and accruals	23	16,544	23,699	16,650
Lease liabilities	14	450	2,595	3,127
Contract liabilities	25	6,309	1,681	1,773
Total current liabilities		23,488	28,289	23,308
NET CURRENT ASSETS		27,492	161,098	114,738
TOTAL ASSETS LESS CURRENT LIABILITIES		50,870	203,404	155,967
NON-CURRENT LIABILITIES				
Lease liabilities	14	127	6,406	4,701
Deferred income	24	461	–	2,000
Total non-current liabilities		588	6,406	6,701
NET ASSETS		50,282	196,998	149,266

APPENDIX I

ACCOUNTANTS’ REPORT

	<i>Notes</i>	As at 31 December		As at
		2020	2021	31 August
		<i>RMB’000</i>	<i>RMB’000</i>	2022
				<i>RMB’000</i>
EQUITY				
Share capital/Paid-in capital	26	50,802	228,000	228,000
Reserves	27	(520)	(57,351)	(101,605)
Equity attributable to owners of the parent		<u>50,282</u>	<u>170,649</u>	<u>126,395</u>
Non-controlling interests		<u>–</u>	<u>26,349</u>	<u>22,871</u>
Total equity		<u>50,282</u>	<u>196,998</u>	<u>149,266</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

Year ended 31 December 2020

	Attributable to owners of the parent						Total	Non-controlling interests	Total equity
	Paid-in capital	Share premium*	Merger reserve*	Exchange fluctuation reserve*	Share award reserve*	Accumulated loss*			
	(note 26)	(note 27)	(note 27)	(note 27)	(note 27)	(note 27)			
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	
As at 1 January 2020	25,401	69,746	68,858	5	100,999	(182,296)	82,713	14,747	97,460
Loss for the year	-	-	-	-	-	(137,085)	(137,085)	(22,248)	(159,333)
Other comprehensive loss for the year:									
Exchange differences related to foreign operations	-	-	-	(110)	-	-	(110)	-	(110)
Total comprehensive loss for the year	-	-	-	(110)	-	(137,085)	(137,195)	(22,248)	(159,443)
Business combination under common control**	25,401	53,713	(68,858)	-	-	-	10,256	(10,256)	-
Equity-settled share award expense (note 28)	-	-	-	-	94,508	-	94,508	17,757	112,265
As at 31 December 2020	50,802	123,459	-	(105)	195,507	(319,381)	50,282	-	50,282

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ACCOUNTANTS’ REPORT

Year ended 31 December 2021

	Attributable to owners of the parent						Total	Non-controlling interests	Total equity
	Share capital	Paid-in capital	Share premium*	Exchange fluctuation reserve*	Share award reserve*	Accumulated loss*			
	(note 26)	(note 26)	(note 27)	(note 27)	(note 27)	(note 27)			
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
As at 1 January 2021	-	50,802	123,459	(105)	195,507	(319,381)	50,282	-	50,282
Loss for the year	-	-	-	-	-	(101,873)	(101,873)	(24,624)	(126,497)
Other comprehensive loss for the year:									
Exchange differences related to foreign operations	-	-	-	39	-	-	39	-	39
Total comprehensive loss for the year	-	-	-	39	-	(101,873)	(101,834)	(24,624)	(126,458)
Capital contribution by shareholders	-	8,750	195,629	-	-	-	204,379	-	204,379
Capital contribution from shareholders of a subsidiary	-	-	-	-	-	-	-	50,973	50,973
Equity-settled share award expense (note 28)	-	-	-	-	17,822	-	17,822	-	17,822
Convert into joint stock	228,000	(59,552)	(168,448)	-	-	-	-	-	-
As at 31 December 2021	228,000	-	150,640	(66)	213,329	(421,254)	170,649	26,349	196,998

APPENDIX I

ACCOUNTANTS’ REPORT

Eight months ended 31 August 2021 (unaudited)

	Attributable to owners of the parent						Total	Non-controlling interests	Total equity
	Share capital	Paid-in capital	Share premium*	Exchange fluctuation reserve*	Share award reserve*	Accumulated loss*			
	(note 26)	(note 26)	(note 27)	(note 27)	(note 27)	(note 27)			
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
As at 1 January 2021	-	50,802	123,459	(105)	195,507	(319,381)	50,282	-	50,282
Loss for the period	-	-	-	-	-	(68,930)	(68,930)	(23,506)	(92,436)
Other comprehensive loss for the period:									
Exchange differences related to foreign operations	-	-	-	32	-	-	32	-	32
Total comprehensive loss for the period	-	-	-	32	-	(68,930)	(68,898)	(23,506)	(92,404)
Capital contribution by shareholders	-	8,750	195,629	-	-	-	204,379	-	204,379
Capital contribution from shareholders of a subsidiary	-	-	-	-	-	-	-	50,973	50,973
Equity-settled share award expense (note 28)	-	-	-	-	13,880	-	13,880	-	13,880
Convert into joint stock	228,000	(59,552)	(168,448)	-	-	-	-	-	-
As at 31 August 2021	228,000	-	150,640	(73)	209,387	(388,311)	199,643	27,467	227,110

APPENDIX I

ACCOUNTANTS’ REPORT

Eight months ended 31 August 2022

	Attributable to owners of the parent					Total	Non-controlling interests	Total equity
	Share capital	Share premium*	Exchange fluctuation reserve*	Share award reserve*	Accumulated loss*			
	(note 26)	(note 27)	(note 27)	(note 27)	(note 27)			
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
As at 1 January 2022	228,000	150,640	(66)	213,329	(421,254)	170,649	26,349	196,998
Loss for the period	-	-	-	-	(57,944)	(57,944)	(3,478)	(61,422)
Other comprehensive loss for the period:								
Exchange differences related to foreign operations	-	-	146	-	-	146	-	146
Total comprehensive loss for the period	-	-	146	-	(57,944)	(57,798)	(3,478)	(61,276)
Equity-settled share award expense (note 28)	-	-	-	13,544	-	13,544	-	13,544
As at 31 August 2022	228,000	150,640	80	226,873	(479,198)	126,395	22,871	149,266

* These reserves accounts comprise the consolidated reserves of negative RMB520,000 and negative RMB57,351,000 and negative RMB101,605,000 in the consolidated statements of financial position as at 31 December 2020 and 2021 and 31 August 2022, respectively.

** In December 2020, the original shareholders of Ningbo SensCure Biotechnology Co., Ltd. (“SensCure”) collectively subscribed for the increased registered capital of RMB25,401,000 by transferring the equity interests they held in SensCure to the Company, which was considered to be business combination under common control, and the Company had held all shares of SensCure since then. For more details of the Equity Swap, Please refer to the section “History, Development and Corporate Structure” in the Document.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i> (unaudited)	<i>RMB’000</i>
CASH FLOWS USED IN OPERATING ACTIVITIES				
Loss before tax	(159,333)	(126,497)	(92,436)	(61,422)
Adjustments for:				
Finance costs	43	375	193	349
Gains on financial assets at fair value through profit or loss	(305)	–	(397)	(13)
Investment income on financial assets at fair value through profit or loss	(1,252)	(2,704)	(1,383)	(445)
Covid-19-related rent concessions from lessors	–	–	–	(100)
Depreciation of property, plant and equipment	2,284	2,728	1,697	2,888
Amortisation of other intangible assets	–	5	1	12
Depreciation of right-of-use assets	863	1,737	845	1,855
Impairment of other receivables	6	118	73	69
Reversal of impairment	(2)	–	–	–
Foreign exchange difference, net	3	567	(51)	(1,877)
Loss on disposal of items of property, plant and equipment	–	123	81	–
Loss on disposal of items of right-of-use assets	–	(9)	(9)	–
Equity-settled share award expense	112,265	17,822	13,880	13,544
Write-down for inventories	43	29	29	(130)
Expenditures of proprietary technologies	–	50,973	50,973	–
	(45,385)	(54,733)	(26,504)	(45,270)
Increase in inventories	(1,448)	(3,621)	(1,805)	(3,931)
Decrease in trade and bills receivables	2,161	–	–	–
Decrease /(increase) in prepayments, other receivables and other assets	969	(3,624)	(4,037)	(9,048)
Increase in trade payables	98	129	419	1,444
Increase/(decrease) in other payables and accruals	8,814	4,447	(687)	(5,256)
Increase/(decrease) in deferred income	(44)	(461)	–	2,000
Increase/(decrease) in contract liabilities	636	(4,628)	(1,266)	92
Net cash flows used in operating activities	(34,199)	(62,491)	(33,880)	(59,969)

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ACCOUNTANTS’ REPORT

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			(unaudited)	
CASH FLOWS FROM/(USED IN)				
 INVESTING ACTIVITIES				
Purchases of items of property, plant and equipment	(1,515)	(12,436)	(8,041)	(2,830)
Proceeds from disposal of financial assets at fair value through profit or loss	139,020	742,830	402,215	209,850
Investment income	1,524	3,295	1,974	445
Purchase of financial assets at fair value through profit or loss	(112,020)	(717,900)	(503,700)	(213,850)
Lease payment before commencement date	–	(72)	–	–
Purchases of items of other intangible assets	–	(64)	(64)	–
Net cash flows from/(used in) investing activities	<u>27,009</u>	<u>15,653</u>	<u>(107,616)</u>	<u>(6,385)</u>
CASH FLOWS (USED IN)/FROM FINANCING ACTIVITIES				
Proceeds from issue of shares	–	204,379	204,379	–
Payment of lease liabilities	(608)	(2,264)	(1,162)	(1,230)
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Net cash flows (used in)/from financing activities	<u>(608)</u>	<u>197,747</u>	<u>202,370</u>	<u>(5,839)</u>
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	<u>(7,798)</u>	<u>150,909</u>	<u>60,874</u>	<u>(72,193)</u>
Cash and cash equivalents at beginning of year/period	15,381	7,486	7,486	157,867
Effect of foreign exchange rate changes, net	(97)	(528)	83	2,022
CASH AND CASH EQUIVALENTS AT END OF YEAR/PERIOD	<u><u>7,486</u></u>	<u><u>157,867</u></u>	<u><u>68,443</u></u>	<u><u>87,696</u></u>

APPENDIX I

ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

		As at 31 December		As at
	<i>Notes</i>	2020	2021	31 August
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
NON-CURRENT ASSETS				
Property, plant and equipment	13	17,143	21,923	21,474
Right-of-use assets	14	57	2,960	2,158
Investments in subsidiaries	15	342,268	415,876	412,862
Other intangible assets		–	59	47
Other non-current assets	16	1,914	4,069	5,247
Total non-current assets		<u>361,382</u>	<u>444,887</u>	<u>441,788</u>
CURRENT ASSETS				
Inventories	17	4,400	5,866	6,597
Prepayments, other receivables and other assets	19	6,062	14,234	28,853
Financial assets at fair value through profit or loss	20	1,075	–	–
Cash and cash equivalents	21	573	84,977	35,458
Total current assets		<u>12,110</u>	<u>105,077</u>	<u>70,908</u>
CURRENT LIABILITIES				
Trade payables	22	153	38	1,144
Other payables and accruals	23	8,793	15,052	7,985
Lease liabilities	14	35	1,111	1,500
Total current liabilities		<u>8,981</u>	<u>16,201</u>	<u>10,629</u>
NET CURRENT ASSETS		<u>3,129</u>	<u>88,876</u>	<u>60,279</u>
TOTAL ASSETS LESS CURRENT LIABILITIES		<u>364,511</u>	<u>533,763</u>	<u>502,067</u>

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	<i>Notes</i>	As at 31 December		As at
		2020	2021	31 August
		<i>RMB’000</i>	<i>RMB’000</i>	2022
				<i>RMB’000</i>
NON-CURRENT LIABILITIES				
Lease liabilities	14	–	1,596	1,036
Total non-current liabilities		–	1,596	1,036
NET ASSETS		364,511	532,167	501,031
EQUITY				
Share capital	26	50,802	228,000	228,000
Reserves	27	313,709	304,167	273,031
Total equity		364,511	532,167	501,031

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II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

Cryofocus Medtech (Shanghai) Co., Ltd. (“the Company”) was incorporated in the People’s Republic of China (“PRC”) on 15 March 2013 as a limited liability company. On 21 July 2021, the Company was converted into a joint stock company with limited liability under the Company Law of PRC. The registered office of the Company is located at No.18, Lane 3339, Kangxin Road, Pudong New District, Shanghai, the PRC.

The Company and its subsidiaries now comprising the Group underwent the reorganization as set out in the paragraph headed “Reorganization” in the section headed “History, Development and Corporate Structure” in the document.

During the Relevant Periods, the Company and its subsidiaries (“the Group”) was a medical device company with a main focus on the field of cryoablation minimally-invasive interventional treatment. Based on the Group’s liquid nitrogen cryoablation technology, it mainly engages in research and development of cardiovascular innovation minimally invasive based on the cryomedical technology and other related medical products.

As at the date of this report, the Company had direct interests in its subsidiaries, all of which are private limited liability companies (or, if incorporated outside Hong Kong, have substantially similar characteristics to a private company incorporated in Hong Kong), the particulars of which are set out below:

<u>Name</u>	<u>Place and date of incorporation/ registration and place of operations</u>	<u>Issued ordinary/ registered share capital</u>	<u>Percentage of equity attributable to the Company Direct</u>	<u>Principal activities</u>
Ningbo SensCure Biotechnology Co., Ltd. (“SensCure”)* (寧波勝杰康生物科技有限公司) (note (a))	People’s Republic of China (“PRC”)/ Mainland China 28 September 2011	RMB19,814,000	100%	Research, development of technology and manufacturing and sales of related products
Cryofocus America Inc. (note (c))	California, The United States of America 4 January 2018	USD1,000,000	100%	Research and Development of cryoablation medical devices and related technical consultation
Beijifeng Biotechnology (Shanghai) Co., Ltd.* (北極豐生物科技(上海)有限公司) (note (b))	PRC/ Mainland China 9 April 2021	RMB41,765,000	71.8310%	Research, development of technology and manufacturing and sales of related products
Huifeng Biotechnology (Shanghai) Co., Ltd.* (輝豐生物科技(上海)有限公司) (note (b))	PRC/ Mainland China 9 April 2021	RMB79,208,000	50.50%	Research, development of technology and manufacturing and sales of related products

* The English names of these entities registered in the PRC represent the best efforts made by the directors of the Company (the “Directors”) to translate the Chinese names as these companies have not been registered with any official English names.

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Notes:

- (a) The statutory financial statements of this entity for the years ended 31 December 2020 and 2021 prepared under the PRC Generally Accounting Principles (the “PRC GAAP”) were audited by Ningbo Fenghua Guangping Certified Public Accountants Co., Ltd. (寧波奉化廣平會計師事務所有限公司) and Cixi Tianbo Certified Public Accountants Co., Ltd. (慈溪天博會計師事務所有限公司), respectively.
- (b) The statutory financial statements of these entities for the year ended 31 December 2021 prepared under the PRC Generally Accounting Principles (the “PRC GAAP”) were audited by Shanghai Zhong Hui Certified Public Accountants Co., Ltd. (上海中惠會計師事務所有限公司).
- (c) As at the date of this report, no audited financial statements have been prepared since the incorporation of this entity as statutory accounts are not required under the relevant rules and regulations in its jurisdiction of incorporation.

2.1 BASIS OF PRESENTATION

The consolidated statements of profit or loss, and statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for the Relevant Periods and the eight months ended 31 August 2021 include the results and cash flows of all companies now comprising the Group from the earliest date presented.

Pursuant to the Reorganisation, as more fully explained in the sub-section headed “Reorganisation” in the section headed “History, Development and Corporate Structure” in the Document, the Company became the holding company of the companies now comprising the Group on 25 December 2020.

The companies now comprising the Group were under the common control of Ms. Li Hui and Mr. Lv Shiwen (collectively, the “Controlling Shareholders”) before and after the Reorganisation, through their personal capacities and entities owned by Ms. Li Hui and Mr. Lv Shiwen. Accordingly, for the purpose of this report, the Historical Financial Information has been prepared by applying the principles of merger accounting as if the Reorganisation had been completed at the beginning of the Relevant Periods.

The consolidated statements of financial position of the Group as at 31 December 2020 and 2021 and 31 August 2022 have been prepared to present the assets and liabilities of the subsidiaries using the existing book values from the controlling shareholder’s perspective. No adjustments are made to reflect fair values or recognise any new assets or liabilities as a result of the Reorganisation.

Equity interests in subsidiaries and businesses held by parties other than the controlling shareholders, and changes therein, prior to the Reorganisation are presented as non-controlling interests in equity in applying the principles of merger accounting.

All intra-group transactions and balances have been eliminated on consolidation.

2.2 BASIS OF PREPARATION

Notwithstanding that the Group is still at the stage of research and development and continually incurred losses from operations, the financial information has been prepared on a going concern basis. The directors of the Company have considered the Group’s sources of liquidity and believe that adequate cash and cash equivalents is available to fulfil the Group’s operating activities, debt obligations and capital expenditure requirements. Accordingly, the directors of the Company are of the opinion that it is appropriate to prepare the Historical Financial Information on a going concern basis.

The Historical Financial Information has been prepared in accordance with HKFRSs (which include all Hong Kong Financial Reporting Standards, Hong Kong Accounting Standards (“HKASs”) and Interpretations) issued by the HKICPA and accounting principles generally accepted in Hong Kong.

All HKFRSs effective for the accounting period commencing from 1 January 2022, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods and in the period covered by the Interim Comparative Financial Information.

The Historical Financial Information has been prepared under the historical cost convention except for certain financial instruments which have been measured at fair value at the end of each of the Relevant Periods and in the period covered by the Interim Comparative Financial Information.

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2.3 ISSUED BUT NOT YET EFFECTIVE HKFRSs

The Group has not applied the following new and revised HKFRSs, that have been issued but are not yet effective, in the Historical Financial Information.

Amendments to HKFRS 10 and HKAS 28 (2011)	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ²
HKFRS 17	<i>Insurance Contracts</i> ¹
Amendments to HKFRS 17	<i>Insurance Contracts</i> ^{1, 4}
Amendments to HKAS 1	<i>Classification of Liabilities as Current or Non-current</i> ^{1, 3}
Amendments to HKAS 1 and HKFRS Practice Statement 2	<i>Disclosure of Accounting Policies</i> ¹
Amendments to HKAS 8	<i>Definition of Accounting Estimates</i> ¹
Amendments to HKAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a single Transaction</i> ¹

¹ Effective for annual periods beginning on or after 1 January 2023

² No mandatory effective date yet determined but available for adoption

³ As a consequence of the amendments to HKAS 1, Hong Kong Interpretation 5 Presentation of Financial Statements – Classification by the Borrower of a Term Loan that Contains a Repayment on Demand Clause was revised in October 2020 to align the corresponding wording with no change in conclusion

⁴ As a consequence of the amendments to HKFRS 17 issued in October 2020, HKFRS 4 was amended to extend the temporary exemption that permits insurers to apply HKAS 39 rather than HKFRS 9 for annual periods beginning before 1 January 2023

The Group is in the process of making an assessment of the impact of these new and revised HKFRS upon initial application. So far, the Group considers that, these new and revised HKFRSs are unlikely to have significant impact on the Group’s results of operations and financial position.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair value measurement

The Group measures unlisted financial instruments at fair value at the end of each of the Relevant Periods. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

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For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Relevant Periods.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories, financial assets and non-current assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs. In testing a cash-generating unit for impairment, a portion of the carrying amount of a corporate asset (e.g., a headquarters building) is allocated to an individual cash-generating unit if it can be allocated on a reasonable and consistent basis or, otherwise, to the smallest group of cash-generating units.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to the statement of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each of the Relevant Periods as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to the statement of profit or loss in the period in which it arises.

Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person's family and that person
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

- (b) the party is an entity where any of the following conditions applies:
 - (i) the entity and the Group are members of the same group;
 - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);
 - (iii) the entity and the Group are joint ventures of the same third party;
 - (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
 - (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
 - (vi) the entity is controlled or jointly controlled by a person identified in (a);

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- (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
- (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Plant and machinery	5%–19%
Motor vehicles	24%
Office equipment	19%
Leasehold improvements	20%–33%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at the end of each of the Relevant Periods.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in the statement of profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents leasehold improvements under construction and equipment under installation, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction during the period of construction. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at the end of each of the Relevant Periods.

Intangible assets are amortised on the straight-line basis over the following useful economic lives:

Software	5 years
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Research and development costs

All research costs are charged to the statement of profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the asset, as follows:

Buildings	2 to 5 years
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If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., a change to future payments resulting from a change in an index or rate) or a change in the assessment of an option to purchase the underlying asset.

(c) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of any machinery and equipment (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment that is considered to be low value.

Lease payments on short-term leases and leases of low-value assets are recognised as an expense on a straight-line basis over the lease term.

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Group as a lessor

When the Group acts as a lessor, it classifies at lease inception (or when there is a lease modification) each of its leases as either an operating lease or a finance lease.

Leases in which the Group does not transfer substantially all the risks and rewards incidental to ownership of an asset are classified as operating leases. When a contract contains lease and non-lease components, the Group allocates the consideration in the contract to each component on a relative stand-alone selling price basis. Rental income is accounted for on a straight-line basis over the lease terms and is included in revenue in the statement of profit or loss due to its operating nature. Initial direct costs incurred in negotiating and arranging an operating lease are added to the carrying amount of the leased asset and recognised over the lease term on the same basis as rental income. Contingent rents are recognised as revenue in the period in which they are earned.

Leases that transfer substantially all the risks and rewards incidental to ownership of an underlying asset to the lessee are accounted for as finance leases.

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under HKFRS 15 in accordance with the policies set out for “Revenue recognition” below.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

All regular way purchases and sales of financial assets are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in the statement of profit or loss when the asset is derecognised, modified or impaired.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognised in the statement of profit or loss.

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Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group’s consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a “pass-through” arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group’s continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At the end of each of the Relevant Periods, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Debt investments at fair value through other comprehensive income and financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables and contract assets which apply the simplified approach as detailed below.

- | | | |
|---------|---|--|
| Stage 1 | – | Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs |
| Stage 2 | – | Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs |

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- Stage 3 – Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables and contract assets that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade payables, other payables and accruals.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortised cost (loans and borrowings)

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in the statement of profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the statement of profit or loss.

Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in the statement of profit or loss.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the first-in, first-out basis and, in the case of work in progress and finished goods, comprises direct materials, direct labour and an appropriate proportion of overheads. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash on hand and demand deposits, and short term highly liquid investments that are readily convertible into known amounts of cash, are

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subject to an insignificant risk of changes in value, and have a short maturity of generally within three months when acquired, less bank overdrafts which are repayable on demand and form an integral part of the Group's cash management.

For the purpose of the consolidated statement of financial position, cash and cash equivalents comprise cash on hand and at banks, including term deposits, and assets similar in nature to cash, which are not restricted as to use.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of each of the Relevant Periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

Deferred tax assets are recognised for all deductible temporary differences, and the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.

The carrying amount of deferred tax assets is reviewed at the end of each of the Relevant Periods and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each of the Relevant Periods and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

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Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognised when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognised will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group with a significant financial benefit for more than one year, revenue recognised under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in HKFRS 15.

Sale of medical consumables

Revenue from the sale of medical consumables is recognised at the point in time when the control of the asset is transferred to the customers, generally on delivery of the medical consumables.

Revenue from other sources

Rental income is recognised on a time proportion basis over the lease terms.

Other income

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Contract liabilities

A contract liability is recognised when a payment is received or a payment is due (whichever is earlier) from a customer before the Group transfers the related goods. Contract liabilities are recognised as revenue when the Group performs under the contract (i.e., transfers control of the related goods to the customer).

Share-based payments

The Company operates a share option scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (“equity-settled transactions”).

The cost of equity-settled transactions with employees for share grants is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 27 to the Historical Financial Information.

The cost of equity-settled transactions is recognised in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each of the Relevant Periods until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will

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ultimately vest. The charge or credit to the statement of profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where grants include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled grant are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the grant are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled grant is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the grant is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled grant, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original grant, as described in the previous paragraph.

Other employee benefits

Pension scheme

The employees of the Group's subsidiaries which operate in Mainland China are required to participate in a central pension scheme operated by the local municipal government. These subsidiaries are required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to the statement of profit or loss as they become payable in accordance with the rules of the central pension scheme.

Dividends

Final dividends are recognised as a liability when they are approved by the shareholders in a general meeting. Proposed final dividends are disclosed in the notes to the financial statements.

Interim dividends are simultaneously proposed and declared, because the Company's memorandum and articles of association grant the directors the authority to declare interim dividends. Consequently, interim dividends are recognised immediately as a liability when they are proposed and declared.

Foreign currencies

The Historical Financial Information is presented in RMB, which is the Company's functional currency. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of each of the Relevant Periods. Differences arising on settlement or translation of monetary items are recognised in the statement of profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item.

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In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

The functional currency of certain overseas subsidiary is currency other than the RMB. As at the end of the Relevant Periods, the assets and liabilities of this entity are translated into RMB at the exchange rate prevailing at the end of the Relevant Periods and that statement of profit or loss is translated into RMB at the exchange rates that approximate to those prevailing at the dates of the transactions.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognised in the statement of profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising on acquisition are treated as assets and liabilities of the foreign operation and translated at the closing rate.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group's financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Judgements

In the process of applying the Group's accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the financial statements:

Research and development costs

All research costs are charged to profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred. Determining the amounts of development costs to be capitalised requires the use of judgements and estimation.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the Relevant Periods, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Recognition of income taxes and deferred tax assets

Determining income tax provision involves judgment on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatments of such transactions are reconsidered periodically to take into account all changes in tax legislation. Deferred tax assets are recognised in respect of deductible temporary differences and unused tax losses. As those deferred tax assets can only be recognised to the extent that it is probable that future taxable profits will be available against which the deductible temporary differences and the losses can be utilised, management's judgment is required to assess the probability of future taxable profits. Management's assessment is revised as necessary and additional deferred tax assets are recognised if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered. Further details are included in note 10.

Share-based payments

The Group has set up the share compensation plan for the Company's directors and the Group's employees.

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Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires determination of the most appropriate inputs to the valuation model including the volatility, risk-free interest rate and exercise multiple and making assumptions about them.

For the measure for the fair value of equity-settled transactions with employees at the grant date, the Group uses a binomial model. The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in note 28.

Impairment of non-financial assets

The Group assesses whether there are any indicators of impairment for all non-financial assets at the end of each of the Relevant Periods. Non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present values of those cash flows.

4. OPERATING SEGMENT INFORMATION

Operating segment information

For management purposes, the Group is not organised into business units based on their products and only has one reportable operating segment. Management monitors the operating results of the Group’s operating segment as a whole for the purpose of making decisions about resource allocation and performance assessment.

Geographical information

Since nearly all of the Group’s non-current assets were located in Mainland China, no geographical segment information is presented in accordance with HKFRS 8 *Operating Segments*.

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000	RMB’000
Revenue from contracts with customers			(unaudited)	
Medical devices revenue	9,054	22,426	12,061	16,431

Revenue from contracts with customers

(a) *Disaggregated revenue information*

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000	RMB’000
Goods transferred at a point in time	9,054	22,426	12,061	16,431

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The following table shows the amounts of revenue recognised during the Relevant Periods that were included in the contract liabilities at the beginning of the Relevant Period and recognised from performance obligations satisfied in previous periods:

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Revenue recognised that was included in contract liabilities at the beginning of the reporting period:				
Medical consumables	4,539	6,309	3,072	1,270

(b) *Performance obligations*

Information about the Group’s performance obligations is summarised below:

Sales of medical consumables

The performance obligation is satisfied at the point in time when the medical consumables are inspected and accepted by the customers. All of Payment in advance is typically required before shipping the medical consumables.

An analysis of other income and gains is as follows:

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000 (unaudited)	RMB'000
Other income				
Government grants*	3,649	1,295	633	3,515
Bank interest income	36	280	125	359
Investment income	1,252	2,704	1,383	445
Others	41	126	9	21
	<u>4,978</u>	<u>4,405</u>	<u>2,150</u>	<u>4,340</u>
Other Gains				
Fair value gains, net:				
Financial assets at fair value through profit or loss	305	–	397	13
Foreign exchange differences, net	–	–	51	1,877
	<u>305</u>	<u>–</u>	<u>448</u>	<u>1,890</u>
	<u>5,283</u>	<u>4,405</u>	<u>2,598</u>	<u>6,230</u>

* The government grants mainly represent subsidies received from the local governments for the purpose of compensation of expenses spent on research and development activities, allowance for development of new medical consumables and funds for talents.

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6. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	Notes	Year ended 31 December		Eight months ended 31 August	
		2020	2021	2021	2022
		RMB’000	RMB’000	RMB’000 (unaudited)	RMB’000
Cost of inventories sold		4,414	6,881	4,146	5,225
Depreciation of property, plant and equipment	13	2,284	2,728	1,697	2,888
Amortisation of intangible assets		–	5	1	12
Depreciation of right-of-use assets	14	863	1,737	845	1,855
Research and development expenses		42,307	89,827	71,647	35,751
Foreign exchange differences, net		3	567	(51)	(1,877)
Impairment of other receivables		6	118	73	69
Reversal of impairment		(2)	–	–	–
Lease payments not included in the measurement of lease liabilities		140	880	699	405
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Staff cost (excluding directors’ and chief executives’ remuneration (note 8)):					
Wages and salaries		23,935	28,774	17,212	31,354
Pension scheme contributions		2,278	5,443	3,896	8,081
Staff welfare expenses		1,087	954	442	777
Equity-settled share award expense		112,265	17,822	13,880	13,544

7. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000 (unaudited)	RMB’000
Interest on lease liabilities (note 14)	43	375	193	349

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8. DIRECTORS’, SUPERVISORS’ AND CHIEF EXECUTIVES’ REMUNERATION

The remuneration of each of the Group’s directors, supervisors and chief executives is set out below:

Group

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000 (unaudited)	RMB’000
Fees	–	–	–	–
Other emoluments:				
Salaries, bonuses, allowances and benefits in kind	2,434	2,931	1,768	1,883
Equity-settled share option expense	15	5,219	4,556	6,493
Pension scheme contributions	113	183	119	146
	<u>2,562</u>	<u>8,333</u>	<u>6,443</u>	<u>8,522</u>

During the Relevant Periods, equity-settled share awards were granted to Mr. Qiu Junkang, Mr. Zhu Jun and Ms. Li Cuiqin in respect of their services to the Group, further details of which are set out in note 28 to the Historical Financial Information. The fair value of such share awards, which has been recognised in the statement of profit or loss over the vesting period, was determined as at the date of grant and the amount included in the Historical Financial Information for the Relevant Periods is included in the above directors’ and supervisors’ remuneration disclosures.

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Executive directors, non-executive directors, supervisors and chief executives

Year ended	Fees	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Equity-settled share award expense	Total remuneration
31 December 2020	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Executive director:					
Mr. Li Kejian (a)	–	–	–	–	–
Non-executive directors:					
Mr. Lv Shiwen (b)	–	73	11	–	84
Mr. Wu Danke (c)	–	–	–	–	–
Mr. Yin Jie (d)	–	–	–	–	–
Mr. Sun Xiaolu (e)	–	–	–	–	–
	–	73	11	–	84
Supervisors:					
Ms. Yuan Dan (f)	–	–	–	–	–
Mr. Qiu Junkang (g)	–	98	11	–	109
Ms. Li Cuiqin (h)	–	628	16	15	659
Mr. Ouyang Ping (i)	–	–	–	–	–
Mr. Shen Qiang (j)	–	–	–	–	–
Ms. Tao Liming (k)	–	–	–	–	–
Mr. Zhu Haorong (l)	–	–	–	–	–
	–	726	27	15	768
Chief executives:					
Thach Buu Duong (m)	–	799	61	–	860
Mr. Zhu Jun (n)	–	836	14	–	850
	–	1,635	75	–	1,710

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Year ended	Fees	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Equity-settled share award expense	Total remuneration
31 December 2021	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Executive directors:					
Mr. Li Kejian (a)	–	–	–	–	–
Mr. Zhu Jun (n)	–	2,244	121	5,088	7,453
	–	2,244	121	5,088	7,453
Non-executive directors:					
Mr. Lv Shiwen (b)	–	–	–	–	–
Mr. Wu Danke (c)	–	–	–	–	–
Mr. Yin Jie (d)	–	–	–	–	–
Mr. Sun Xiaolu (e)	–	–	–	–	–
Mr. Chen Xinxing (o)	–	–	–	–	–
Mr. Zhao Chunsheng (p)	–	–	–	–	–
	–	–	–	–	–
Supervisors:					
Ms. Yuan Dan (f)	–	–	–	–	–
Mr. Qiu Junkang (g)	–	138	25	20	183
Ms. Li Cuiqin (h)	–	549	37	111	697
Mr. Ouyang Ping (i)	–	–	–	–	–
Mr. Shen Qiang (j)	–	–	–	–	–
Mr. Zhu Haorong (l)	–	–	–	–	–
	–	687	62	131	880
Chief executives:					
Mr. Zhu Jun (n)	–	2,244	121	5,088	7,453

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Eight months ended 31 August 2021 (Unaudited)	Fees	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Equity-settled share award expense	Total remuneration
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Executive directors:					
Mr. Li Kejian (a)	–	–	–	–	–
Mr. Zhu Jun (n)	–	1,469	79	4,469	6,017
	–	1,469	79	4,469	6,017
Non-executive directors:					
Mr. Lv Shiwen (b)	–	–	–	–	–
Mr. Wu Danke (c)	–	–	–	–	–
Mr. Yin Jie (d)	–	–	–	–	–
Mr. Sun Xiaolu (e)	–	–	–	–	–
Mr. Chen Xinxing (o)	–	–	–	–	–
Mr. Zhao Chunsheng (p)	–	–	–	–	–
	–	–	–	–	–
Supervisors:					
Ms. Yuan Dan (f)	–	–	–	–	–
Mr. Qiu Junkang (g)	–	90	16	13	119
Ms. Li Cuiqin (h)	–	209	24	74	307
Mr. Ouyang Ping (i)	–	–	–	–	–
Mr. Shen Qiang (j)	–	–	–	–	–
Mr. Zhu Haorong (l)	–	–	–	–	–
	–	299	40	87	426
Chief executives:					
Mr. Zhu Jun (n)	–	1,469	79	4,469	6,017

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Eight months ended 31 August 2022	Fees	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Equity-settled share award expense	Total remuneration
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Executive directors:					
Mr. Li Kejian (a)	–	–	–	–	–
Mr. Zhu Jun (n)	–	1,593	87	6,406	8,086
	–	1,593	87	6,406	8,086
Non-executive directors:					
Mr. Lv Shiwen (b)	–	–	–	–	–
Mr. Zhao Chunsheng (p)	–	–	–	–	–
Mr. Sun Xiaolu (e)	–	–	–	–	–
	–	–	–	–	–
Supervisors:					
Mr. Qiu Junkang (g)	–	96	21	13	130
Ms. Li Cuiqin (h)	–	194	38	74	306
Mr. Zhu Haorong (l)	–	–	–	–	–
	–	290	59	87	436
Chief executives:					
Mr. Zhu Jun (n)	–	1,593	87	6,406	8,086

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- (a) Mr. Li Kejian was appointed as the chairman of the board of directors in March 2013.
- (b) Mr. Lv Shiwen was appointed as a non-executive director in July 2014.
- (c) Mr. Wu Danke was appointed as a non-executive director of the Company in May 2017 and resigned in July 2021.
- (d) Mr. Yin Jie was appointed as a non-executive director of the Company in August 2019 and resigned in January 2021.
- (e) Mr. Sun Xiaolu was appointed as a non-executive director of the Company in November 2018.
- (f) Ms. Yuan Dan was appointed as a supervisor of the Company in May 2017 and resigned in November 2021.
- (g) Mr. Qiu Junkang was appointed as a supervisor of the Company in November 2018.
- (h) Ms. Li Cuiqin was appointed as a supervisor of the Company in November 2018.
- (i) Mr. Ouyang Ping was appointed as a supervisor of the Company in November 2018 and resigned in November 2021.
- (j) Mr. Shen Qiang was appointed as a supervisor of the Company in November 2018 and resigned in November 2021.
- (k) Ms. Tao Liming was appointed as a supervisor of the Company in May 2019 and resigned in June 2020.
- (l) Mr. Zhu Haorong was appointed as a supervisor of the Company in June 2020.
- (m) Mr. Thach Buu Duong was appointed as a Chief executive from May 2017 to September 2020. In October 2020, he was appointed as a deputy general manager and director of overseas affairs.
- (n) Mr. Zhu Jun was appointed as a chief executive in October 2020, and was appointed as an executive director in January 2021.
- (o) Mr. Chen Xinxing was appointed as a non-executive director of the Company in January 2021 and resigned in November 2021.
- (p) Mr. Zhao Chunsheng was appointed as a non-executive director of the Company in June 2021.

9. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the Relevant period and the eight months ended 31 August 2021 included zero, one, one and one chief executive, respectively, details of whose remuneration are set out in note 8 above. Details of the remuneration of the remaining five, four, four and four highest paid employees who are neither a director nor chief executive of the Company are as follows:

	Year ended 31 December		Eight months ended 31 August	
	2020 <i>RMB'000</i>	2021 <i>RMB'000</i>	2021 <i>RMB'000</i>	2022 <i>RMB'000</i>
Salaries, bonuses, allowances, and benefits in kind	4,944	3,452	2,050	2,456
Equity-settled share option expenses	2,589	4,194	2,952	2,362
Pension scheme contributions	183	321	185	297
	<u>7,716</u>	<u>7,967</u>	<u>5,187</u>	<u>5,115</u>

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The number of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands is as follows:

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000 (unaudited)	RMB’000
Nil to HKD1,000,000	–	–	–	–
HKD1,000,001 to HKD1,500,000	1	1	2	2
HKD1,500,001 to HKD2,000,000	2	1	2	2
HKD2,000,001 to HKD2,500,000	2	2	–	–
	<u>5</u>	<u>4</u>	<u>4</u>	<u>4</u>

10. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate. The Group’s principal applicable taxes and tax rates are as follows:

Mainland China

No provision for Mainland China income tax has been provided for at a rate of 25% pursuant to the Corporate Income Tax Law of the PRC and the related regulations (the “CIT Law”), as the Group’s PRC entities have no estimated assessable profits. One of the subsidiaries of the Group was recognised as a High and New Technology Enterprise and was entitled to a preferential tax rate of 15% during the Relevant Periods and the eight months ended 31 August 2021.

United States of America

The subsidiary incorporated in California, the United States is subject to statutory United States federal corporate income tax at a rate of 21%. It was also subject to the state income tax in California during the Relevant Periods. No provision for federal corporate income tax and the state income tax has been provided as the subsidiary was loss-making during the Relevant Periods.

A reconciliation of the tax expense applicable to loss before tax at the statutory rate for the country in which the Group’s major operating activities are domiciled to the tax expense at the effective tax rates, is as follows:

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000 (unaudited)	RMB’000
Loss before tax	159,333	126,497	92,436	61,422
Tax at the statutory tax rate (25%)	(39,833)	(31,624)	(23,109)	(15,355)
Different tax rate enacted by local authority	7,255	1,971	1,332	1,390
Additional deductible allowance for qualified research and development expenses	(5,219)	(4,791)	(2,591)	(4,937)
Expenses not deductible for tax	589	264	189	845
Deductible temporary difference and tax losses not recognised	<u>37,208</u>	<u>34,180</u>	<u>24,179</u>	<u>18,057</u>
Tax charge at the Group’s effective rate	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>

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The Group has accumulated tax losses in Mainland China of RMB361,241,000, RMB477,847,000, RMB452,875,000 and RMB538,264,000 as at 31 December 2020 and 2021, and 31 August 2021 and 2022, respectively, that will expire in one to five years for offsetting against future taxable profits of the companies in which the losses arose.

The Group also has accumulated tax losses in the United States of America of RMB2,312,000, RMB3,664,000, RMB3,162,000 and RMB4,667,000 accumulated as at 31 December 2020 and 2021, and 31 August 2021 and 2022, respectively, that will be carried forward indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

Deferred tax assets have not been recognised in respect of these losses as it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

11. DIVIDENDS

No dividend was paid or declared by the Company during the Relevant Periods.

12. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amounts is based on the loss attributable to owners of the parent, and the weighted average number of ordinary shares of 194,500,408, 224,377,198, 228,000,000 and 222,558,342 in issue during the Relevant Periods and the eight months ended 31 August 2021, respectively, as adjusted to reflect the rights issue during the year or period. The weighted average number of ordinary shares in issue before the conversion from a limited liability company into a joint stock company was determined by assuming that the paid-in capital had been fully converted into share capital upon transformation into a joint stock company in July 2021 (note 26).

No adjustment has been made to the basic loss per share amounts presented for the Relevant Periods and the eight months ended 31 August 2021 in respect of a dilution as the Group had no potentially dilutive ordinary shares in issue during the Relevant Periods and the eight months ended 31 August 2021.

13. PROPERTY, PLANT AND EQUIPMENT

Group

	<u>Plant and machinery</u>	<u>Motor vehicles</u>	<u>Office equipment</u>	<u>Leasehold improvements</u>	<u>Construction in progress</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2020						
At 1 January 2020:						
Cost	24,204	629	865	5,736	–	31,434
Accumulated depreciation	(5,243)	(94)	(527)	(4,989)	–	(10,853)
Net carrying amount	<u>18,961</u>	<u>535</u>	<u>338</u>	<u>747</u>	<u>–</u>	<u>20,581</u>
At 1 January 2020, net of accumulated depreciation	18,961	535	338	747	–	20,581
Additions	1,121	–	223	168	–	1,512
Depreciation provided during the year	(1,701)	(121)	(132)	(330)	–	(2,284)
Exchange realignment	–	–	(1)	–	–	(1)
At 31 December 2020, net of accumulated depreciation	<u>18,381</u>	<u>414</u>	<u>428</u>	<u>585</u>	<u>–</u>	<u>19,808</u>

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	<u>Plant and machinery</u>	<u>Motor vehicles</u>	<u>Office equipment</u>	<u>Leasehold improvements</u>	<u>Construction in progress</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 31 December 2020:						
Cost	25,325	629	1,087	5,904	–	32,945
Accumulated depreciation	<u>(6,944)</u>	<u>(215)</u>	<u>(659)</u>	<u>(5,319)</u>	<u>–</u>	<u>(13,137)</u>
Net carrying amount	<u><u>18,381</u></u>	<u><u>414</u></u>	<u><u>428</u></u>	<u><u>585</u></u>	<u><u>–</u></u>	<u><u>19,808</u></u>
31 December 2021						
At 1 January 2021:						
Cost	25,325	629	1,087	5,904	–	32,945
Accumulated depreciation	<u>(6,944)</u>	<u>(215)</u>	<u>(659)</u>	<u>(5,319)</u>	<u>–</u>	<u>(13,137)</u>
Net carrying amount	<u><u>18,381</u></u>	<u><u>414</u></u>	<u><u>428</u></u>	<u><u>585</u></u>	<u><u>–</u></u>	<u><u>19,808</u></u>
At 1 January 2021, net of accumulated depreciation	18,381	414	428	585	–	19,808
Additions	1,096	352	2,028	3,458	5,226	12,160
Depreciation provided during the year	(1,575)	(145)	(227)	(781)	–	(2,728)
Transfer	–	–	–	1,961	(1,961)	–
Disposals	<u>(115)</u>	<u>–</u>	<u>(9)</u>	<u>–</u>	<u>–</u>	<u>(124)</u>
At 31 December 2021, net of accumulated depreciation	<u><u>17,787</u></u>	<u><u>621</u></u>	<u><u>2,220</u></u>	<u><u>5,223</u></u>	<u><u>3,265</u></u>	<u><u>29,116</u></u>
At 31 December 2021:						
Cost	25,567	981	2,994	9,563	3,265	42,370
Accumulated depreciation	<u>(7,780)</u>	<u>(360)</u>	<u>(774)</u>	<u>(4,340)</u>	<u>–</u>	<u>(13,254)</u>
Net carrying amount	<u><u>17,787</u></u>	<u><u>621</u></u>	<u><u>2,220</u></u>	<u><u>5,223</u></u>	<u><u>3,265</u></u>	<u><u>29,116</u></u>

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	Plant and machinery	Motor vehicles	Office equipment	Leasehold improvements	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Eight months ended 31 August 2022						
At 1 January 2022:						
Cost	25,567	981	2,994	9,563	3,265	42,370
Accumulated depreciation	(7,780)	(360)	(774)	(4,340)	–	(13,254)
Net carrying amount	<u>17,787</u>	<u>621</u>	<u>2,220</u>	<u>5,223</u>	<u>3,265</u>	<u>29,116</u>
At 1 January 2022, net of accumulated depreciation						
	17,787	621	2,220	5,223	3,265	29,116
Additions	1,703	–	737	124	27	2,591
Depreciation provided during the period	(1,161)	(127)	(378)	(1,222)	–	(2,888)
Transfer	–	–	–	173	(173)	–
Exchange Realignment	–	–	1	–	–	1
At 31 August 2022, net of accumulated depreciation	<u>18,329</u>	<u>494</u>	<u>2,580</u>	<u>4,298</u>	<u>3,119</u>	<u>28,820</u>
At 31 August 2022:						
Cost	27,270	981	3,732	9,860	3,119	44,962
Accumulated depreciation	(8,941)	(487)	(1,152)	(5,562)	–	(16,142)
Net carrying amount	<u>18,329</u>	<u>494</u>	<u>2,580</u>	<u>4,298</u>	<u>3,119</u>	<u>28,820</u>

As at 31 December 2020, 2021 and 31 August 2022, there were no pledged property, plant and equipment.

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Company

	Plant and machinery	Motor vehicles	Office equipment	Leasehold improvements	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2020						
At 1 January 2020:						
Cost	20,609	487	369	1,760	–	23,225
Accumulated depreciation	<u>(3,239)</u>	<u>(54)</u>	<u>(229)</u>	<u>(1,760)</u>	<u>–</u>	<u>(5,282)</u>
Net carrying amount	<u>17,370</u>	<u>433</u>	<u>140</u>	<u>–</u>	<u>–</u>	<u>17,943</u>
At 1 January 2020, net of accumulated depreciation	17,370	433	140	–	–	17,943
Additions	344	–	58	–	–	402
Depreciation provided during the year	<u>(1,071)</u>	<u>(93)</u>	<u>(38)</u>	<u>–</u>	<u>–</u>	<u>(1,202)</u>
At 31 December 2020, net of accumulated depreciation	<u>16,643</u>	<u>340</u>	<u>160</u>	<u>–</u>	<u>–</u>	<u>17,143</u>
At 31 December 2020:						
Cost	20,953	487	427	1,760	–	23,627
Accumulated depreciation	<u>(4,310)</u>	<u>(147)</u>	<u>(267)</u>	<u>(1,760)</u>	<u>–</u>	<u>(6,484)</u>
Net carrying amount	<u>16,643</u>	<u>340</u>	<u>160</u>	<u>–</u>	<u>–</u>	<u>17,143</u>

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	Plant and machinery	Motor vehicles	Office equipment	Leasehold improvements	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2021						
At 1 January 2021:						
Cost	20,953	487	427	1,760	–	23,627
Accumulated depreciation	(4,310)	(147)	(267)	(1,760)	–	(6,484)
Net carrying amount	<u>16,643</u>	<u>340</u>	<u>160</u>	<u>–</u>	<u>–</u>	<u>17,143</u>
At 1 January 2021, net of accumulated depreciation	16,643	340	160	–	–	17,143
Additions	170	–	971	1,200	3,850	6,191
Depreciation provided during the year	(1,066)	(92)	(98)	(141)	–	(1,397)
Transfer	–	–	–	584	(584)	–
Disposals	(8)	–	(6)	–	–	(14)
At 31 December 2021, net of accumulated depreciation	<u>15,739</u>	<u>248</u>	<u>1,027</u>	<u>1,643</u>	<u>3,266</u>	<u>21,923</u>
At 31 December 2021:						
Cost	20,956	487	1,303	1,784	3,266	27,796
Accumulated depreciation	(5,217)	(239)	(276)	(141)	–	(5,873)
Net carrying amount	<u>15,739</u>	<u>248</u>	<u>1,027</u>	<u>1,643</u>	<u>3,266</u>	<u>21,923</u>

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	<u>Plant and machinery</u>	<u>Motor vehicles</u>	<u>Office equipment</u>	<u>Leasehold improvements</u>	<u>Construction in progress</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Eight months ended 31 August 2022						
At 1 January 2022:						
Cost	20,956	487	1,303	1,784	3,266	27,796
Accumulated depreciation	<u>(5,217)</u>	<u>(239)</u>	<u>(276)</u>	<u>(141)</u>	<u>–</u>	<u>(5,873)</u>
Net carrying amount	<u>15,739</u>	<u>248</u>	<u>1,027</u>	<u>1,643</u>	<u>3,266</u>	<u>21,923</u>
At 1 January 2022, net of accumulated depreciation						
	15,739	248	1,027	1,643	3,266	21,923
Additions	707	–	93	–	26	826
Depreciation provided during the period	(741)	(62)	(156)	(316)	–	(1,275)
Transfer	<u>–</u>	<u>–</u>	<u>–</u>	<u>173</u>	<u>(173)</u>	<u>–</u>
At 31 August 2022, net of accumulated depreciation						
	<u>15,705</u>	<u>186</u>	<u>964</u>	<u>1,500</u>	<u>3,119</u>	<u>21,474</u>
At 31 August 2022:						
Cost	21,663	487	1,396	1,957	3,119	28,622
Accumulated depreciation	<u>(5,958)</u>	<u>(301)</u>	<u>(432)</u>	<u>(457)</u>	<u>–</u>	<u>(7,148)</u>
Net carrying amount	<u>15,705</u>	<u>186</u>	<u>964</u>	<u>1,500</u>	<u>3,119</u>	<u>21,474</u>

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14. LEASES

The Group as a lessee

The Group has lease contracts for various items of properties used in its operations. Leases of properties generally have lease terms between 2 and 5 years. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group.

(a) Right-of-use assets

The carrying amounts of the Group’s right-of-use assets and the movements during the Relevant Periods are as follows:

Group	Buildings
	<i>RMB’000</i>
As at 1 January 2020	853
Additions	290
Depreciation charge	(863)
Exchange realignment	(16)
	<u>264</u>
At 31 December 2020	<u>264</u>
As at 1 January 2021	264
Additions	10,614
Depreciation charge	(1,737)
Termination of a lease	(163)
Exchange realignment	(1)
	<u>8,977</u>
At 31 December 2021	<u>8,977</u>
As at 1 January 2022	8,977
Depreciation charge	(1,855)
Revision of a lease term arising from a change in the non-cancellable period of a lease	(192)
	<u>6,930</u>
At 31 August 2022	<u>6,930</u>

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Company	Buildings
	<i>RMB’000</i>
As at 1 January 2020	192
Depreciation charge	(135)
	<hr/>
At 31 December 2020	57
	<hr/> <hr/>
As at 1 January 2021	57
Additions	3,673
Depreciation charge	(770)
	<hr/>
At 31 December 2021	2,960
	<hr/> <hr/>
As at 1 January 2022	2,960
Depreciation charge	(802)
	<hr/>
At 31 August 2022	2,158
	<hr/> <hr/>

(b) Lease liabilities

The carrying amounts of lease liabilities and the movements during the Relevant Periods are as follows:

Group

	As at 31 December		As at
	2020	2021	31 August
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Carrying amount at 1 January	855	577	9,001
New leases	290	10,527	–
Accretion of interest recognised during the year/period	43	375	349
Covid-19-related rent concessions from lessors	–	–	(100)
Payments	(608)	(2,264)	(1,230)
Termination of a lease	–	(214)	–
Revision of a lease term arising from a change in the non-cancellable period of a lease	–	–	(192)
Exchange realignment	(3)	–	–
	<hr/>	<hr/>	<hr/>
Carrying amount at the end of year/period	577	9,001	7,828
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>
Analysed into:			
Current portion	450	2,595	3,127
Non-current portion	127	6,406	4,701
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

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Company

	As at 31 December		As at
	2020	2021	31 August
	RMB'000	RMB'000	2022
			RMB'000
Carrying amount at 1 January	171	35	2,707
New leases	–	3,618	–
Accretion of interest recognised during the year/period	8	119	105
Payments	(144)	(1,065)	(276)
Carrying amount at the end of year/period	<u>35</u>	<u>2,707</u>	<u>2,536</u>
Analysed into:			
Current portion	35	1,111	1,500
Non-current portion	–	1,596	1,036

(c) The amounts recognised in the statement of profit or loss in relation to leases are as follows:

Group

	Year ended 31 December		Eight months ended	
	2020	2021	31 August	
	RMB'000	RMB'000	2021	2022
			(unaudited)	
			RMB'000	RMB'000
Interest on lease liabilities	43	375	193	349
Depreciation charge of right-of-use assets	863	1,737	845	1,855
Expense relating to short-term leases (included in administrative expenses)	126	825	681	377
Expense relating to leases of low-value assets (included in administrative expenses)	14	55	18	28
Total amount recognised in the statement of profit or loss	<u>1,046</u>	<u>2,992</u>	<u>1,737</u>	<u>2,609</u>

Company

	Year ended 31 December		Eight months ended	
	2020	2021	31 August	
	RMB'000	RMB'000	2021	2022
			(unaudited)	
			RMB'000	RMB'000
Interest on lease liabilities	8	119	60	105
Depreciation charge of right-of-use assets	135	770	359	802
Expense relating to short-term leases (included in administrative expenses)	–	515	502	92
Expense relating to leases of low-value assets (included in administrative expenses)	7	38	3	6
Total amount recognised in the statement of profit or loss	<u>150</u>	<u>1,442</u>	<u>924</u>	<u>1,005</u>

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15. INVESTMENTS IN SUBSIDIARIES

	As at 31 December		As at 31 August
	2020	2021	2022
	RMB'000	RMB'000	RMB'000
Investment costs of subsidiaries	336,270	407,565	408,199
Investment arising from equity-settled share-based payment*	5,998	8,311	4,663
	<u>342,268</u>	<u>415,876</u>	<u>412,862</u>

* The amount represents share-based payment expenses arising from the grant restricted shares of the Company to employees of the subsidiaries (Note 28) in exchange for their services provided to these subsidiaries, which were deemed to be investments made by the Company into these subsidiaries.

16. OTHER NON-CURRENT ASSETS

Group

	As at 31 December		As at 31 August
	2020	2021	2022
	RMB'000	RMB'000	RMB'000
Prepayments for insurance	244	102	131
Value-added tax recoverable	3,062	4,052	5,181
Prepayments for long-term assets	–	–	120
	<u>3,306</u>	<u>4,154</u>	<u>5,432</u>

Company

	As at 31 December		As at 31 August
	2020	2021	2022
	RMB'000	RMB'000	RMB'000
Prepayments for insurance	100	56	95
Value-added tax recoverable	1,814	4,013	5,152
	<u>1,914</u>	<u>4,069</u>	<u>5,247</u>

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17. INVENTORIES

Group

	As at 31 December		As at
	2020	2021	31 August
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	6,365	10,298	13,101
Work in progress	304	749	1,691
Finished goods	1,452	745	965
Goods shipped in transit	101	51	17
	8,222	11,843	15,774
Less: Provision for inventories	119	147	17
	8,103	11,696	15,757

Company

	As at 31 December		As at
	2020	2021	31 August
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	4,400	5,866	6,597

18. TRADE AND BILLS RECEIVABLES

Group

	As at 31 December		As at
	2020	2021	31 August
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade receivables	74	74	74
Impairment	(74)	(74)	(74)
	–	–	–
Bills receivables	–	–	–
	–	–	–

The Group’s main trading customers are the distributors. The Group’s trading terms with its customers are mainly on advance payments from the customers, except for some customers, which is with lower credit risk evaluated by the senior management and the Group seeks to maintain strict control over its outstanding receivables to minimize credit risk. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

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An ageing analysis of the trade receivables as at the end of each Relevant Periods, based on the invoice date and net of loss allowance, is as follows:

	As at 31 December		As at
	2020	2021	31 August
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
More than 2 years	74	74	74

The movements in the loss allowance for impairment of trade receivables are as follows:

	As at 31 December		As at
	2020	2021	31 August
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At beginning of year/period	76	74	74
Impairment losses, net	(2)	-	-
At end of year/period	74	74	74

An impairment analysis is performed at the end of the Relevant Periods using a provision matrix to measure expected credit losses. The provision rates are based on days past due for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the reporting date about past events, current conditions and forecasts of future economic conditions.

Set out below is the information about the credit risk exposure on the Group’s trade receivables using a provision matrix:

	As at 31 December 2020		
	Expected credit loss rate	Gross carrying amount	Expected credit losses
		<i>RMB'000</i>	<i>RMB'000</i>
Over 2 years	100.00%*	74	74

	As at 31 December 2021		
	Expected credit loss rate	Gross carrying amount	Expected credit losses
		<i>RMB'000</i>	<i>RMB'000</i>
Over 2 years	100.00%*	74	74

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	As at 31 August 2022		
	Expected credit loss rate	Gross carrying amount	Expected credit losses
		RMB'000	RMB'000
Over 2 years	100.00%*	74	74

* The Group sold medical products to a third party in 2018, and confirmed trade receivable of RMB74,000 on 31 December 2018, the management conducted a credit risk assessment on the trade receivable, and believed that the amount had suffered credit impairment and the trade receivable was not expected to be settled. Therefore, the Group made provision for impairment of trade receivable with the expected credit loss rate of 100%. During the Relevant Periods, except for the above trade receivable, the Group had no other trade receivables.

19. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

Group

	As at 31 December		As at 31 August
	2020	2021	2022
	RMB'000	RMB'000	RMB'000
Amounts due from related parties (note 31)	380	250	341
Prepayment to suppliers	8,907	9,207	15,935
Employee reserve fund	286	769	1,283
Deposits	223	1,429	1,986
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Others	102	1,447	1,566
	9,898	19,970	30,795
Impairment loss for other receivables	(28)	(146)	(215)
	9,870	19,824	30,580

The movements in provision for impairment of other receivables are as follows:

	As at 31 December		As at 31 August
	2020	2021	2022
	RMB'000	RMB'000	RMB'000
At beginning of year/period	22	28	146
Impairment losses, net	6	118	69
At end of year/period	28	146	215

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	As at 31 December		As at
	2020	2021	31 August
	RMB’000	RMB’000	2022
			RMB’000
Amounts due from related parties	380	186	10,186
Prepayment to suppliers	5,607	4,918	6,261
Employee reserve fund	–	9	61
Deposits	34	1,085	9,684
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Others	54	1,262	1,217
	6,075	14,328	29,013
Impairment loss for other receivables	(13)	(94)	(160)
	<u>6,062</u>	<u>14,234</u>	<u>28,853</u>

The movements in provision for impairment of other receivables are as follows:

	As at 31 December		As at
	2020	2021	31 August
	RMB’000	RMB’000	2022
			RMB’000
At beginning of year/period	5	13	94
Impairment losses, net	8	81	66
At end of year/period	<u>13</u>	<u>94</u>	<u>160</u>

20. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

Group

	As at 31 December		As at
	2020	2021	31 August
	RMB’000	RMB’000	2022
			RMB’000
Other unlisted investments, at fair value	25,521	–	4,013

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	As at 31 December		As at
	2020	2021	31 August
	RMB’000	RMB’000	2022
			RMB’000
Other unlisted investments, at fair value	1,075	–	–

The above unlisted investments were wealth management products issued by banks in Mainland China. They were mandatorily classified as financial assets at fair value through profit or loss as their contractual cash flows are not solely payments of principal and interest.

21. CASH AND CASH EQUIVALENTS

Group

	As at 31 December		As at
	2020	2021	31 August
	RMB’000	RMB’000	2022
			RMB’000
Cash and bank balances	7,486	157,867	87,696
Denominated in:			
RMB	7,163	125,270	71,627
USD	323	32,597	16,069
Cash and cash equivalents	7,486	157,867	87,696

Company

	As at 31 December		As at
	2020	2021	31 August
	RMB’000	RMB’000	2022
			RMB’000
Cash and bank balances	573	84,977	35,458
Denominated in:			
RMB	514	52,553	20,136
USD	59	32,424	15,322
Cash and bank balances	573	84,977	35,458

The RMB is not freely convertible into other currencies, however, under Mainland China’s Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short term time deposits are made for varying periods of between one day and three months depending on the immediate cash requirements of the Group, and earn interest at the respective short term time deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default.

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22. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice dates, is as follows:

Group

	As at 31 December		As at
	2020	2021	31 August
	RMB'000	RMB'000	2022
			RMB'000
Within 1 year	185	314	1,758

Company

	As at 31 December		As at
	2020	2021	31 August
	RMB'000	RMB'000	2022
			RMB'000
Within 1 year	153	38	1,144

The trade payables are non-interest-bearing and are normally settled within one month.

23. OTHER PAYABLES AND ACCRUALS

Group

	As at 31 December		As at
	2020	2021	31 August
	RMB'000	RMB'000	2022
			RMB'000
Amounts due to related parties (<i>note 31</i>)	81	63	135
Payroll and welfare payable	7,098	10,961	9,364
Other taxes and surcharges payable	1,256	1,408	1,317
Government grants payable*	960	960	960
Accrued expenses	7,092	10,104	4,492
Other payables	57	203	382
	<u>16,544</u>	<u>23,699</u>	<u>16,650</u>

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	As at 31 December		As at
	2020	2021	31 August
	RMB’000	RMB’000	2022
			RMB’000
Amounts due to related parties (note 31)	7	7	7
Payroll and welfare payable	3,212	3,959	3,489
Government grants payable*	960	960	960
Accrued expenses	4,204	9,329	2,615
Other payables	410	797	914
	<u>8,793</u>	<u>15,052</u>	<u>7,985</u>

* Government grants payable represents the payable which has not been recognised in profit or loss because the criteria attached to the grants have not been met by the Group.

Other payables and accruals are unsecured, non-interest-bearing and repayable on demand.

24. DEFERRED INCOME

Group

	As at 31 December		As at
	2020	2021	31 August
	RMB’000	RMB’000	2022
			RMB’000
Government grants	<u>461</u>	<u>–</u>	<u>2,000</u>

The government grants mainly represent the Group received from the local governments for compensating expenses arising from research activities and rewarding research and development costs incurred for certain projects.

The movements in government grants during the Relevant Periods are as follows:

	As at 31 December		As at
	2020	2021	31 August
	RMB’000	RMB’000	2022
			RMB’000
At beginning of the year/period	505	461	–
Grants received during the year/period	–	–	2,000
Amounts released to profit or loss during the year/period	<u>(44)</u>	<u>(461)</u>	<u>–</u>
At end of the year/period	<u>461</u>	<u>–</u>	<u>2,000</u>

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25. CONTRACT LIABILITIES

Group

The Group recognised the following revenue-related contract liabilities:

	As at 31 December		As at
	2020	2021	31 August
	RMB'000	RMB'000	2022
Advance received from customer:			RMB'000
Sale of medical consumables	6,309	1,681	1,773

During the Relevant Periods, a contract liability is recognised when a payment is received or a payment is due (whichever is earlier) from a customer before the Group transfers the related goods.

26. SHARE CAPITAL/PAID-IN CAPITAL

The Company was incorporated in March 2013 with initial authorised paid-in capital of USD2,000,000 with a par value of USD1 each. For the change of paid-in capital before the Relevant Periods, please refer to the section headed “History, Development and Corporate Structure” in this document.

A summary of movements in the Company’s issued share capital/paid-in capital during the Relevant Periods is as follows:

Share capital

	Total
	<i>RMB'000</i>
Issued and fully paid as at 1 January 2020 and 1 January 2021	–
Issue of ordinary shares upon conversion into a joint stock company (c)	228,000
As at 31 December 2021 and 31 August 2022	<u>228,000</u>

Paid-in capital

	Total
	<i>RMB'000</i>
As at 1 January 2020	25,401
Capital contribution by shareholders (a)	<u>25,401</u>
As at 31 December 2020 and 1 January 2021	50,802
Capital contribution by shareholders (b)	8,750
Conversion into a joint stock company (c)	<u>(59,552)</u>
As at 31 December 2021 and 31 August 2022	<u>–</u>

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Note:

- (a) In December 2020, the original shareholders of Ningbo SensCure Biotechnology Co., Ltd (“SensCure”) used the equity of SensCure they held as a consideration to contribute to the Company, which allowed the Company to increase its registered capital by RMB25,401,000. This equity exchange and reorganisation led to an increase of RMB25,401,000 in the Group’s paid-in capital. Please refer to the section “History, Development and Corporate Structure” in the Document.
- (b) In December 2020, the Company entered into a capital increase agreement with Ningbo Hongyingkang Enterprise Management Partnership (Limited Partnership) (寧波弘盈康企業管理合夥企業(有限合夥)). According to the capital increase agreement, Ningbo Hongyingkang Enterprise Management Partnership (Limited Partnership) subscribed for RMB3,243,000 registered capital, and fully paid in February 2021. In January 2021, Suzhou Proxima Venture Investment L.P. (Limited Partnership) (蘇州比鄰星創業投資合夥企業(有限合夥)), Zhuhai Gao Ling Junheng Equity Investment Partnership (Limited Partnership) (珠海高瓴鈞恒股權投資合夥企業(有限合夥)), Shenzhen Furong No. 1 Venture Capital Partnership Enterprise (Limited Partnership) (深圳富鎔一號創業投資合夥企業(有限合夥)), FutureX Investment I Company Limited, Qingdao Marine Innovation Industry Investment Fund Co., Ltd. (青島海洋創新產業投資基金有限公司), Ningbo Tongshang Venture Capital Partnership (Limited Partnership) (寧波通商創業投資合夥企業(有限合夥)) subscribed for RMB255,000, RMB2,895,000, RMB170,000, RMB1,192,000, RMB426,000 and RMB569,000 registered capital, respectively. As at 28 February 2021, the amount of capital injected by the above shareholders has all been paid.
- (c) In July 2021, the Company converted into a joint stock company with limited liability under the Company Law of the PRC. The net assets of the Company as of the conversion base date were converted into 228,000,000 ordinary shares at RMB1.00 each. The excess of the net assets converted over the nominal value of the ordinary shares was credited to the Company’s share premium.

27. RESERVES

The amounts of the Group’s reserves and the movements therein are presented in the consolidated statements of changes in equity on pages I-8 to I-11 of the Historical Financial Information.

28. SHARE-BASED PAYMENTS

The Group operates a share option scheme (the “Share Option Scheme”) for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Eligible participants of the Share Option Scheme include the Company’s directors and Group’s employees, via Ningbo Maishang Investment L.P. (Limited Partnership), Ningbo Kangrui Investment Management Partnership (Limited Partnership) and Ningbo Hongyingkang Enterprise Management Partnership (Limited Partnership). The eligible participants may achieve an option to subscribe for the shares of the Company at an exercise price and subject to other terms under the Share Option Scheme.

The share options granted during the Relevant Periods are as follows:

<u>Date of grant</u>	<u>Number of options granted</u>	<u>Exercise price per share</u>	<u>Vesting Period</u>
		<i>(RMB)</i>	<i>(months)</i>
2020/1/2	374,000	2	60
2021/1/2	732,728	2	60
2021/8/2	5,733,173	1.31	49-58

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The following share options were outstanding under the Share Option Scheme during the Relevant Periods:

	Weighted average exercise price per share	Number of options
	<i>RMB</i>	
At 1 January 2020	1.84	1,118,100
Granted during the year	2.00	374,000
Forfeited during the year	1.00	(2,800)
	<u>1.88</u>	<u>1,489,300</u>
At 31 December 2020 and 1 January 2021	1.88	1,489,300
At 1 January 2021	1.88	1,489,300
Granted during the year	1.38	6,465,901
Exercised during the year	0.75	(450,100)
	<u>1.51</u>	<u>7,505,101</u>
At 31 December 2021 and 1 January 2022	1.51	7,505,101
At 1 January 2022	1.51	7,505,101
Exercised during the period	1.00	(153,400)
	<u>1.52</u>	<u>7,351,701</u>
As at 31 August 2022	1.52	7,351,701

The fair value of equity-settled share options granted in the year ended 31 December 2020 and 2021 was estimated as at the date of grant using a binomial model, taking into account the terms and conditions upon which the options were granted. The following table lists the key assumptions that the model used.

	31 December	
	2020	2021
Expected volatility (%)	37.51%	45.76%-46.28%
Risk-free interest rate (%)	2.77%	2.13%-2.83%
Exercise multiple	2.2-2.8	2.2-2.8
Expected life	5 years	5 years
Expected dividend yield	0%	0%

During the year ended 31 December 2020 and 2021, the fair value of the shares granted were RMB109,032,000 and RMB72,018,000, respectively. There was no grants during the eight months ended 31 August 2022. The Group recognised equity-settled share award expense RMB112,265,000, RMB17,822,000 and RMB13,544,000 during the year ended 31 December 2020, 2021 and eight months ended 31 August 2022, respectively.

29. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the year ended 31 December 2020 and 2021, the Group had non-cash additions to right-of-use assets of RMB290,000 and RMB10,614,000, and non-cash additions to lease liabilities of RMB290,000 and RMB10,527,000, respectively, in respect of lease arrangements for buildings.

Pursuant to the board resolutions dated 1 December 2020, the registered capital of the Company was increased from RMB25,401,000 to RMB54,045,000. Among the increased registered capital of RMB28,644,000, the original shareholders of Ningbo SensCure Biotechnology Co., Ltd (“SensCure”) collectively subscribed for the increased registered capital of RMB25,401,000 by transferring the equity interests they held in Ningbo SensCure to the Company. For more details of the Equity Swap, please refer to the section “History, Development and Corporate Structure” in the Document.

Pursuant to the shareholders’ resolutions dated 15 June 2021 and the Promoters’ agreement dated 15 June 2021, then existing shareholders of the Company agreed to convert the Company into a joint stock limited liability company with a registered capital of RMB228,000,000. The net asset value of the Company as of the conversion base date amounted to RMB556,785,000, of which RMB228,000,000 has been converted into 228,000,000 shares of a par value of RMB1.00 each and issued to the then shareholders of the Company. The excess of the net assets converted over the nominal value of the ordinary shares was credited to the Company’s share premium. The details of the increase of registered capital are presented the section “History, Development and Corporate Structure” in the Document.

On 9 August 2021, the Company and Mr. Diao Yuepeng jointly funded the establishment of Beijifeng Biotechnology (Shanghai) Co., Ltd. and Huifeng Biotechnology (Shanghai) Co., Ltd. Mr. Diao Yuepeng separately made capital contributions to the two companies in the form of his own proprietary technologies and completed the transfer of property rights on 9 August 2021.

Based on the development of the two proprietary technologies in the market, the management of the Group estimates that the proprietary technologies contributed by Mr. Diao Yuepeng cannot be capitalised, because the requirements under *HKAS 38 Intangible Assets* cannot be fully satisfied. Therefore, the management recognised the two proprietary technologies as research and development expense.

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(b) Changes in liabilities arising from financing activities

	Lease liabilities
	<i>RMB’000</i>
At 1 January 2020	855
Changes from financing cash flows	(608)
New leases	290
Finance costs on lease liabilities	43
Exchange realignment	(3)
At 31 December 2020 and 1 January 2021	577
Lease payment	(2,264)
New leases	10,527
Interest expense	375
Termination of a lease	(214)
At 31 December 2021 and 1 January 2022	9,001
Lease payment	(1,230)
Covid-19-related rent concessions from lessors	(100)
Interest expense	349
Revision of a lease term arising from a change in the non-cancellable period of a lease	(192)
At 31 August 2022	7,828

(c) Total cash outflow for leases

The total cash outflow for leases included in the statement of cash flows is as follows:

	Year ended 31 December		Eight months ended 31 August
	2020	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Within operating activities	140	880	405
Within financing activities	608	2,264	1,230
	748	3,144	1,635

30. COMMITMENTS

The Group had the following capital commitments at the end of each of the Relevant Periods:

	As at 31 December		As at 31 August
	2020	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Contracted, but not provided for:			
Plant and machinery	–	1,094	772

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31. RELATED PARTY TRANSACTIONS

- (a) Related parties for the year ended 31 December 2020 and 2021 and the eight months ended 31 August 2022 were as follows:

Name	Relationship with the Company
Ningbo Linfeng Biotechnology Co., Ltd.	Controlled by a Controlling Shareholder
Jenscare Scientific Co., Ltd.	Controlled by a Controlling Shareholder
Ningbo Linstant Polymer Materials Co., Ltd.	Controlled by a Controlling Shareholder
Ningbo Hicren Biotechnology Co., Ltd.	Controlled by a Controlling Shareholder
Shanghai Jianshi Bio-tech Co., Ltd.	Controlled by a Controlling Shareholder
Ningbo Hangzhou Bay New District Muhe Property Co., Ltd.	Controlled by a Controlling Shareholder
Ningbo Shidi Medical Technology Co., Ltd.	Controlled by a Controlling Shareholder
Ningbo Diochange Medical Technology Co., Ltd.	Controlled by a Controlling Shareholder
Ningbo Trando 3D Medical Technology Co., Ltd.	Controlled by a Controlling Shareholder
VitaView MedTech (Zhejiang) Co., Ltd.	Controlled by a Controlling Shareholder
Ningbo Lide Medical Technology Co., Ltd.	Controlled by a Controlling Shareholder
Ningbo Shouquanzhai Pharmaceutical Retail Co., Ltd.	Controlled by a Controlling Shareholder
TD Engineering	An entity controlled by a member of key management personnel of the Company
Mr. Diao Yuepeng	Key management personnel of the Company

- (b) The Group had the following transactions with related parties during the Relevant Periods and eight months ended 31 August 2021:

	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			(unaudited)	
Advances of payroll from a related party				
Ningbo Hicren Biotechnology Co., Ltd.	23	–	–	–
Shanghai Jianshi Bio-tech Co., Ltd.	114	–	–	–
	<u>137</u>	<u>–</u>	<u>–</u>	<u>–</u>
Advances of payroll to a related party				
Jenscare Scientific Co., Ltd.	40	–	–	–
Shanghai Jianshi Bio-tech Co., Ltd.	89	16	–	–
Ningbo Shidi Medical Technology Co., Ltd.	9	–	–	–
	<u>138</u>	<u>16</u>	<u>–</u>	<u>–</u>
Advances of tax to a related party				
Ningbo Diochange Medical Technology Co., Ltd.	7	–	–	–
	<u>7</u>	<u>–</u>	<u>–</u>	<u>–</u>
Expenditures of proprietary technologies				
Mr. Diao Yuepeng*	–	50,973	50,973	–
	<u>–</u>	<u>50,973</u>	<u>50,973</u>	<u>–</u>

* The details were disclosed in Note 29 (a) in this Accountants’ Report.

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	Year ended 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i> (unaudited)	<i>RMB’000</i>
Advance of a utility bill to a related party				
Ningbo Linfeng Biotechnology Co., Ltd.	456	486	260	635
Purchases of products				
Ningbo Linstant Polymer Materials Co., Ltd.	41	14	14	63
TD Engineering	158	376	272	865
Ningbo Trando 3D Medical Technology Co., Ltd.	–	59	–	–
Ningbo Shouquanzhai Pharmaceutical Retail Co., Ltd.	–	22	–	–
	<u>199</u>	<u>471</u>	<u>286</u>	<u>928</u>
Purchases of service				
Shanghai Jianshi Bio-tech Co., Ltd.	29	–	–	–
Ningbo Hangzhou Bay New District Muhe Property Co., Ltd.	50	160	35	303
Ningbo Shidi Medical Technology Co., Ltd.	31	203	99	99
	<u>110</u>	<u>363</u>	<u>134</u>	<u>402</u>

The pricing of products and services was made according to the published prices and conditions similar to those offered to the major customers of the suppliers.

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(c) Outstanding balances with related parties:

	As at 31 December		As at
	2020	2021	31 August
	RMB'000	RMB'000	RMB'000
Prepayments, other receivables and other assets:			
Due from related parties:			
Jenscare Scientific Co., Ltd.*	89	–	–
Shanghai Jianshi Bio-tech Co., Ltd.***	136	110	110
Ningbo Linstant Polymer Materials Co., Ltd.*	18	17	17
TD Engineering*	137	64	152
Ningbo Trando 3D Medical Technology Co., Ltd.*	–	59	59
Ningbo Shidi Medical Technology Co., Ltd.*	–	–	3
	<u>380</u>	<u>250</u>	<u>341</u>
Other payables and accruals:			
Due to related parties:			
Ningbo Linfeng Biotechnology Co., Ltd.***	60	56	121
Shanghai Jianshi Bio-tech Co., Ltd.*	7	7	7
Jenscare Scientific Co., Ltd.**	1	–	–
Ningbo Diochange Medical Technology Co., Ltd.**	13	–	–
Ningbo Hangzhou Bay New District Muhe Property Co., Ltd.*	–	–	7
	<u>81</u>	<u>63</u>	<u>135</u>

* The balances are trade in nature.

** The balances are non-trade in nature.

*** The balances include both trade balances and non-trade balances in nature.

As confirmed by the directors of the Company, except for utility payables due to Ningbo Linfeng, all outstanding non-trade balances with related parties (including non-trade balance of amounts due from Shanghai Jianshi Bio-tech Co., Ltd.) will be fully settled before the [REDACTED], and the Company does not plan to have additional non-trade related party transactions in the future. As of December 31, 2020 and 2021, and August 31, 2022, the utility payables due to Ningbo Linfeng were RMB33,000, RMB56,000, RMB121,000, respectively.

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(d) Compensation of key management personnel of the Group:

	As at 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Salaries, bonuses, allowances, and benefits in kind	5,476	7,424	4,672	5,797
Pension scheme contributions	239	652	420	528
Equity-settled share award expense	2,105	8,691	6,951	9,032
Total compensation paid to key management personnel	7,820	16,767	12,043	15,357

(e) Leases with related parties

The Group as a lessor

The Group as a lessor

	As at 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Shanghai Jianshi Bio-tech Co., Ltd.	17	–	–	–
Jenscare Scientific Co., Ltd.	13	–	–	–
	30	–	–	–

The office areas of approximately 99 and 126 square metres of the Group’s building in Pudong New District, Shanghai, were provided respectively to the Group’s related parties for their occupation starting from 1 January 2018 to 31 December 2020. The leases of the premises have been charged at a mutually agreed amount ranging from RMB42 to RMB47 per month per square metres. At 31 March 2020, the rental contracts with the Group’s related parties were terminated in advance.

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The Group as a lessee

The Group has rental contracts with Ningbo Linfeng Biotechnology Co., Ltd., VitaView MedTech (Zhejiang) Co., Ltd., Ningbo Lide Medical Technology Co., Ltd. At the end of each of the Relevant Periods, the Group had total lease liabilities with Ningbo Linfeng Biotechnology Co., Ltd. under non-cancellable leases falling due as follows:

The Group as a lessee

	As at 31 December		Eight months ended 31 August	
	2020	2021	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			(unaudited)	
Short term				
Rental fee	126	343	83	63

The Group as a lessee

	As at 31 December		As at 31 August
	2020	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Long term			
Lease liabilities – current	396	454	473
Lease liabilities – non-current	127	1,543	1,318
	523	1,997	1,791

At the end of each of the Relevant Periods, the Group’s right-of-use assets relating to such rental contracts amounted to RMB190,000, RMB1,939,000 and RMB1,616,000, respectively.

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32. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

As at 31 December 2020

Financial assets

	Financial assets at fair value through profit or loss	Financial assets at amortised cost	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Financial assets at fair value through profit or loss	25,521	–	25,521
Financial assets included in prepayments, other receivables and other assets	–	297	297
Cash and cash equivalents	–	7,486	7,486
	<u>25,521</u>	<u>7,783</u>	<u>33,304</u>

Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB'000</i>
Trade payables	185
Financial liabilities included in other payables and accruals	4,792
	<u>4,977</u>

As at 31 December 2021

Financial assets

	Financial assets at fair value through profit or loss	Financial assets at amortized cost	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Financial assets included in prepayments, other receivables and other assets	–	2,730	2,730
Cash and cash equivalents	–	157,867	157,867
	<u>–</u>	<u>160,597</u>	<u>160,597</u>

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Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB'000</i>
Trade payables	314
Financial liabilities included in other payables and accruals	9,052
	9,366

As at 31 August 2022

Financial assets

	Financial assets at fair value through profit or loss	Financial assets at amortised cost	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Financial assets at fair value through profit or loss	4,013	–	4,013
Financial assets included in prepayments, other receivables and other assets	–	2,954	2,954
Cash and cash equivalents	–	87,696	87,696
	4,013	90,650	94,663

Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB'000</i>
Trade payables	1,758
Financial liabilities included in other payables and accruals	2,429
	4,187

33. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

The carrying amounts and fair values of the Group’s financial instruments approximate to fair values. The carrying amounts and fair values of the Group’s financial instruments, other than those with carrying amounts that reasonably approximate to fair values, are as follows:

	Carrying amounts			Fair value		
	As at 31 December 2020	2021	As at 31 August 2022	As at 31 December 2020	2021	As at 31 August 2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Financial assets						
Financial assets at fair value through profit or loss	25,521	–	4,013	25,521	–	4,013

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Management has assessed that the fair values of cash and cash equivalents, trade receivables, trade payables, financial assets included in prepayments, other receivables and other assets, and financial liabilities included in other payables and accruals approximate to their carrying amounts largely due to the short term maturities of these instruments.

The Group’s finance department is responsible for determining the policies and procedures for the fair value measurement of financial instruments. At the end of each of the Relevant Periods, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The directors review the results of the fair value measurement of financial instruments periodically for financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. The following methods and assumptions were used to estimate the fair values:

Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

Assets measured at fair value:

As at 31 December 2020

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable markets (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Financial assets at fair value through profit or loss	–	25,521	–	25,521

As at 31 December 2021

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable markets (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Financial assets at fair value through profit or loss	–	–	–	–

As at 31 August 2022

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable markets (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Financial assets at fair value through profit or loss	4,013	–	–	4,013

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34. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments comprise cash and cash equivalents. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various other financial assets and liabilities such as other receivables and other payables, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are foreign currency risk, credit risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarised below.

Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from purchases by operating units in currencies other than the units’ functional currencies.

The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in foreign currency exchange rate, with all other variables held constant, of the Group’s loss before tax (due to changes in the fair value of forward currency contracts) and the Group’s equity.

	Increase/ (decrease) in rate of foreign currency	Increase/ (decrease) in loss before tax	Increase/ (decrease) in equity
	%	RMB’000	RMB’000
31 December 2020			
If RMB weakens against USD	5	7	7
If RMB strengthens against USD	(5)	(7)	(7)
31 December 2021			
If RMB weakens against USD	5	1,624	1,624
If RMB strengthens against USD	(5)	(1,624)	(1,624)
31 August 2022			
If RMB weakens against USD	5	791	791
If RMB strengthens against USD	(5)	(791)	(791)

Credit risk

The Group trades only with recognised and creditworthy third parties. It is the Group’s policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and the Group’s exposure to bad debts is not significant.

The credit risk of the Group’s other financial assets, which comprise cash and bank balances, financial assets included in prepayments, other receivables and other assets, with a maximum exposure equal to the carrying amount of these instruments.

Since the Group trades only with recognised and creditworthy third parties, there is no requirement for collateral. Concentrations of credit risk are managed by customer/counterparty, by geographical region and by industry sector. There are no significant concentrations of credit risk within the Group as the customer bases of the Group’s other receivables are widely dispersed in different sectors and industries.

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Maximum exposure and year/period-end staging as at 31 December 2020 and 2021 and 31 August 2022

The table below shows the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year/period-end staging classification as at 31 December 2020 and 2021 and 31 August 2022. The amounts presented are gross carrying amounts for financial assets.

As at 31 December 2020

	12-month	Lifetime ECLs			Total
	ECLs				
	Stage 1	Stage 2	Stage 3	Simplified approach	
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Trade and bills receivables	74	–	–	–	74
Financial assets included in prepayments, deposits and other receivables					
– Normal*	297	–	–	–	297
Cash and cash equivalents					
– Not yet past due	7,486	–	–	–	7,486
Total	7,857	–	–	–	7,857

As at 31 December 2021

	12-month	Lifetime ECLs			Total
	ECLs				
	Stage 1	Stage 2	Stage 3	Simplified approach	
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Trade and bills receivables	74	–	–	–	74
Financial assets included in prepayments, deposits and other receivables					
– Normal*	2,730	–	–	–	2,730
Cash and cash equivalents					
– Not yet past due	157,867	–	–	–	157,867
Total	160,671	–	–	–	160,671

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As at 31 August 2022

	12-month ECLs		Lifetime ECLs		Total
	Stage 1	Stage 2	Stage 3	Simplified approach	
	RMB’000	RMB’000	RMB’000	RMB’000	
Trade and bills receivables	74	–	–	–	74
Financial assets included in prepayments, deposits and other receivables					
– Normal*	2,954	–	–	–	2,954
Cash and cash equivalents					
– Not yet past due	87,696	–	–	–	87,696
Total	90,724	–	–	–	90,724

* The credit quality of the financial assets included in prepayments, other receivables and other assets is considered to be “normal” when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be “doubtful”.

Liquidity risk

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

	As at 31 December 2020				Total
	On demand	Less than 3 months	3 to less than 12 months	1 to 5 years	
	RMB’000	RMB’000	RMB’000	RMB’000	
Trade payables	185	–	–	–	185
Financial liabilities in other payables and accruals	4,792	–	–	–	4,792
Lease liabilities	312	62	117	98	589
	5,289	62	117	98	5,566

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As at 31 December 2021

	On demand	Less than 3 months	3 to less than 12 months	1 to 5 years	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables	314	–	–	–	314
Financial liabilities in other payables and accruals	9,052	–	–	–	9,052
Lease liabilities	–	714	2,379	6,972	10,065
	<u>9,366</u>	<u>714</u>	<u>2,379</u>	<u>6,972</u>	<u>19,431</u>

As at 31 August 2022

	On demand	Less than 3 months	3 to less than 12 months	1 to 5 years	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables	1,758	–	–	–	1,758
Financial liabilities in other payables and accruals	2,429	–	–	–	2,429
Lease liabilities	535	785	2,302	4,953	8,574
	<u>4,722</u>	<u>785</u>	<u>2,302</u>	<u>4,953</u>	<u>12,761</u>

Capital management

The primary objectives of the Group’s capital management are to safeguard the Group’s ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders’ value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Relevant Periods.

35. EVENTS AFTER THE RELEVANT PERIODS

There were no significant events after the end of the Relevant Periods that require additional disclosure or adjustments.

36. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Group or any of its subsidiaries in respect of any period subsequent to 31 August 2022.

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

The following information does not form part of the Accountants’ Report from Ernst & Young, Certified Public Accountants, Hong Kong, the Company’s reporting accountants, as set out in Appendix I to this Document, and is included herein for information purpose only. The unaudited [REDACTED] financial information should be read in conjunction with the section headed “Financial Information” in this document and the Accountants’ Report set out in Appendix I to this document.

A. UNAUDITED [REDACTED] STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited [REDACTED] adjusted consolidated net tangible assets of the Group prepared in accordance with Rule 4.29 of the Listing Rules and with reference to Accounting Guideline 7 Preparation of [REDACTED] Financial Information for inclusion in Investment Circulars issued by the Hong Kong Institute of Certified Public Accountants for illustration purposes only, and is set out here to illustrate the effect of the [REDACTED] on the consolidated net tangible assets of the Group attributable to owners of the parent as if the [REDACTED] had taken place on 31 August 2022.

The unaudited [REDACTED] statement of adjusted consolidated net tangible assets of the Group has been prepared for illustrative purpose only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group to owners of the parent had the [REDACTED] been completed as at 31 August 2022 or at any future dates.

Audited consolidated net tangible assets of the Group attributable to owners of the Company as at 31 August 2022	Estimated net [REDACTED] from the [REDACTED]	Unaudited [REDACTED] adjusted consolidated net tangible assets as at 31 August 2022	Unaudited [REDACTED] adjusted consolidated net tangible assets per Share as at 31 August 2022	
<i>RMB’000</i> (Note 1)	<i>RMB’000</i> (Note 2)	<i>RMB’000</i>	<i>RMB</i> (Note 3)	<i>HK\$</i> (Note 4)
Based on an [REDACTED] of HK\$[REDACTED] per Share	126,348	[REDACTED]	[REDACTED]	[REDACTED]
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

Notes:

1. The consolidated net tangible assets of the Group attributable to owners of the Company as at 31 August 2022 is based on audited consolidated net tangible assets of the Group attributable to owners of the Company as at 31 August 2022 of RMB126,395,000 set out in the Accountants’ Report in Appendix I to this document, after deducting of other intangible assets of RMB47,000.
2. The estimated net [REDACTED] from the [REDACTED] are based on an [REDACTED] of HK\$[REDACTED] per Share after deduction of the [REDACTED] fees and other related expenses payable by the Company.
3. The unaudited [REDACTED] adjusted consolidated net tangible assets per Share is calculated based on [REDACTED] Shares in issue immediately following the completion of the [REDACTED].
4. For the purpose of this unaudited [REDACTED] statement of adjusted net tangible assets, the balances stated in RMB are converted into HK\$ at the rate of RMB1.00 to HK\$1.0952.
5. No adjustment has been made to the unaudited [REDACTED] adjusted consolidated net tangible assets to reflect any trading results or other transactions of the Group entered into subsequent to 31 August 2022.

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED [REDACTED] FINANCIAL INFORMATION

[REDACTED]

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

TAXATION ON DIVIDENDS

Individual Investor

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) (the "IIT Law"), which was last amended on August 31, 2018 and came into effect on January 1, 2019 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was last amended on December 18, 2018 and came into effect on January 1, 2019, for individual income including interest, dividend and bonus, shall pay individual income tax with applicable proportional tax rate of 20%. Unless otherwise provided by the competent financial and taxation authorities under the State Council, all the interest, dividend and bonus derived from enterprises, institutions, other organisations in PRC and resident individuals' income from the aforesaid are deemed as derived from the PRC whether the payment place is in the PRC. Pursuant to the Circular on Certain Issues Concerning the Policies of Individual Income Tax (《關於個人所得稅若干政策問題的通知》) promulgated by the Ministry of Finance and the State Administration of Taxation on May 13, 1994, overseas individuals are exempted from the individual income tax for dividends or bonuses received from foreign-invested enterprises.

Enterprise Investors

In accordance with the Enterprise Income Tax Law of the People's Republic of China (《中華人民共和國企業所得稅法》) (the "EIT Law"), which was amended on December 29, 2018 and became effective on the same date, and the Implementation Provisions of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》), which was amended on April 23, 2019 and became effective on the same date, a non-resident enterprise is generally subject to enterprise income tax at a rate of 10% on PRC-sourced income (including dividends received from a PRC resident enterprise that issues shares in Hong Kong), if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. The aforesaid income tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due.

The Circular on Issues Relating to the Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid to Overseas Non-Resident Enterprise Shareholders of H Shares (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) (Guo Shui Han[2008]No. 897), which was issued by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold enterprise income tax at a rate of 10% on the dividends of 2008 and onwards that it distributes to overseas non-resident enterprise shareholders of H Shares. In addition, the Response to Questions on Levying Enterprise Income Tax on Dividends Derived by Non-resident Enterprise from Holding Stock such as B Shares (《關於非居民企業取得B股等股票股息徵收企業所得稅問題的批覆》) (Guo Shui Han[2009]No. 394), which was issued by the SAT and came into effect on July 24, 2009, further provides that any PRC-resident enterprise whose shares are listed on overseas stock exchanges must withhold and remit enterprise income tax at a rate of 10% on dividends of 2008 and onwards that it distributes to non-resident enterprises. Such tax rate may be further modified pursuant to the tax treaty or agreement that China has entered into with a relevant country or area, where applicable.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《〈內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排〉第五議定書》), which came in to effect on December 6, 2019, adds a criteria for the qualification of entitlement to enjoy treaty benefits. Although there may be other provisions under the Arrangement, the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Agreement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law documents, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) (Guo Shui Han[2009]No. 81).

Tax Treaties

Non-PRC resident investors residing in countries which have entered into treaties for the avoidance of double taxation with the PRC or residing in Hong Kong or Macau are entitled to a reduction of the withholding taxes imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties/Arrangements with a number of countries and regions including Hong Kong, Macau, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant income tax agreements or arrangements are required to apply to the Chinese tax authorities for a refund of the withholding tax in excess of the agreed tax rate, and the refund payment is subject to approval by the Chinese tax authorities.

TAXATION ON SHARE TRANSFER

Individual Investor

According to the IIT Law and its implementation provisions, gains realized on the sale of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

Pursuant to the Circular of Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) (Cai Shui Zi[1998]No. 61) issued by the MOF and the State Administration of Taxation on March 20, 1998, from January 1, 1997, income of individuals from transfer of the shares of listed enterprises continues to be exempted from individual income tax. On December 31, 2009, the MOF, the State Administration of Taxation and CSRC jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》)

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(Cai Shui[2009]No. 167), which became effective on December 31, 2009, states that individuals' income from the transfer of listed shares on the Shanghai Stock Exchange and the Shenzhen Stock Exchange shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction (as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals' Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) (Cai Shui[2010]No. 70) jointly issued by the above three departments on November 10, 2010).

As of the Latest Practicable Date, no aforesaid provisions had expressly provided that whether individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges. To the knowledge of the Company, in practice, the PRC tax authorities have not levied income tax from non-PRC resident individuals on gains from the transfer of PRC resident enterprises listed on overseas stock exchange. However, there is no assurance that the PRC tax authorities will not change these practices which could result in levying income tax on non-PRC resident individuals on gains from the sale of H shares.

Enterprise Investors

In accordance with the EIT Law and its implementation provisions, a non-resident enterprise is generally subject to enterprise income tax at the rate of a 10% on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. Such income tax payable for non-resident enterprises are deducted at source, where the payer of the income are required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

Stamp Duty

Pursuant to the Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例》), which came into effect on October 1, 1988 and amended on January 8, 2011, and the Implementation Provisions of Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例施行細則》), which came into effect on October 1, 1988, PRC stamp duty only applies to specific proof executed or received within the PRC, having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

The PRC currently does not impose any estate duty.

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MAJOR TAXES ON THE COMPANY IN THE PRC

Enterprise Income Tax Law

According to the Enterprise Income Tax Law of the People's Republic of China (《中華人民共和國企業所得稅法》) (the "**Enterprise Income Tax Law**"), which was amended on December 29, 2018 and became effective on the same date and the Regulation on the Implementation of the Enterprise Income Tax Law of the People's Republic of China (《中華人民共和國企業所得稅法實施條例》), which was amended on April 23, 2019 and became effective on the same date, the applicable enterprise income tax rate of both domestic and foreign-funded enterprises shall be 25%. Enterprises are classified into resident and non-resident enterprises. A resident enterprise shall pay enterprise income tax on its incomes derived from both inside and outside China. For a non-resident enterprise having offices or establishments inside China, it shall pay enterprise income tax on its incomes derived from China as well as on incomes that it earns outside China but which has real connection with the said offices or establishments, the enterprise income tax rate applicable shall be 25%. For a non-resident enterprise having no office or establishment inside China, or for a non-resident enterprise whose incomes have no actual connection to its office or establishment inside China, it shall pay enterprise income tax on the incomes derived from China the enterprise income tax rate applicable shall be 10%.

Value-Added Tax

According to the Interim Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》) which was promulgated by the State Council on December 13, 1993, and amended on November 10, 2008, February 6, 2016 and November 19, 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》) which was promulgated by the Ministry of Finance on December 25, 1993 and subsequently amended on December 15, 2008 and October 28, 2011 (collectively, the "**VAT Law**"), all enterprises and individuals that engage in the sale of goods, the provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods within the territory of the PRC shall pay value-added tax at the rate of 0%, 6%, 11% and 17% for the different goods it sells and different services it provides, except when specified otherwise.

According to the Notice on the Adjustment to VAT Rates (《關於調整增值稅稅率的通知》) (Cai Shui[2018]No. 32), promulgated by the MOF and the State Administration of Taxation on April 4, 2018 and became effective as of May 1, 2018, the VAT rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Announcement on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值稅改革有關政策的公告》) (2019 No. 39 of MOF, State Administration of Taxation and General Administration of Customs), promulgated by the MOF, the State Administration of Taxation and the General Administration of Customs on March 20, 2019 and became effective on April 1, 2019, the VAT rates of 16% and 10% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 13% and 9%, respectively.

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TAXATION AND FOREIGN EXCHANGE

Shenzhen-Hong Kong Stock Connect Taxation Policy

On November 5, 2016, the Ministry of Finance, the State Taxation Administration and the China Securities Regulatory Commission jointly promulgated the Circular on the Relevant Taxation Policy regarding the Pilot Inter-connected Mechanism for Trading on the Shenzhen Stock Market and the Hong Kong Stock Market (《關於深港股票市場交易互聯互通機制試點有關稅收政策的通知》) (the “**SZHK Stock Connect Tax Policies**”), which clearly set forth tax policies applicable to transactions via SZHK Stock Connect and took effect on December 5, 2016.

According to the SZHK Stock Connect Tax Policies, during China’s pilot fiscal reform, the spread gained by mainland individual investors arising from the trade of shares on the Hong Kong Stock Exchange through the SZHK Stock Connect shall be exempted from VAT during China’s pilot fiscal reform where the business tax is to be replaced by VAT. The dividends obtained by mainland individual investors from the listing of H-shares on the Hong Kong Stock Exchange via SZHK Stock Connect shall be subject to 20% personal income tax, provided that the H-share companies shall submit application to China Securities Depository and Clearing Corporation Limited (“**CSDC**”), after which CSDC will furnish them with a roster of the mainland individual investors, and the H-share companies shall withhold personal income tax at a rate of 20%. If, however, dividends are generated from the listing of non-H-shares on the Hong Kong Stock Exchange via SZHK Stock Connect, such personal income tax at the rate of 20% will be deducted by CSDC. In case the individual investors have paid taxes in advance in other jurisdictions by withdrawal in advance, the investors may apply for tax exemption to the tax authority in charge of CSDC by producing tax payment proofs. Dividends gained by mainland securities investment funds via investing in shares listed on the Hong Kong Stock Exchange via SZHK Stock Connect shall be subject to personal income tax according to the aforementioned provisions (as if they are individual investors).

According to the SZHK Stock Connect Tax Policies, gains received by mainland corporate investors in the PRC from their transfer of shares that they have invested in the shares listed in the Hong Kong Stock Exchange via SZHK Stock Connect shall be included in their total revenues and subject to company income tax, and if it is the mainland governmental bodies that earn incomes through trading shares listed on the Hong Kong Stock Exchange via SZHK Stock Connect, these incomes are exempted from VAT as they are now during the pilot period of replacement of business tax by VAT. If mainland company investors gain dividends through investment in shares listed on the Hong Kong Stock Exchange via SZHK Stock Connect, such dividends shall be calculated in the total revenue of the companies and will be subject to income tax accordingly, in which case, a mainland domiciled company legally holding H shares for no less than 12 consecutive months will be exempted from company income tax for the amounts earned from the H shares during such 12-month period, while in case of a H-share company listed on the Hong Kong Stock Exchange, the company shall apply to CSDC, who will provide to it the roster of mainland company investors, upon which the H-share company refrains from deducting income tax from the dividends, and payable income tax shall be declared and paid by the investors themselves; when declaring company income tax, if a mainland company investor has any tax imposed on the dividends deducted by a non-H-share company listed on the Hong Kong Stock Exchange, the investor may apply for tax offset.

According to the SZHK Stock Connect Tax Policies, in case that any mainland investor trades, inherits or gives as gift shares listed on the Hong Kong Stock Exchange, stamp tax will be imposed thereon according to the tax law currently prevalent in Hong Kong SAR, and the both CSDC and Hong Kong Securities Clearing Company Limited may collect the stamp tax on behalf of one another.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

TAXATION IN HONG KONG

Taxation on Dividends

No tax is payable by any person or corporation under the laws of Hong Kong in respect of dividends paid by our Company.

Profits Tax

Hong Kong profits tax will not be payable by any Shareholders (other than Shareholders carrying on a trade, profession or business in Hong Kong and holding the Shares for trading purposes) on any capital gains made on the sale or other disposal of the Shares. Shareholders should take advice from their own professional advisers as to their particular tax position.

Stamp Duty

Hong Kong stamp duty will be charged on the sale and purchase of Shares at the current rate of 0.26% of the consideration for, or (if greater) the value of, the Shares being sold or purchased, whether or not the sale or purchase is on or off the Hong Kong Stock Exchange. The Shareholder selling the Shares and the purchaser will each be liable for one-half of the amount of Hong Kong stamp duty payable upon such transfer. In addition, a fixed duty of HK\$5 is currently payable on any instrument of transfer of Shares.

Estate Duty

The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong, pursuant to which no Hong Kong estate duty is payable and no estate duty clearance papers are needed for an application of a grant of representation in respect of holders of H Shares whose deaths occur on or after February 11, 2006.

TAXATION OF OUR COMPANY IN HONG KONG

Profits Tax

Our Company will be subject to Hong Kong profits tax in respect of profits arising in or derived from Hong Kong at the current rate of 16.5%. Dividend income derived by our Company from its subsidiaries will be excluded from Hong Kong profits tax.

FOREIGN EXCHANGE

The lawful currency of the PRC is Renminbi, which is currently subject to foreign exchange control and cannot be freely converted into foreign currency. The SAFE, with the authorization of the PBOC, is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

On January 29, 1996, the State Council promulgated the Regulations of the PRC on Foreign Exchange Control (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Control Regulations**”) and it came into effect on April 1, 1996. The Foreign Exchange Control Regulations classifies all international payments and transfers into current items and capital items. Most of the current items are not subject to the approval of foreign exchange administration agencies, while capital items are subject to the approval of foreign exchange administration agencies. The Foreign Exchange Control Regulations were subsequently amended on January 14, 1997, August 5, 2008 and came into effect on the same day. According to the latest amendment to the Foreign Exchange Control Regulations, PRC will not impose any restriction on international current payments and transfers.

The Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) promulgated by PBOC on June 20, 1996 and effective on July 1, 1996 does not impose any restrictions on convertibility of foreign exchange under current items, while imposing restrictions on foreign exchange transactions under capital account items.

According to the Announcement on Improving the Reform of the Renminbi Exchange Rate Formation Mechanism (《關於完善人民幣匯率形成機制改革的公告》), which was issued by the PBOC and implemented on July 21, 2005, the PRC has started to implement a managed floating exchange rate system in which the exchange rate would be determined based on market supply and demand and adjusted with reference to a basket of currencies since July 21, 2005. Therefore, the Renminbi exchange rate was no longer pegged to the U.S. dollar. PBOC would publish the closing price of the exchange rate of the Renminbi against trading currencies such as the U.S. dollar in the interbank foreign exchange market after the closing of the market on each working day, as the central parity of the currency against Renminbi transactions on the following working day.

According to the relevant laws and regulations in the PRC, PRC enterprises (including foreign investment enterprises) which need foreign exchange for current item transactions may, without the approval of the foreign exchange administrative authorities, effect payment through foreign exchange accounts opened at financial institutions that carries foreign exchange business or operating institutions that carries settlement and sale business, on the strength of valid receipts and proof. Foreign investment enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange may, on the strength of resolutions of the board of directors or the shareholders’ meeting on the distribution of profits, effect payment from foreign exchange accounts opened at financial institutions that carries foreign exchange business or institutions that carries settlement and sale business, or effect exchange and payment at financial institutions that carries foreign exchange business or institutions that carries settlement and sale business.

On October 23, 2014, the State Council issued the Decision of the State Council on Canceling and Adjusting a Group of Administrative Approval Items and Other Matters (《國務院關於取消和調整一批行政審批項目等事項的決定》), which canceled the administrative approval by the SAFE and its branches for matters concerning the repatriation and settlement of foreign exchange of overseas-raised funds through overseas listing.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

On December 26, 2014, the SAFE issued the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) (Hui Fa[2014]No. 54). Pursuant to the notice, a domestic company shall, within 15 business days of the date of the end of its overseas listing issuance, register the overseas listing with the Administration of Foreign Exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents. A domestic company (except for bank financial institutions) shall present its certificate of overseas listing to open a "special account for overseas listing of domestic company" at a local bank for its initial public offering (or follow-on offering) and repurchase business to handle the exchange, remittance and transfer of funds for the business concerned.

According to the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) (Hui Fa[2015]No. 13) promulgated by the SAFE on February 13, 2015 and imposed on June 1, 2015, two of the administrative examination and approval items, being the confirmation of foreign exchange registration under domestic direct investment and the confirmation of foreign exchange registration under overseas direct investment have been canceled. Instead, banks shall directly examine and handle foreign exchange registration under domestic direct investment and foreign exchange registration under overseas direct investment, and the SAFE and its branch offices shall indirectly regulate the foreign exchange registration of direct investment through banks.

According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionize and Regulate Capital Account Settlement Management Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (Hui Fa[2016]No. 16) issued by the SAFE and came into effect on June 9, 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of foreign exchange capital, foreign loans and raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions. The tentative percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%, subject to adjustment of the SAFE in due time in accordance with international revenue and expenditure situations.

On January 26, 2017, the SAFE issued the Notice of the State Administration of Foreign Exchange on Further Promoting the Reform of Foreign Exchange Administration and Improving the Examination of Authenticity and Compliance (《國家外匯管理局關於進一步推進外匯管理改革完善真實合規性審核的通知》) (Hui Fa[2017]No. 3) to further expand the scope of settlement for domestic foreign exchange loans, allow settlement for domestic foreign exchange loans with export background under goods trading, allow repatriation of funds under domestic guaranteed foreign loans for domestic utilization, allow settlement for domestic foreign exchange accounts of foreign institutions operating in the Free Trade Pilot Zones, and adopt the model of full-coverage RMB and foreign currency overseas lending management, where a domestic institution engages in overseas lending, the sum of its outstanding overseas lending in RMB and outstanding overseas lending in foreign currencies shall not exceed 30% of its owner's equity in the audited financial statements of the preceding year.

APPENDIX IV SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

This appendix contains a summary of laws and regulations on companies and securities in the PRC, certain major differences between the PRC Company Law and the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Companies Ordinance as well as the additional regulatory provisions of the Stock Exchange on joint stock limited companies of the PRC. The principal objective of this summary is to provide potential [REDACTED] with an overview of the principal laws and regulations applicable to us. This summary is with no intention to include all the information which may be important to potential [REDACTED]. For discussion of laws and regulations specifically governing the business of the Company, please refer to the section headed “Regulatory Overview” in this document.

PRC LEGAL SYSTEM

The PRC legal system is based on the *Constitution of the PRC* (《中華人民共和國憲法》) (the “**Constitution**”) and consists of written laws, administrative regulations, local regulations, separate regulations, autonomous regulations, rules and regulations of departments, rules and regulations of local governments, international treaties of which the PRC government is a signatory, and other regulatory documents. Court verdicts do not constitute binding precedents, but may serve as judicial reference and guidance.

Pursuant to the Constitution and the *Legislation Law of the PRC (2015 Revision)* (《中華人民共和國立法法(2015年修訂)》) (the “**Legislation Law**”), the NPC and the NPC Standing Committee exercise the legislative power of the State. The NPC formulates and amends basic laws governing civil and criminal matters, state organs and other matters. The NPC Standing Committee formulates and amends laws other than those required to be enacted by the NPC, and supplements and amends any parts of laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest administrative organ of the PRC and has the power to formulate administrative regulations based on the Constitution and laws.

The people’s congresses of provinces, autonomous regions and municipalities and their respective standing committees may formulate local regulations based on the specific circumstances and actual requirements of their respective administrative areas, provided that such local regulations do not contravene any provision of the Constitution, laws or administrative regulations.

The ministries and commissions of the State Council, the PBOC, the National Audit Office and other organs with administrative functions directly under the State Council may, in accordance with laws and the administrative regulations, decisions and orders of the State Council and within the limits of their power, formulate rules and regulations.

The people’s congresses of cities with district divisions and their respective standing committees may formulate local regulations in terms of urban and rural development and management, environmental protection, and historical and cultural protection based on the specific circumstances and actual requirements of such cities, provided that such local regulations do not contravene the Constitution, laws, administrative regulations, and the local regulations of the provinces or autonomous regions concerned. The people’s congresses of ethnic autonomous areas have the power to enact autonomous regulations and separate regulations in light of the political, economic and cultural characteristics of the local ethnic groups in the areas concerned.

APPENDIX IV SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The people's governments of provinces, autonomous regions, municipalities directly under the central government and cities with district division and autonomous prefectures may enact rules and regulations in accordance with laws, administrative regulations and the local regulations of their respective provinces, autonomous regions or municipalities.

The Constitution has supreme legal authority. No laws, administrative regulations, local regulations, autonomous regulations or separate regulations may contravene the Constitution. The authority of laws is greater than that of administrative regulations and local rules and regulations. The authority of administrative regulations is greater than that of local rules and regulations. The authority of local regulations is greater than that of the rules and regulations of local governments at or below the corresponding level. The authority of the rules and regulations enacted by the people's governments of provinces or autonomous regions is greater than that of the rules and regulations enacted by the people's governments of cities with district divisions or autonomous prefectures within the administrative areas of the provinces and the autonomous regions.

The NPC has the power to alter or annul any inappropriate laws enacted by its Standing Committee, and to annul any autonomous regulations or separate regulations which have been approved by its Standing Committee but which contravene the Constitution or the Legislation Law. The NPC Standing Committee has the power to annul any administrative regulations that contravene the Constitution and laws, to annul any local regulations that contravene the Constitution, laws or administrative regulations, and to annul any autonomous regulations or local regulations which have been approved by the standing committees of the people's congresses of the relevant provinces, autonomous regions or municipalities directly under the central government, but which contravene the Constitution and the Legislation Law. The State Council has the power to alter or annul any inappropriate rules and regulations of its ministries and local governments. The people's congresses of provinces, autonomous regions and municipalities directly under the central government have the power to alter or annul any inappropriate local regulations enacted and approved by their respective standing committees. The people's governments of provinces and autonomous regions have the power to alter or annul any inappropriate rules and regulations enacted by the people's governments at a lower level.

Pursuant to the Constitution and the Legislation Law, the power to interpret laws is vested in the NPC Standing Committee. According to the *Resolution of the NPC Standing Committee Regarding the Strengthening of Interpretation of Laws* (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) passed on June 10, 1981, the Supreme People's Court (the "**Supreme People's Court**") shall provide general interpretation on issues relating to the specific application of laws and decrees in court trials. The State Council and competent authorities shall interpret the specific application of other laws and decrees that are beyond trial and prosecution work. The competent authorities of the people's governments of provinces, autonomous regions and municipalities shall interpret the specific application of local regulations.

APPENDIX IV SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

PRC JUDICIAL SYSTEM

Under the Constitution and the *PRC Law on the Organization of People’s Courts (2018 Revision)* (《中華人民共和國人民法院組織法(2018年修訂)》), people’s courts comprise the Supreme People’s Court, local people’s courts and special people’s courts.

Local people’s courts comprise primary, intermediate and higher people’s courts. Higher people’s courts supervise primary and intermediate people’s courts. People’s procuratorates also have the power to exercise legal supervision over the civil proceedings of people’s courts at the same and lower levels. The Supreme People’s Court is the highest judicial body in the PRC and supervises the judicial work of local people’s courts at all levels.

The *PRC Civil Procedure Law (2017 Revision)* (《中華人民共和國民事訴訟法(2017年修訂)》) (the “**Civil Procedure Law**”), which was adopted in 1991 and amended in 2007, 2012 and 2017, sets forth the criteria for instituting a civil action, the jurisdiction of people’s courts, the procedures to be observed for conducting a civil action and the procedures for enforcement of a civil judgment or order. All parties to a civil action conducted within the PRC shall comply with the Civil Procedure Law. Generally, a civil case is first heard by a local court of the municipality or province in which the defendant resides. The parties to a contract or a dispute over other property rights and interests may select by written agreement the jurisdiction of the people’s court at the place of residence of the defendant, the place of performance of the contract, the place where the contract was signed, the place of residence of the plaintiff, the place where the subject matter of the dispute is located and other places that have a practical connection with the dispute, provided that the provisions of this law regarding the level of jurisdiction and exclusive jurisdiction are not contravened.

Foreigners, stateless persons or foreign enterprises and organizations have the same litigation rights and obligations as PRC citizens or legal persons and other organizations. If a foreign court imposes limitations on the civil litigation rights of PRC citizens, enterprises and organizations, the PRC courts may apply the same limitations within the PRC to the citizens, enterprises and organizations of that foreign country.

Civil judgment or verdict with legal effect shall be observed by the parties concerned. If any party refuses to comply, the other party(ies) may apply to the people’s court for the enforcement of the same. Application for such enforcement shall take place within two years of such judgment or verdict. If a person fails to satisfy a judgment made by the court within the stipulated time, the court will, upon application by any party, enforce the judgment in accordance with the law.

A party seeking to enforce a judgment or verdict of a people’s court with legal effect against a party who is not or whose property is not within the PRC may apply to a foreign court with jurisdiction over the case for recognition and enforcement of the judgment or verdict, or have the people’s court apply for such recognition and enforcement by the foreign court according to the provisions of the international treaties that the PRC has entered into or acceded to or according to the principle of reciprocity, unless the people’s court finds such recognition and enforcement to result in violation of the basic principles of the PRC laws, national sovereignty, security or social and public interest.

APPENDIX IV SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

COMPANY LAW, SPECIAL REGULATIONS AND MANDATORY PROVISIONS

A PRC-incorporated joint stock limited company and seeking a listing on the Hong Kong Stock Exchange is mainly subject to the following three PRC laws and regulations:

- *PRC Company Law* promulgated by the NPC Standing Committee on December 29, 1993, effective on July 1, 1994 and amended on December 25, 1999, August 28, 2004, October 27, 2005 and December 28, 2013 respectively, and last amended and implemented on October 26, 2018;
- *Special Regulations of the State Council on Overseas Share Offering and Listing by Joint Stock Limited Companies* (the “**Special Regulations**”) promulgated by the State Council on August 4, 1994 pursuant to the then effective Articles 85 and 155 of the Company Law, which are applicable to the overseas share subscription and listing of joint stock limited companies; and
- *Mandatory Provisions of Articles of Association of Companies Listing Overseas* (the “**Mandatory Provisions**”) promulgated jointly by the former Securities Commission of the State Council and the former State Economic Restructuring Commission on August 27, 1994, setting out the mandatory provisions for the articles of association of a joint stock limited company seeking an overseas listing. As such, the Mandatory Provisions are set out in the articles of association of the Company, the summary of which is set out in the section headed “Appendix V — Summary of Articles of Association” in this document.

On April 21, 2018, the National Equities Exchange and Quotations Co., Ltd. and the Hong Kong Stock Exchange signed the Memorandum of Understanding, providing that the listing on the Hong Kong Stock Exchange by companies listed on the NEEQ shall conform to the Special Regulations and the relevant rules of CSRC. No pre-examination or special conditions are imposed by the National Equities Exchange and Quotations Co., Ltd.

Below sets out a summary of the major provisions of the Company Law, the Special Regulations and the Mandatory Provisions applicable to the Company.

General

A joint stock limited company refers to an enterprise legal person incorporated under the Company Law with its registered capital divided into shares of equal par value. The liability of its shareholders is limited to the number of shares held by them and the company is liable to its creditors for an amount equal to the total value of its assets.

A joint stock limited company shall conduct its business in accordance with laws and administrative regulations. It may invest in other limited liability companies and joint stock limited companies, with its liabilities with respect to such invested companies to be limited to the amount invested. Unless otherwise provided by law, a joint stock limited company shall not be a contributor that undertakes joint and several liabilities for the debts of the invested companies.

APPENDIX IV SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Incorporation

A joint stock limited company may be incorporated by promotion or public subscription.

A joint stock limited company may be incorporated by a minimum of two but no more than 200 promoters. At least half of the promoters must have residence within the PRC. Pursuant to the Special Regulations, state-owned enterprises or enterprises with the majority of their assets owned by the PRC government may be restructured into joint stock limited companies and may issue shares to overseas investors in accordance with relevant regulations. Such companies, if incorporated by promotion, may have less than five promoters and may issue new shares once incorporated.

The promoters must convene an inaugural meeting within 30 days after the issued shares are paid up, and must give notice to all subscribers or make an announcement of the date of the inaugural meeting 15 days before the meeting. The inaugural meeting may be convened only with the presence of promoters or subscribers representing at least half of the shares in the company. The inaugural meeting shall address matters such as the adoption of the articles of association and the election of members of the board of directors and the board of supervisors of the company. All resolutions of the meeting require the approval of subscribers with more than half of the voting rights present at the meeting.

Within 30 days after the conclusion of the inaugural meeting, the board of directors must apply to the registration authority to register the incorporation of the joint stock limited company. A company will be formally established with the status of a legal person when a business license is issued by relevant registration authority. Joint stock limited companies established through share subscription shall file its approval documents issued by the securities regulatory authority of the State Council with the company registration authority for record.

Promoters of a joint stock limited company shall undertake: (i) joint and several liability for the payment of all expenses and liabilities incurred in the incorporation process, if the company cannot be incorporated; (ii) joint and several liability for the refund of subscription monies to the subscribers together with interest at bank rates for a deposit of the same term, if the company cannot be incorporated; and (iii) the liability for the damages suffered by the company due to negligence by the promoters during the incorporation of the company. Pursuant to the *Interim Regulations on the Administration of Share Issuance and Trading* (《股票發行與交易管理暫行條例》) promulgated by the State Council on April 22, 1993 (only applicable to the issuance and trading of shares and related activities in the PRC), if a company is established by means of public subscription, the promoters of such company are required to provide signatures on the documents to ensure that they are free from any misrepresentation, serious misleading statements or material omissions, and assume joint and several liability for such documents.

Share Capital

The promoters of a company can make capital contributions in cash or in kind, which can be valued in currency based on their appraised value and transferable according to law, such as intellectual property rights or land use rights.

If capital contribution is made other than in cash, the contributed property shall be valued, verified and converted into shares.

A company may issue registered or bearer shares. However, shares issued to promoter(s) or legal person(s) shall be registered shares under the name(s) of such promoter(s) or legal person(s), and shall not be registered under a different name or the name of a representative.

APPENDIX IV SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The Special Regulations and the Mandatory Provisions provide that shares issued to foreign investors and listed overseas shall be issued as registered shares, denominated in RMB and subscribed for in foreign currency.

Under the Special Regulations and the Mandatory Provisions, overseas listed shares issued to foreign investors and investors from the territories of Hong Kong, Macau and Taiwan are known as overseas listed foreign invested shares. Shares issued to investors within the PRC other than the territories specified above are known as domestic shares.

A company may offer its shares to foreign investors with approval by the securities regulatory authority of the State Council. Specific provisions shall be formulated by the CSRC. Under the Special Regulations, upon approval of the CSRC, a company may agree, in the underwriting agreement in respect of an issue of overseas listed foreign invested shares, to retain no more than 15% of all overseas listed foreign invested shares to be issued after taking into account the number of underwritten shares.

The share offering price may be equal to or greater than nominal value, but shall not be less than nominal value.

The transfer of shares by shareholders shall be conducted via a legally established stock exchange or in other methods stipulated by the State Council. Shareholders may transfer their registered shares through endorsement or by other means stipulated by laws or administrative regulations. Bearer shares can be transferred by delivery of the share certificates to the transferee.

Shares held by a promoter of the company shall not be transferred within one year after the date of the company's incorporation. Shares issued by a company prior to the public offer shall not be transferred within one year from the date of listing of the shares of the company on a stock exchange. Directors, supervisors and senior management of the company shall not transfer over 25% of the shares held by each of them in the company each year during their term of office, and shall not transfer any share of the company held by each of them within one year after the listing date. There is no restriction under the Company Law as to the percentage of shareholding by a single shareholder in a company.

Transfers of shares shall not be entered in the register of shareholders within 20 days before the date of a shareholders' meeting or within five days before the record date set for the purpose of distribution of dividends.

Allotment and Issue of Shares

All shares issued by a joint stock limited company shall be in the principles of equality and fairness. The same class of shares must carry equal rights. Shares issued at the same time and within the same class shall be issued on the same conditions and at the same price. Shares may be issued at par value or at a premium, but not below the par value.

APPENDIX IV SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

A company shall obtain the approval of the CSRC to offer its shares to the overseas public. Under the Special Regulations, shares issued to foreign investors by joint stock limited companies and listed overseas are known as “overseas listed and foreign invested shares”. Shares issued to investors within the PRC by joint stock limited companies, which also issue overseas listed shares, are known as “domestic shares”. Upon approval of the securities regulatory authority of the State Council, a company issuing overseas listed foreign invested shares (with the total number of shares determined by the issuance program) may agree with underwriters in the underwriting agreement to retain no more than 15% of all its overseas listed foreign invested shares outside the underwritten amount. The issuance of the retained shares is deemed to be a part of this issuance.

Registered Shares

Under the Company Law, shareholders may make capital contributions in cash or with such non-monetary property as physical items, intellectual property rights and land use rights that can be valued in currency and transferred in accordance with law. Pursuant to the Special Regulations, overseas listed foreign invested shares shall be issued as registered shares, denominated in RMB and subscribed for in a foreign currency. Domestic shares shall also be issued as registered shares.

Under the Company Law, a company that issues registered shares shall maintain a register of shareholders, stating the following matters:

- the name and domicile of each shareholder;
- the number of shares held by each shareholder;
- the serial numbers of shares held by each shareholder; and
- the date on which each shareholder acquired the shares.

Increase of Share Capital

According to the Company Law, when a joint stock limited company issues new shares, resolutions shall be passed at a shareholders’ general meeting to approve the class and number of the new shares, their issue price, the dates of starting and ending the new share issuance, and the class and number of new shares to be issued to existing shareholders. When launching a public issuance of new shares with the approval of the securities regulatory authority of the State Council, the company shall publish documents and financial and accounting reports, and prepare share subscription forms. After the new shares to be issued are paid up, the change shall be registered with the company registration authorities and an announcement shall be made.

APPENDIX IV SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Reduction of Share Capital

A company may reduce its registered capital according to the following procedures prescribed by the Company Law:

- it shall prepare a balance sheet and a property list;
- the reduction of registered capital shall be approved by a shareholders' general meeting;
- it shall inform its creditors of the reduction in capital within 10 days and publish an announcement of the reduction in the newspaper within 30 days after the resolution approving the reduction is passed;
- creditors may require the company to pay off its debts or provide debt guarantees within 30 days after receiving the notice, or within 45 days of the public announcement if no notice is received;
- it shall apply to the relevant registration bureau to register the reduction in registered capital.

Repurchase of Shares

Pursuant to the Company Law, a joint stock limited company shall not purchase its shares other than for one of the following purposes: (i) reducing its registered capital; (ii) merging with another company that holds its shares; (iii) granting shares under an employee stock ownership scheme or equity incentive scheme; (iv) purchasing shares from shareholders who are against the resolution regarding the merger or division with other companies at a shareholders' general meeting; (v) using shares for conversion of convertible corporate bonds issued by a listed company; and (vi) a share buyback necessary for a listed company to maintain its company value and protect its shareholders' interests.

The purchase of shares on the grounds set out in (i) and (ii) above requires approval by way of a resolution passed at the shareholders' general meeting. For a company's share buyback under any of the circumstances set out in (iii), (v) or (vi) above, a resolution at a meeting of the company's board of directors shall be made by a two-third majority of directors attending the meeting according to the provisions of the company's articles of association or as authorized by the shareholders' meeting.

Following the purchase of shares according to (i), such shares shall be cancelled within 10 days from the date of purchase. The shares shall be assigned or deregistered within six months if the share buyback is made under the circumstances set out in (ii) or (iv). All the shares held by a company after a share buyback under any circumstances set out in (iii), (v) or (vi) shall not exceed 10% of the company's total outstanding shares, and shall be assigned or deregistered within three years.

Listed companies making a share buyback shall perform their obligation of information disclosure pursuant to the provisions of the Securities Law. If the share buyback is made under any circumstances set out in (iii), (v) or (vi) hereof, such buyback shall take place by way of open and centralized trading.

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Transfer of Shares

Shares held by shareholders may be transferred in accordance with relevant laws and regulations. Pursuant to the Company Law, transfer of shares by shareholders shall be carried out at a legally established stock exchange or in other ways stipulated by the State Council. No change of registration in the share register caused by share transfer shall take place within 20 days prior to the convening of a shareholder's general meeting or five days prior to the base date for determination of dividend distributions. However, where there are separate provisions by law on change of registration in the share register of a listed company, such provisions shall prevail. Pursuant to the Mandatory Provisions, no change of registration in the share register caused by share transfer shall take place within 30 days prior to the convening of a shareholder's general meeting or five days prior to the base date for determination of dividend distributions.

Under the Company law, shares issued prior to the public issuance of shares shall not be transferred within one year from the date of listing of the joint stock limited company on a stock exchange. Directors, supervisors and senior management shall declare to the company their shareholdings in the company and any changes of such shareholdings. They shall not transfer more than 25% of all their shares held in the company annually during their tenure. They shall not transfer their shares held within one year from the date on which the company's shares are listed or within six months after resignation from their positions with the company.

Shareholders

Under the Company Law and the Mandatory Provisions, the rights of holders of ordinary shares of a joint stock limited company include:

- the right to attend or appoint a proxy to attend shareholders' general meetings and to vote thereat;
- the right to transfer shares in accordance with laws, administrative regulations and provisions of the articles of association;
- the right to inspect the company's articles of association, share register, counterfoil of company debentures, minutes of shareholder's general meetings, resolutions of meetings of the board of directors and the board of supervisors, and financial and accounting reports and to make proposals or enquiries on the company's operations;
- the right to bring an action to the people's court to rescind the resolutions passed by shareholder's general meetings and the board of directors where such resolutions violate the articles of association;
- the right to receive dividends and other types of interest distributed in proportion to the number of shares held;
- in the event of termination or liquidation of the company, the right to participate in the distribution of residual properties of the company in proportion to the number of shares held; and
- other rights granted by laws, administrative regulations, other regulatory documents and the company's articles of association.

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The obligations of a shareholder include the obligation to abide by the company's articles of association, to pay the subscription moneys in respect of the shares subscribed for and based on the form of capital contributions, to be liable for the company's liabilities to the extent of the amount of his or her share subscription, and any other shareholder obligations specified in the company's articles of association.

Shareholders' General Meetings

The shareholders' general meeting is the organ of authority of the company, which exercises its powers in accordance with the Company Law.

Under the Company Law, the shareholders' general meeting may exercise the following principal powers:

- to decide on the company's operational policies and investment plans;
- to elect or replace directors and supervisors (other than the employee representatives of the company) and to decide on the remuneration of directors and supervisors;
- to consider and approve reports of the board of directors;
- to consider and approve reports of the board of supervisors;
- to consider and approve the company's proposed annual financial budget and final accounts;
- to consider and approve the company's proposals for profit distribution and loss recovery plans;
- to decide on any increase or reduction of the company's registered capital;
- to decide on the issue of bonds by the company;
- to decide on issues such as merger, division, dissolution and liquidation of the company and other matters;
- to amend the company's articles of association; and
- other powers as provided for in the articles of association.

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Annual general meetings shall be convened once every year. Under the Company Law, an extraordinary general meeting shall be convened within two months after the occurrence of any of the following circumstances:

- the number of directors is less than two thirds of the number stipulated by law or required under the articles of association;
- the total unrecovered losses of the company account for one-third of the company's total paid-up share capital;
- shareholders severally or collectively holding 10% or more of the company's shares request the convening of an extraordinary general meeting;
- whenever the board of directors deems necessary;
- when the board of supervisors so requests; or
- other circumstances as provided for in the articles of associations.

Under the Company Law, shareholders' general meetings shall be convened by the board of directors, and presided over by the chairman of the board of directors. In the event that the chairman cannot or does not perform his/her duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman cannot or does not perform his/her duties, a director nominated by more than half of directors shall preside over the meeting.

Where the board of directors cannot or does not perform its duties of convening the shareholders' general meeting, the board of supervisors shall convene and preside over such meeting in a timely manner. Where the board of supervisors fails to convene and preside over such meeting, shareholders severally or collectively holding more than 10% of the company's shares for 90 consecutive days may unilaterally convene and preside over such meeting.

Under the Company Law, notice of a shareholders' general meeting shall be given to all shareholders 20 days before the meeting, stating the time and venue of and matters to be considered at the meeting. Notice of an extraordinary general meeting shall be given to all shareholders 15 days prior to the meeting. Under the Special Regulations and the Mandatory Provisions, such notice shall be delivered to all registered shareholders 45 days in advance to the meeting, stating the matters to be considered as well as the time and venue of the meeting. A written reply of shareholders planning to attend the meeting shall be delivered to the company 20 days in advance of the meeting.

There is no specific provision in the Company Law regarding the number of shareholders constituting a quorum at a shareholders' meeting. Pursuant to the Special Regulations and the Mandatory Provisions, a shareholder's general meeting may be convened where the number of voting shares held by the shareholders present at the meeting reaches half or more of the company's total voting shares. If this is not attained, the company shall within five days re-notify the shareholders of the matters to be considered and the time and venue of the meeting by way of a public announcement. The company may convene the shareholders' general meeting after such public announcement. Pursuant to the Mandatory Provisions, modification or abrogation of rights conferred to any class of shareholders shall be approved by both a special resolution of the shareholders' general meeting and a class meeting convened respectively by shareholders of the affected class.

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Pursuant to the Special Regulations, where the company convenes an annual general meeting, shareholders holding more than 5% of voting shares have the right to submit new proposals to the company in writing, in which the matters within the scope of a shareholder's general meeting shall be placed in the agenda of the meeting.

Under the Company Law, shareholders present at a shareholders' general meeting have one vote for each share they hold, save that the shares held by the company are not entitled to any voting rights.

Pursuant to the provisions of the articles of association or a resolution of the shareholders' general meeting, the accumulative voting system may be adopted for the election of directors and supervisors at the shareholders' general meeting. Under the accumulative voting system, each share shall have vote rights equivalent to the number of directors or supervisors to be elected at the shareholders' general meeting, and shareholders may consolidate their voting rights when casting a vote.

Pursuant to the Company Law and the Mandatory Provisions, resolutions of the shareholders' general meeting shall be adopted by shareholders with more than half of the voting rights at the meeting. However, resolutions of the shareholders' general meeting regarding the following matters shall be adopted by shareholders with more than two-thirds of the voting rights at the meeting: (i) amendments to the articles of association; (ii) increase or decrease of registered capital; (iii) issue of any class of shares, warrants or other similar securities; (iv) issue of debentures; (v) merger, division, dissolution, liquidation or change in the form of the company; (vi) other matters deemed to have a material impact on the company and approved by way of an ordinary resolution at the shareholders' general meeting, and those to be adopted by way of a special resolution.

Under the Company Law, minutes of a meeting shall be prepared in respect of the decisions on matters discussed at the shareholders' general meeting. The chairman of the meeting and directors attending the meeting shall provide their signatures to endorse such minutes. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

Board of Directors

Under the Company Law, a joint stock limited company shall establish a board of directors, which shall consist of 5 to 19 members. Members of the board of directors may include employee representatives of the company, who shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. The term of a director shall be stipulated in the articles of association, but shall not exceed three years. Directors may serve consecutive terms if re-elected. A director shall continue to perform his/her duties in accordance with laws, administrative regulations and the articles of association till a duly re-elected director takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office, or if the resignation of directors results in the number of directors being less than the quorum.

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Under the Company Law, the board of directors mainly exercises the following powers:

- to convene shareholders' general meetings and report on its work thereat;
- to implement the resolutions passed at shareholders' general meetings;
- to determine the company's business plans and investment proposals;
- to formulate the company's proposed annual financial budget and final accounts;
- to formulate the company's profit distribution and loss recovery proposals;
- to formulate proposals for the increase or reduction of the company's registered capital and the issuance of corporate bonds;
- to prepare plans for the merger, division, dissolution and change in the form of the company;
- to formulate the company's basic management system; and
- to exercise any other power under the articles of association.

Board Meetings

Under the Company Law, meetings of the board of directors of a joint stock limited company shall be convened at least twice a year. The board of directors shall issue a notice of meeting to all directors and supervisors 10 days before the meeting is convened. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of voting rights, more than one-third of directors or the board of supervisors. The chairman shall convene and preside over such meeting within 10 days after receiving such proposal. Meetings of the board of directors shall be held only if half or more of the directors are present. Resolutions of the board of directors shall be passed by more than half of all directors. Each director shall have one vote for resolutions to be approved by the board of directors. Directors shall attend board meetings in person. If a director is unable to attend a board meeting, he/she may appoint another director by a written power of attorney that shall specify the scope of authorization to attend the meeting on his/her behalf.

If a resolution of the board of directors violates laws, administrative regulations or the articles of association and causes the company to suffer serious losses, the directors participating in the resolution are liable to compensate the company. However, if a director is proven to have expressly objected to the resolution when it was voted on and such objection was recorded in the minutes of the meeting, such director may be released from that liability.

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Chairman of the Board

Under the Company Law, the board of directors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman are elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and examine the implementation of board resolutions. The vice chairman shall assist the work of the chairman. In the event that the chairman cannot or does not perform his/her duties, the duties shall be performed by the vice chairman. In the event that the vice chairman cannot or does not perform his/her duties, a director nominated by more than half of the directors shall perform the duties.

Qualification of Directors

The Company Law provides that the following persons shall not serve as directors:

- a person who is unable or has limited capacity to undertake any civil act;
- a person convicted of bribery, corruption, embezzlement or misappropriation of property or the destruction of socialist market economy order, or deprived of his/her political rights due to his/her crimes, in each case where less than five years have elapsed since the date of completion of the sentence;
- a person who served as a former director, factory manager or general manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of completion of the bankruptcy and liquidation of the company or enterprise;
- a person who was a legal representative of a company or an enterprise that had its business license revoked due to violations of the law and was ordered to close down by the law, and who was personally responsible, where less than three years have elapsed since the date of such revocation; or
- a person who is liable for a relatively large amount of debts that are overdue.

Other circumstances under which a person is disqualified from directorship are set out in the Mandatory Provisions.

Board of Supervisors

A joint stock limited company shall establish a board of supervisors, which shall consist of no less than three members. The board of supervisors shall comprise shareholder representatives and an appropriate proportion of employee representatives of the company. Among them, no less than one-third shall be employee representative supervisors, with the actual proportion to be set out in the articles of association. Employee representatives of the company in the board of supervisors shall be democratically elected by the employees at the employees' representative assembly, employees' general meeting or otherwise.

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Directors and senior management shall not act concurrently as supervisors.

The board of supervisors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the board of supervisors are elected with approval of more than half of all the supervisors. The chairman of the board of supervisors shall convene and preside over the meetings of the board of supervisors. In the event that the chairman of the board of supervisors cannot or does not perform his/her duties, the vice chairman of the board of supervisors shall convene and preside over the meetings of the board of supervisors. In the event that the vice chairman of the board of supervisors cannot or does not perform his/her duties, a supervisor nominated by more than half of the supervisors shall convene and preside over the meetings of the board of supervisors.

Each term of office of a supervisor is three years and he or she may serve consecutive terms if re-elected. A supervisor shall continue to perform his/her duties in accordance with laws, administrative regulations and the articles of association till a duly re-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office, or if the resignation of supervisors during their term results in the number of supervisors being less than the quorum.

The board of supervisors of a company shall convene at least one meeting every six months. A resolution of the board of supervisors shall be passed by more than half of all the supervisors pursuant to the *PRC Company Law*, and by more than two-thirds of all the supervisors according to the *Letter of Opinions on the Supplementary Amendments to the Articles of Association of Companies Listed in Hong Kong* (《關於到香港上市公司對組織章程細則作補充修改的意見的函》).

The board of supervisors exercises the following powers:

- to review the company’s financial position;
- to supervise directors and senior management in performing their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or the resolutions of shareholders’ general meetings;
- to require correction of the acts of directors and senior management when such acts harm the company’s interests;
- to propose the convening of extraordinary shareholders’ general meetings, and to convene and preside over shareholders’ general meetings when the board of directors fails to perform the duty of convening and presiding over shareholders’ general meetings under this law;
- to initiate proposals for resolutions to shareholders’ general meetings;
- to initiate proceedings against directors and senior management; and
- other powers specified in the articles of association.

Supervisors may attend board meetings and make enquiries or proposals in respect of board resolutions. The board of supervisors may initiate investigations into any irregularities identified in the operation of the company and, where necessary, may engage an accounting firm to assist their work at the company’s expense.

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Manager and Senior Management

Under the Company Law, a company shall have a manager appointed or removed by the board of directors. The manager shall report to the board of directors of the company and may exercise the following powers:

- to supervise the business and administration of the company and arrange for the implementation of resolutions of the board of directors;
- to arrange for the implementation of the company's annual business plans and investment proposals;
- to formulate the general administration system of the company;
- to formulate the company's basic rules and regulations;
- to recommend the appointment or dismissal of the Company's deputy general managers and person in charge of finance;
- to appoint or dismiss administration officers (other than those required to be appointed or dismissed by the board of directors); and
- other powers conferred by the board of directors or the articles of association.

The manager shall comply with other provisions of the articles of association. The manager shall attend board meetings.

Pursuant to the Company Law, senior management refers to the manager, deputy manager(s), person in charge of finance, board secretary (for a listed company) and other personnel of a company as stipulated in the articles of association.

Duties of Directors, Supervisors and Senior Management

Pursuant to the Company Law, directors, supervisors and senior management of the company shall comply with relevant laws, regulations and the articles of association, and fulfill the obligation of integrity and diligence to the company. Directors, supervisors and senior management shall not abuse their powers to accept bribes or other unlawful income or misappropriate the company's properties. Directors and senior management shall not:

- misappropriate the company's capital;
- deposit the company's capital into accounts under his/her own name or the name of other individuals;
- loan company funds to others or provide guarantees in favor of others with the company's assets in violation of the articles of association or without prior approval of the shareholders' general meeting or the board of directors;

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- enter into contracts or deals with the company in violation of the articles of association or without prior approval of the shareholders' general meeting;
- use their position and powers to procure business opportunities for themselves or others that should have otherwise been available to the company, or operate for their own benefits or on behalf of others business similar to that of the company without prior approval of the shareholders' general meeting;
- accept and possess commissions paid by a third party for transactions conducted with the company;
- unauthorized divulgence of business secrets of the company; or
- other acts in violation of their fiduciary duty to the company.

Directors, supervisors or senior management shall be personally liable to the company if they contravene any laws, regulations or the company's articles of association in the performance of their duties, which results in any loss to the company.

Finance and Accounting

Under the Company Law, a company shall establish financial and accounting systems according to laws, administrative regulations and the regulations under the Ministry of Finance of the State Council and shall at the end of each financial year prepare a financial and accounting report which shall be audited by an accounting firm as required by law. The company's financial and accounting report shall be prepared in accordance with provisions of the laws, administrative regulations and the regulations under the Ministry of Finance of the State Council.

Pursuant to the Company Law, the company shall deliver its financial and accounting reports to all shareholders within the time limit stipulated in the articles of association and make its financial and accounting reports available at the company for inspection by the shareholders at least 20 days before convening an annual general meeting. It must also publish its financial and accounting reports.

When allocating each year's after-tax profits, a company shall set aside 10% of its after-tax profits into a statutory common reserve fund (except where the fund has reached 50% of its registered capital).

If its statutory common reserve fund is not sufficient to make up losses of the previous year, profits of the current year shall be applied to make up such losses before allocation is made to the statutory common reserve fund pursuant to the above provisions.

After allocation of the statutory common reserve fund from after-tax profits, it may, upon a resolution passed at the shareholders' general meeting, allocate discretionary common reserve fund from after-tax profits.

The remaining after-tax profits after making up losses and allocation of common reserve fund shall be distributed in proportion to the number of shares held by the shareholders, unless otherwise stipulated in the articles of association.

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Shares held by a company shall not be entitled to any distribution of profit.

The premium received through issuance of shares at prices above par value and other incomes required by the Ministry of Finance of the State Council to be allocated to the capital reserve fund shall be allocated to the company's capital reserve fund.

A company's reserve fund shall be applied to make up its losses, expand its business operations or be converted to increase the registered capital of the company. However, the capital reserve fund may not be applied to make up the company's losses. Upon the conversion of statutory common reserve fund into capital, the balance of the statutory common reserve fund shall not be less than 25% of the registered capital of the company before such conversion.

A company shall keep no other accounting books except the statutory accounting books. No account shall be opened under the name of any individual to deposit the company's assets.

Appointment and Retirement of an Accounting Firm

Pursuant to the Company Law, the appointment or dismissal of accounting firms responsible for the auditing of the company shall be determined by shareholders' general meeting or board of directors in accordance with provisions of articles of association. The accounting firm should be allowed to make representations when the shareholders' general meeting or board of directors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidences, books, financial and accounting reports and other accounting data to the accounting firm it employs without any refusal, withholding and misrepresentation.

The Special Regulations provide that a company shall engage an independent accounting firm who shall comply with the relevant regulations of the PRC to audit its annual report and review other financial reports of the company. The accounting firm's term of office shall commence from their appointment at the shareholders' general meeting to the conclusion of the next shareholders' general meeting.

Distribution of Profits

According to the Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve is drawn. Under the Mandatory Provisions, a company shall appoint a receiving agent on behalf of holders of the overseas listed and foreign invested shares to receive on behalf of such shareholders dividends and other distributions payable in respect of their overseas listed and foreign invested shares.

Amendments to Articles of Association

Any amendments to the company's articles of association must be made in accordance with the relevant laws, administrative regulations and the requirements under the Articles of Association. Any amendment of the provisions in the Articles of Association in connection with the Mandatory Provisions shall only be effective after approval by the company's approval department authorized by the State Council and the CSRC. In relation to matters involving the company's registration, change of registration shall be completed with the authority in accordance to the laws.

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Dissolution and Liquidation

According to the Company Law, a company shall be dissolved if: (i) the term of its operations set out in the articles of association has expired or other events of dissolution specified in the articles of association have occurred; (ii) it is resolved in the shareholders' general meeting that the company shall resolve; (iii) the company is dissolved by reason of merger or division; (iv) the business license is legally revoked; the company is ordered to close down or be dissolved; or (v) the company is dissolved by the people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all of its shareholders, on the ground that the company suffers from significant hardship in its operation and management that cannot be resolved through other means, and the ongoing existence of the company would bring significant losses for shareholders.

In the event of (i) above, it may carry on its existence by amending its articles of association. The amendment of the articles of association in accordance with provisions set out above shall require approval of more than two-thirds of voting rights of shareholders attending a shareholders' general meeting.

Where the company is dissolved in the circumstances described in sub-paragraphs (i), (ii), (iii), or (v) above, a liquidation team shall be established and the liquidation process shall commence within 15 days after the occurrence of an event of dissolution.

The members of the company's liquidation team shall be composed of its directors or the personnel appointed by the shareholders' general meeting. If a liquidation team is not established within the stipulated period, creditors may apply to the people's court and request the court to appoint relevant personnel to form the liquidation team. The people's court should accept such application and form a liquidation team to conduct liquidation in a timely manner.

The liquidation team shall exercise the following powers during the liquidation period:

- to handle the company's assets and to prepare a balance sheet and an inventory of the assets;
- to notify creditors through notice or public announcement;
- to handle the company's outstanding businesses related to liquidation;
- to pay any tax overdue as well as tax amounts arising from the process of liquidation;
- to claim credits and pay off debts;
- to handle the company's remaining assets after its debts have been paid off; and
- to represent the company in civil lawsuits.

The liquidation team shall notify the company's creditors within 10 days after its establishment and issue a public notice in newspapers within 60 days. A creditor shall lodge his claim with the liquidation team within 30 days after receiving the notification, or within 45 days of the public notice if he did not receive any notification. A creditor shall state all matters relevant to his creditor rights in making his claim and furnish evidence. The liquidation team shall register such creditor rights. The liquidation team shall not make any debt settlement with the creditors during the period of claim.

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Upon liquidation of the company’s properties and the preparation of the balance sheet and list of assets, the liquidation team shall draw up a liquidation plan to be submitted to the shareholders’ general meeting or a people’s court for confirmation.

The company’s remaining assets after payment of liquidation expenses, wages, social insurance expenses and statutory compensation, outstanding taxes and debts shall be distributed to shareholders according to the proportion of their shareholding. It shall continue to exist during the liquidation period, although it can only engage in any operating activities that are related to the liquidation. The company’s properties shall not be distributed to the shareholders before repayments are made in accordance to the foregoing provisions.

Upon liquidation of the company’s properties and the preparation of the balance sheet and inventory of assets, if the liquidation team becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to the people’s court for a declaration for bankruptcy.

Following the declaration of bankruptcy, the liquidation team shall hand over all matters relating to the liquidation to the people’s court.

Upon completion of the liquidation, the liquidation team shall submit a liquidation report to the shareholders’ general meeting or the people’s court for verification. Thereafter, the report shall be filed with the registration authority of the company in order to cancel the company’s registration, and a public notice of its termination shall be issued. Members of the liquidation team are required to discharge their duties honestly and in compliance with the relevant laws. Members of the liquidation team shall be prohibited from abusing their powers to accept bribes or other unlawful income and from misappropriating the company’s properties.

If a company and its creditors suffer from any losses arising from intentional or gross negligence by a member of the liquidation team, he/she is liable to make compensation to the company and its creditors.

Overseas Listing

According to the Special Regulations, a company shall obtain an approval from CSRC to list its shares overseas. A company’s plan to issue overseas listed and foreign invested shares and domestic shares which has been approved by the CSRC may be implemented by the board of directors of the company by way of separate issue within 15 months after an approval is obtained from CSRC.

Loss of Share Certificates

If a registered share certificate is lost, stolen or destroyed, the relevant shareholder may apply, in accordance with the relevant provisions set out in the Civil Procedure Law, to a people’s court to declare such certificate invalid. After the people’s court declares the invalidity of such certificate, the shareholder may apply to the company for a replacement share certificate. A separate procedure regarding the loss of overseas listed and foreign invested share certificates is provided for in the Mandatory Provisions.

Suspension and Termination of Listing

The Company Law has deleted the provisions governing suspension and termination of listing. The *PRC Securities Law (2019 revision)* (《中華人民共和國證券法》(2019年修訂)) has also deleted the

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provisions regarding suspension of listing. Where listed securities fall under the delisting circumstances stipulated by a stock exchange, the stock exchange shall terminate their listing and trading in accordance with the business rules.

Where the stock exchange decides on delisting of securities, it shall promptly make an announcement and file with a securities regulatory authority of the State Council.

Merger and Demerger

Companies may merge through merger by absorption or through the establishment of a new corporation. If it merges by absorption, the company which is absorbed shall be dissolved. If it merges by forming a new corporation, both companies will be dissolved.

SECURITIES LAW AND REGULATIONS

The PRC has promulgated a number of regulations that relate to the issue and trading of shares and disclosure of information. In October 1992, the State Council established the Securities Committee and the CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities-related institutions in the PRC and administering the CSRC. The CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions of securities markets, supervising securities companies, regulating public offers of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking relevant research and analysis. In April 1998, the two departments were consolidated by the State Council and the CSRC was reformed.

The *Interim Provisional Regulations on the Administration of Share Issuance and Trading* (《股票發行與交易管理暫行條例》) deals with the application and approval procedures for public offerings of equity securities, trading in equity securities, the acquisition of listed companies, the deposit, clearing and transfer of listed equity securities, the information disclosure, investigation, penalties and dispute settlement with respect to a listed company.

On December 25, 1995, the State Council promulgated and implemented the *Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies* (《國務院關於股份有限公司境內上市外資股的規定》). These regulations deal mainly with the issue, subscription, trading and declaration of dividends and other distributions of domestic listed and foreign invested shares, and the disclosure of information of joint stock limited companies having domestic listed and foreign invested shares.

The *PRC Securities Law* (《中國證券法》) took effect on July 1, 1999 and was revised on August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. This is the first national securities law in the PRC, comprising 14 chapters and 226 articles to regulate, among other things, the issue and trading of securities, acquisition of listed companies, securities exchanges, the duties and responsibilities of securities companies and the State Council's securities regulatory authorities. Article 224 of the *PRC Securities Law* provides that for a domestic enterprise to list its shares outside the PRC, it shall comply with the relevant provisions of the State Council. At present, the issue and trading of foreign issued shares (including H shares) are mainly governed by the rules and regulations promulgated by the State Council and the CSRC.

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ARBITRATION AND ENFORCEMENT OF ARBITRAL AWARDS

The *Arbitration Law of the PRC* (《中華人民共和國仲裁法》) (the “**Arbitration Law**”) was passed by the Standing Committee of the NPC on August 31, 1994, came into effect on September 1, 1995 and was amended on August 27, 2009 and September 1, 2017. Under the Arbitration Law, an arbitration committee may, before the promulgation by the PRC Arbitration Association of arbitration regulations, formulate interim arbitration rules in accordance with the Arbitration Law and the Civil Procedure Law. Where the parties have by agreement provided arbitration as the method for dispute resolution, the people’s court will refuse to handle the case except when the arbitration agreement is declared invalid.

The Mandatory Provisions require an arbitration clause to be included in the articles of association of an issuer. Matters for arbitration include any disputes or claims in relation to the issuer’s affairs or as a result of any rights or obligations arising under the articles of association, the Company Law or other relevant laws and administrative regulations.

Where the dispute or claim stated in the preceding paragraph are filed for arbitration, the entire claim or dispute shall file for arbitration, and all parties who have a cause of action based on the same facts giving rise to the dispute or claim or whose participation is necessary for the resolution of such dispute or claim shall comply with the arbitration. Disputes in respect of the definition of shareholder and disputes in relation to the issuer’s register of shareholders need not be resolved by arbitration.

A claimant may elect for arbitration to be carried out at either the China International Economic and Trade Arbitration Commission (中國國際經濟貿易仲裁委員會) (“**CIETAC**”) in accordance with its arbitration rules or the Hong Kong International Arbitration Centre (“**HKIAC**”) in accordance with its Securities Arbitration Rules (the “**Securities Arbitration Rules**”). Once a claimant files a dispute or claim for arbitration, the counter-party shall submit to the arbitral body elected by the claimant. If the claimant elects for arbitration to be carried out at the HKIAC, any party to the dispute or claim may apply for a hearing to take place in Shenzhen in accordance with the Securities Arbitration Rules. In accordance with the *Arbitration Regulations of CIETAC* (《中國國際經濟貿易仲裁委員會仲裁規則》) which was amended on November 4, 2014 and implemented on January 1, 2015, CIETAC shall deal with economic and trading disputes over contractual or non-contractual transactions, including disputes involving Hong Kong, based on an agreement of the parties. CIETAC is based in Beijing with branches and centers set up in Shenzhen, Shanghai, Tianjin, Chongqing, Zhejiang, Hubei, Fujian, Shanxi, Jiangsu, Sichuan and Shandong.

Under the Arbitration Law and the Civil Procedure Law, an arbitral award is final and binding on both parties to the arbitration. If one party to the arbitration fails to comply with an award, the other party to the award may apply to the people’s court for enforcement. A people’s court may refuse to enforce an arbitral award made by an arbitration commission if there is any wrongdoing on the procedures or composition of arbitrators specified by law or the award exceeds the scope of the arbitration agreement or is outside the jurisdiction of the arbitration commission.

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A party seeking to enforce an arbitral award from PRC arbitration panel against a party who, or whose properties, is not within the PRC, may apply to a foreign court with jurisdiction over the case for enforcement. Similarly, an arbitral award made by a foreign arbitration body may be recognized and enforced by a PRC court in accordance with the principles of reciprocity or any international treaty concluded or acceded to by the PRC. The PRC acceded to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the “**New York Convention**”) adopted on June 10, 1958 pursuant to a resolution of the Standing Committee of the NPC passed on December 2, 1986. The New York Convention provides that all arbitral awards made in a state which is a party to the New York Convention shall be recognized and enforced by all other parties to the New York Convention, subject to their right to refuse enforcement under certain circumstances, including where the enforcement of the arbitral award is against the public policy of the state to which the application for enforcement is made. It was declared by the Standing Committee of the NPC simultaneously with the accession of the PRC that (i) the PRC will only recognize and enforce foreign arbitral awards on the principle of reciprocity and (ii) the PRC will only apply the New York Convention in disputes considered under PRC laws to arise from contractual and non-contractual mercantile legal relations.

An arrangement was reached between Hong Kong and the Supreme People’s Court for the mutual enforcement of arbitral awards. On June 18, 1999, the Supreme People’s Court adopted the *Arrangement on Mutual Enforcement of Arbitral Awards between Mainland China and Hong Kong* (《關於內地與香港特別行政區相互執行仲裁裁決的安排》), which became effective on February 1, 2000. In accordance with this arrangement, awards made by PRC arbitral authorities under the Arbitration Ordinance of Hong Kong can be enforced in Hong Kong, and Hong Kong arbitration awards are also enforceable in the PRC.

Judicial judgment and its enforcement

According to the *Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region* (《最高人民法院關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) promulgated by the Supreme People’s Court on July 3, 2008 and implemented on August 1, 2008, in the case of final judgment, defined with payment amount and enforcement power, made between People’s Court of China and the court of the Hong Kong Special Administrative Region in a civil and commercial case with written jurisdiction agreement, any party concerned may apply to the People’s Court of China or the court of the Hong Kong Special Administrative Region for recognition and enforcement based on this arrangement. “Written jurisdiction agreement” refers to a written agreement defining the exclusive jurisdiction of either the People’s Court of China or the court of the Hong Kong Special Administrative Region in order to resolve dispute with particular legal relation occurred or likely to occur by the party concerned. Therefore, a party may apply to a court on the PRC or a court in Hong Kong Special Administrative Region to recognize and enforce the final judgment made in China or Hong Kong that meet certain conditions of the aforementioned regulations.

Shanghai-Hong Kong Stock Connect

On April 10, 2014, CSRC and the Securities and Futures Commission of Hong Kong (hereinafter referred to as “**HKSFC**”) issued the *Joint Announcement of the China Securities Regulatory Commission and the Securities and Futures Commission of Hong Kong — Principles for the Prospective Implementation of the Pilot Program of an Interconnection Mechanism for Transactions in the Shanghai and Hong Kong Stock Markets* (《中國證券監督管理委員會、香港證券及期貨事務監察委員會聯合公告 — 預期實行滬港股票市場交易互聯互通機制試點時將需遵循的原則》) (hereinafter referred to as

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“Shanghai-Hong Kong Stock Connect”) by the Shanghai Stock Exchange (hereinafter referred to as “SSE”), the Stock Exchange, China Securities Depository and Clearing Co., Ltd. (hereinafter referred to as “CSDCC”) and HKSCC. Shanghai-Hong Kong Stock Connect comprises two parts, Northbound Trading Link and Southbound Trading Link. Southbound Trading Link refers to the entrustment of China securities houses by China investors to trade stocks listed on the Stock Exchange within a stipulated range via filing by the securities trading service company established by the SSE with the Stock Exchange. During the initial period of the pilot program, the stocks of Southbound Trading Link consist of constituent stocks of the Stock Exchange Hang Seng Composite Large Cap Index and the Hang Seng Composite MidCap Index as well as stocks of A+H stock companies concurrently listed on the Stock Exchange and the SSE. The total limit of Southbound Trading Link is RMB250 billion and the daily limit is RMB10.5 billion. During the initial period of the pilot program, it is required by HKSFC that the PRC investors participating in Southbound Trading Link are only limited to institutional investors and individual investors with a combined securities account and capital account balance of not less than RMB500,000.

On November 10, 2014, CSRC and HKSFC issued the Joint Announcement to approve the official launch of Shanghai-Hong Kong Stock Connect by SSE, the Stock Exchange, CSDCC and HKSCC. According to the Joint Announcement, trading of stocks under Shanghai-Hong Kong Stock Connect will commence on November 17, 2014.

On September 30, 2016, CSRC issued the *Provisions on the Recordation of the Placement of Shares to Existing Domestic Shareholders by Hong Kong-Listed Companies under the Southbound Trading Link* (《關於港股通下香港上市公司向境內原股東配售股份的備案規定》) which came into effect on the same day. Placement of shares by Hong Kong listed companies to existing domestic shareholders under Southbound Trading Link shall be filed with CSRC. Hong Kong listed companies shall file the application materials and approved documents with CSRC after obtaining approval from the Stock Exchange for their share placement applications. CSRC will carry out supervision based on the approved opinion and conclusion from Hong Kong.

SUMMARY OF MATERIAL DIFFERENCES BETWEEN HONG KONG AND PRC COMPANY LAW

The laws of Hong Kong applicable to a company incorporated in Hong Kong are based on the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Companies Ordinance. It is supplemented by common law and the rules of equity that are applicable to Hong Kong. As a joint stock limited company established in the PRC which seeks a [REDACTED] of shares on the [REDACTED], we are governed by the Company Law and all other rules and regulations promulgated pursuant to the Company Law.

Set out below is a summary of certain material differences between the Companies Ordinance of Hong Kong applicable to a company incorporated in Hong Kong and the Company Law applicable to a joint stock limited company incorporated and existing under the Company Law. This summary is, however, not intended to be an exhaustive comparison.

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Existence of a Company

Under the Companies Ordinance of Hong Kong, a company with share capital shall be incorporated by the Registrar of Companies in Hong Kong, which will issue a certificate of incorporation to the company upon its incorporation and the company will then acquire an independent existence. A company may be incorporated as a public company or a private company. Pursuant to the Companies Ordinance, the articles of association of a private company incorporated in Hong Kong shall contain certain provisions on first refusal. A public company’s articles of association do not contain such provisions on first refusal.

Under the Company Law, a joint stock limited company may be incorporated by means of promotion or public subscription.

Share Capital

Directors of a Hong Kong company may, with the prior approval of the shareholders, issue new shares of the company, if required. The Company Law does not provide for authorized share capital. Our registered capital represents our issued share capital. Any increase in our registered capital must be approved by our shareholders’ general meeting and filed with the relevant PRC governmental and regulatory authorities.

Under the Company Law, the shares may be subscribed for in the form of monetary or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws and administrative regulations). For non-monetary assets to be used as capital contributions, appraisals and verification must be carried out to ensure that no assets are over-estimated or under-estimated. There is no such restriction for a Hong Kong company under the laws of Hong Kong.

Restrictions on Shareholding and Transfer of Shares

Generally, overseas listed shares, which are denominated in Renminbi and subscribed for in a currency other than Renminbi, may only be subscribed for, and traded by, investors from Hong Kong, Macau and Taiwan or any country and territory outside the PRC, or qualified domestic institutional investors as allowed under the *Trial Measures for the Administration of Overseas Securities Investment by Qualified Domestic Institutional Investors* (《合格境內機構投資者境外證券投資管理試行辦法》). If the H Shares are eligible securities under the Southbound Trading Link, they are also available to be subscribed for and traded by PRC investors in accordance with the rules and restrictions under Shanghai-Hong Kong Stock Connect or Shenzhen-Hong Kong Stock Connect.

Under the Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares held by it for a period of one year after the date of establishment of the company. Shares in issue prior to our [REDACTED] cannot be transferred within one year from the date of the shares [REDACTED] on a [REDACTED]. Shares transferred by the directors, supervisors and management of a joint stock limited liability company each year during their term of office shall not exceed 25% of the total shares they hold in the company, and the shares they hold in the company shall not be transferred within one year from the listing date of the shares, nor within half a year after they have left office. The articles of association may set out other restrictive requirements on the transfer of the company’s shares held by its directors, supervisors and officers. There are no such restrictions on shareholdings and

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transfers of shares under the laws of Hong Kong apart from the six-month lockup on the company’s issue of shares and the 12-month lockup on controlling shareholders’ disposal of shares, as stated in the undertakings given by the Company and our controlling shareholders to the [REDACTED].

Financial Assistance for Acquisition of Shares

The Company Law does not prohibit or restrict a joint stock limited company or its subsidiaries from providing financial assistance for the purpose of acquisition of its own or its holding company’s shares. However, the Mandatory Provisions contain certain restrictions for a company and its subsidiaries to provide such financial assistance, which are similar to those under the Companies Ordinance of Hong Kong.

Variation of Class Rights

The Company Law has no special provisions relating to variation of class rights. However, the Company Law states that the State Council may otherwise promulgate regulations relating to other classes of shares. The Mandatory Provisions contain annotated provisions relating to the circumstances which are deemed to be variations of class rights and its subsequent approval procedures required to be completed. These provisions have been incorporated in the Articles of Association, which are summarized in “Appendix V — Summary of Articles of Association”.

Under the Companies Ordinance, no rights attached to any class of shares can be varied except:

- (i) if there are provisions in the articles of association relating to the variation of those rights, those provisions shall be complied with;
- (ii) if there are no relevant provisions in the articles of associations, either (1) it is consented in writing by at least three-fourths of the total voting rights of holders of the shares in the class in question; or (2) it is approved by a special resolution of the holders of the relevant class at a separate meeting.

We have incorporated the provisions in respect to protecting the rights of class shares into the Articles of Association in a similar way as required by the laws of Hong Kong in accordance with the Hong Kong Listing Rules and Mandatory Provisions. The holders of overseas listed shares and domestic shares are defined in the Articles of Association as shareholders of different classes of shares. The special procedures for voting by class shareholders are not applicable in the following circumstances: (i) after approval by a special resolution at a shareholders’ general meeting, the Company shall issue domestic shares and overseas listed foreign shares separately at an interval of every 12 months or at the same time, and the proposed number of domestic shares and overseas listed foreign shares to be issued, respectively, will not exceed 20% of the outstanding shares of such class; (ii) the plans to issue domestic shares and overseas listed foreign shares upon establishment of the Company shall complete within 15 months from the date of approval by the securities regulatory authority of the State Council; and (iii) after the Company has issued H shares in an overseas region, and after approval has been granted by the State Council or the securities regulatory authority of the State Council, the shareholders of the Company may [REDACTED] the unlisted shares held by them for [REDACTED] and [REDACTED] in such overseas region.

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Directors, Senior Management and Supervisors

The Company Law, unlike the Companies Ordinance of Hong Kong, does not contain any requirements relating to the declaration of directors' interests in material contracts, restrictions on directors' authority in making major disposals, restrictions on companies providing certain benefits to directors and guarantees in respects of directors' liability and prohibitions against compensation for loss of office without shareholders' approval. The Mandatory Provisions, however, contain certain restrictions on major disposals and specify the circumstances under which a director may receive compensation for loss of office.

Board of Supervisors

Under the Company Law, directors and managers of a joint stock limited company shall be supervised by a supervisors committee. There is no mandatory requirement for the establishment of a board of supervisors for a company incorporated in Hong Kong. The Mandatory Provisions provide that each supervisor has a duty, in the exercise of his powers, to act in good faith and honestly in what he considers to be in the best interests of the Company and to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

Derivative Action by Minority Shareholders

Under the laws of Hong Kong, a shareholder may, with the permission given from a court, initiate a derivative action on behalf of a company for any misconduct committed by its directors against the company. For example, permission may be granted where the directors control a majority of votes at a shareholders' general meeting, and could thereby prevent the company from suing the directors in its own name.

The Company Law provides that the shareholders of a joint stock limited company with the right so that in the event where the directors and senior management violate their fiduciary obligations to a company, the shareholders individually or jointly holding over 1% of the shares in the company for more than 180 consecutive days may request in writing the board of supervisors to initiate proceedings in a the people's court. In the event that the board of supervisors violates their fiduciary duties to a company, the above said shareholders may send written request to the board of directors to initiate proceedings in the people's court. Upon receipt of such written request from the shareholders, if the board of supervisors or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days upon receipt of the request, or in case of urgency if under urgent situations, failure to initiating an immediate proceeding may cause irremediable damages to the company, the shareholders mentioned above shall, for the benefit of the company's interests, have the right to initiate proceedings directly to the court in their own name.

The Mandatory Provisions provide further remedies against the directors, supervisors and senior management who breach their duties to the company. In addition, as a condition to the shares listed on the Hong Kong Stock Exchange, each director and supervisor of a joint stock limited company is required to give an undertaking in favor of the company acting as agent for the shareholders. This allows minority shareholders to take action against directors and supervisors in default.

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Protection of Minorities

Under the laws of Hong Kong, the company may be wound up by a the court if the court considers that it is just and equitable to do so. In addition, a shareholder who complains that the affairs of a company incorporated in Hong Kong are conducted in a manner unfairly prejudicial to his interests may petition to the court to make an appropriate order regulating the affairs of the company. Furthermore, under certain circumstances, the Financial Secretary of Hong Kong may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated in Hong Kong. The PRC law does not contain similar requirements on protection.

The Mandatory Provisions, however, contain provisions that a controlling shareholder may not exercise its voting rights in a manner prejudicial to the interests of the shareholders generally or of a proportion of the shareholders of a company to relieve a director or supervisor of his duty to act honestly in the best interests of the company or to approve the exploitation by a director or supervisor of the company’s assets or the individual rights of other shareholders.

Notice of Shareholders’ General Meetings

Under the Company Law, notice of a shareholder’s annual general meeting must be given not less than 20 days before the meeting. According to the *Official Reply of the State Council regarding Adjusting the Application of Provisions to Matters Including the Notice Period for Convention of Shareholders’ General Meetings by Overseas Listed Companies* (《國務院關於調整適用在境外上市公司召開股東大會通知期限等事項規定的批覆》) promulgated by the State Council on October 17, 2019, the notice period for a shareholders’ meeting, the shareholder proposal right, and the procedures for convening a shareholders’ meeting, for those joint stock companies established inside China but listed outside China, should be governed by the PRC Company Law. For a company incorporated in Hong Kong with limited liability, the minimum period of notice of an annual general meeting is 14 days. Further, where a meeting involves consideration and review of a resolution requiring a special notice, the company must also give its shareholders notice of the resolution at least 14 days before the meeting. The notice period for an annual shareholders’ general meeting is 21 days.

Quorum for Shareholders’ General Meetings

Under the laws of Hong Kong, the quorum for a shareholders’ general meeting must be at least two members unless the articles of association of the company otherwise provide or the company has only one member, in which case the quorum shall be one. For companies with only one member, the quorum shall be one member. The Company Law does not specify any quorum requirement for a shareholders’ general meeting, but the Special Regulations and the Mandatory Provisions provide that a shareholders’ general meeting may only be convened when replies to the notice of that meeting have been received from shareholders whose shares represent at least 50% of the voting rights at least 20 days before the proposed date of the meeting. If such 50% level is not reached, the company shall further notify its shareholders within five days by way of a public announcement, and the shareholders’ general meeting may then be held.

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Voting

Under the laws of Hong Kong, an ordinary resolution shall be passed by a simple majority of votes cast by members present in person or by proxy at a shareholders' general meeting, and a special resolution shall be passed by a majority of not less than three-fourths of votes cast by members present in person or by proxy at a shareholders' general meeting. Under the Company Law, the passing of any resolution requires affirmative votes of shareholders representing more than half of the voting rights represented by the shareholders who attend the shareholders' general meeting except in cases of proposed amendments to a company's articles of association, increase or decrease of registered capital, merger, division or dissolution, or change of form of corporation, which require affirmative votes of shareholders representing more than two-thirds of the voting rights represented by the shareholders who attend the shareholders' general meeting.

Financial Disclosure

Under the Company Law, a financial report of a joint stock limited company shall be made available in the company required to make available at the company for inspection by shareholders its financial report 20 days prior to its annual general meeting is held for inspection by its shareholders. In addition, the public offering of shares by a joint stock limited company of which the shares are publicly offered must be published in its financial report.

The Companies Ordinance requires a company incorporated in Hong Kong to send to every shareholder a copy of its balance sheet, auditors' report and directors' report, those documents shall be presented before the company in its annual general meeting, not less than 21 days before such meeting. A joint stock limited liability company is required under the PRC law to prepare its financial statements in accordance with the PRC GAAP. The Mandatory Provisions require that a company shall, in addition to preparing financial statements according to the PRC GAAP, have its financial statements prepared and audited in accordance with international or Hong Kong accounting standards, and its financial statements shall also contain a statement in respect of the financial effect caused by the material differences, if any, from the financial statements prepared in accordance with the PRC GAAP.

The Special Regulations require that there shall not be any inconsistency between the information disclosed inside and outside the PRC and that, to the extent that there are differences in the information disclosed in accordance with the relevant PRC and overseas laws, regulations and requirements of the relevant stock exchanges, such differences shall also be disclosed simultaneously.

Information on Directors and Shareholders

Shareholders are entitled to the right to inspect the company's articles of association, minutes of the shareholders' general meetings, and financial and accounting reports under the Company Law. Under the Articles of Association, Shareholders are entitled to the right to inspect and receive a copy (at a reasonable fee) certain information on shareholders and on directors which is similar to the shareholders' rights of Hong Kong companies under the laws of Hong Kong.

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Receiving Agent

Under the Company Law and the laws of Hong Kong, dividends once declared are debts payable to shareholders. The period of limitation for debt recovery action is six years under the laws of Hong Kong, while such period of limitation is three years under the PRC Civil Code (《中華人民共和國民法典》), which was promulgated on May 28, 2020 and became effective on January 1, 2021. The Mandatory Provisions require the relevant company to appoint a trust company registered under the Hong Kong Trustee Ordinance (Chapter 29 of the Laws of Hong Kong) as a receiving agent to receive on behalf of holders of shares dividends declared and all other monies owed by the company in respect of its shares.

Corporate Reorganization

Corporate reorganization of a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, or a compromise or arrangement between the company and its creditors or between the company and its members pursuant to Section 673 and Division 2 of Part 13 of the Companies Ordinance, which requires the sanction of the court. Under PRC laws, merger, division, dissolution or change to the form of a joint stock limited liability company shall be approved by shareholders in a shareholders' general meeting.

Arbitration of Disputes

In Hong Kong, disputes between shareholders and a company incorporated in Hong Kong or its directors may be resolved through legal proceedings in a court. The Mandatory Provisions provide that such disputes should be file for arbitration at either the HKIAC or the CIETAC, at the claimant's choice.

Mandatory Deductions

Under the Company Law, a joint stock limited liability company is required to make transfers equivalent to certain prescribed percentages of its after tax profit to the statutory common reserve fund. There are no corresponding provisions under the laws of Hong Kong.

Remedies of the Company

Under the Company Law, if a director, supervisor or manager in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, such director, supervisor or manager should be held accountable to that company for such damages. In addition, the Listing Rules require listed companies' articles of association to provide for remedies of the company which are similar to those available under the laws of Hong Kong (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management).

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Dividends

A company has the power in certain circumstances to withhold and pay to the relevant tax authorities, any tax payable under PRC law on any dividends or other distributions payable to a shareholder. Under the laws of Hong Kong, the term for an action to recover a debt (including the claim of dividends) is six years, whereas under PRC laws, such term is three years. The company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable term.

Fiduciary Duties

In Hong Kong, directors have fiduciary duties to the company, including the duty not to act in conflict with the company's interests. Furthermore, the Companies Ordinance has codified the directors' statutory duty of care. Under the Special Regulations, directors, supervisors, managers, and other members of senior management of the company shall honestly and diligently perform their duties for the company.

Closure of Register of Shareholders

The Companies Ordinance requires that the register of shareholders of a company shall not generally be closed for the registration of transfers of shares for more than 30 days (may extend to 60 days in certain circumstances) in a year, whereas, as required by the Company Law and the Mandatory Provisions, no share transfers shall be registered within 30 days before the date of a shareholders' meeting or within five days before the base date set for the purpose of distribution of dividends.

Any person who wishes to obtain detailed advice as to the PRC law or the laws of any jurisdiction is recommended to seek independent legal advice.

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

This Appendix sets out summaries of the main provisions of our Articles of Association (Draft) (the “**Articles of Association**”) adopted by Cryofocus Medtech (Shanghai) Co., Ltd. (the “**Company**”) on December 2, 2021, which shall become effective as at the date on which the H shares are [REDACTED] on the [REDACTED]. As the main purpose of this Appendix is to provide prospective [REDACTED] with an overview of the Articles of Association, it may not necessarily contain all information that is important for prospective [REDACTED]. As discussed in “Appendix VII — Documents Delivered to the Registrar of Companies and Available On Display” to this document, the full text of the Articles of Association in Chinese is available for inspection.

1 DIRECTORS AND BOARD OF DIRECTORS

(1) Power to allocate and issue Shares

The Articles of Association does not contain provisions that authorize the Board to allocate or issue Shares. The Board shall prepare proposals for Share issue, which are subject to approval by the Shareholders at the general meeting in the form of a special resolution.

The Company’s increase of capital by issuing new shares shall, after being approved in accordance with the provisions of the Articles of Association, be conducted in accordance with the procedures stipulated in relevant laws, administrative regulations and the listing rules of the region where the Company’s Shares are listed.

The Board of the Company shall make implementation arrangements for the issuance of domestic Shares and overseas-listed foreign Shares respectively, as approved by the securities regulatory authority under the State Council.

(2) Power to dispose assets of our Company or any subsidiary

When the Board intends to dispose a fixed asset, if sum of the expected value of the said fixed asset and the value obtained from the fixed assets that are disposed within four months before this disposal proposal exceeds 33% of the value of fixed assets as shown in the balance sheet latest reviewed at the general meeting, then the Board shall not dispose or agree to dispose of the said fixed asset without the approval of the general meeting.

The disposal of fixed asset refers to the transfer of interests in certain assets, but does not include the provision of guarantees with fixed assets.

The validity of the transactions with respect to the disposal of fixed assets by our Company shall not be affected by the violation of the above provisions.

(3) Appointment, resignation and dismissal

The Company has established a Board of Directors, which is responsible and report to the general meeting, comprising of eight Directors, including three independent non-executive Directors. The Board of Directors shall have a chairperson, who shall be elected and removed by a simple majority of the Board with a three-year term of office and may be re-elected upon the expiration of the term of the Directors. Save as otherwise provided in the Articles of Association, the number of independent non-executive Directors shall not be less than three and shall constitute at least one-third of the total number of Directors at any time.

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The Directors shall be elected or replaced by the Shareholders at the general meeting for a term of three years. Directors may be re-elected upon expiration of their term of office. There is no mandatory retirement age for Directors under the Articles of Association.

Any Director may be removed from office by an ordinary resolution at the general meeting prior to the expiration of his or her term of office, subject to compliance with the provisions of relevant laws and administrative regulations. Such removal shall be without prejudice to any claim for damages under any contract of such Director.

(4) Borrowing powers

The Articles of Association do not contain any special provision in respect of the manner in which borrowing powers may be exercised by the Directors, except (i) the provision regarding the power of the Directors to formulate proposals for our Company to issue bonds; and (ii) the provision stating that the issuance of bonds to be approved by the Shareholders of the Company at general meeting by way of a special resolution.

2 DIRECTORS, SUPERVISORS, GENERAL MANAGER AND OTHER SENIOR MANAGEMENT

(1) Emoluments or compensation for Directors and Supervisors

The Company shall enter into written contract with Directors or Supervisors in relation to emoluments. The emoluments are subject to approval at general meeting in advance. The aforesaid emoluments include:

- i. emoluments in respect of his service as a Director, Supervisor, or a member of senior management of the Company;
- ii. emoluments in respect of his service as a Director, Supervisor or a member of senior management of any subsidiary of the Company;
- iii. emoluments in respect of other service in relation to the management of the Company and any of its subsidiaries;
- iv. payment of compensation for loss of office or retirement from office of the Director or Supervisor.

The Company' written contract with Directors or Supervisors and senior management shall at least include the following provisions:

- i. an undertaking to the Company to comply with the Company Law, the Special Regulations, the Articles of Association, the Code on Takeovers and Mergers and Share Buy-backs, the Hong Kong Listing Rules and other requirements by the HKSF and Hong Kong Stock Exchange, and an agreement to entitle the Company to enjoy the remedies provided in the Articles of Association. The contract and his office shall not be consigned;
- ii. an undertaking to the Company to comply with and perform his obligations to Shareholders as provided in the Articles of Association;
- iii. an arbitration clause provided in the Articles of Association and the Hong Kong Listing Rules.

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No proceedings may be brought by a Director, Supervisor and senior management against the Company for anything due to him in respect of the aforesaid matters except pursuant to the aforesaid contract.

The contract concerning the emoluments between the Company and its Directors or Supervisors should provide that in the event that the Company is acquired, the Directors and Supervisors shall, subject to the prior approval of Shareholders at general meeting, have the right to receive compensation or other payment in respect of his loss of office or retirement.

The aforesaid acquisition of the Company refers to any of the following:

- i. an offer made by any person to all Shareholders;
- ii. an offer made by any person with a view to make the offeror become the Controlling Shareholder of the Company. The definition of Controlling Shareholder is the same as defined in the Articles of Association.

If the relevant Director or Supervisor fails to comply with this Article, any payment received shall belong to the persons who sell the Shares in acceptance of the aforesaid offer. The Director or Supervisor shall bear all expenses arising from the distribution of such payments to the persons in proportion and all such expenses shall not be deducted from these payments distributed.

(2) Loans or guarantees for loans to Directors, Supervisors, general manager or other senior management

The Company shall not provide loans or guarantees for loans, either directly or indirectly, to the Directors, Supervisors, senior management of the Company and its Controlling Shareholders, nor shall provide loans or guarantees for loans to the personnel related to above personnel.

The aforesaid provisions are not applicable to the following:

- i. The Company provides its subsidiaries with loans or guarantees for loans;
- ii. The Company provides any of the Directors, Supervisors or senior management of the Company with loans, guarantees for loans or any other funds pursuant to the employment contract(s) approved at the general meeting to pay all expenses incurred for the purpose of the Company or performing duties for the Company; and
- iii. In case that the normal business scope of the Company covers the provision of loans and guarantees for loans, the Company may provide such Directors, Supervisors or senior management and other related personnel with loans and guarantees for loans, provided that the conditions of the above loans or guarantees for loans shall be the normal commercial conditions.

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Guarantees for loans provided by the Company in breach of the Articles of Association shall not be enforced, except where:

- i. The lender unknowingly provides loans to personnel related to the Directors, Supervisors, senior management of the Company or its Controlling Shareholders;
- ii. The collateral provided by the Company is sold lawfully by the lender to the buyer in good faith.

Guarantees mentioned above include the acts of the guarantor assuming obligations or providing properties to ensure the performance of the obligations by the obligor.

(3) Disclosure of interests in contracts, transactions or arrangements with the Company

Where a Director, Supervisor and senior management, directly or indirectly, has material interests in the contracts, transactions or arrangements that the Company has entered into or plans to enter into (except for employment contracts entered into by the Company with the Directors, Supervisor and senior management), the above personnel shall disclose the nature and degree of his/her interests to the Board as soon as possible no matter whether such matters are subject to the approval of the Board.

Save as otherwise provided by the laws and regulations, regulatory documents and the securities regulatory authorities of the place where the Shares of the Company are listed, a Director shall be abstained from voting on any resolution approving any contract, transaction or arrangement in which such Director or any of his/her close associates (as defined in the Hong Kong Listing Rules) has a material interest nor shall such Director be counted in the quorum present at the meeting. Unless the interested Director, Supervisor and senior management of the Company discloses his/her interests to the Board in accordance with the paragraph 1 above and the matters are approved by the Board at a meeting where the interested Director, Supervisor and senior management is not counted in the quorum and refrains from voting, the Company shall have the right to cancel such contracts, transactions or arrangements, except where the counterparty is a party in good faith without knowledge of the acts of such Directors, Supervisors and senior management violating their obligations.

A Director, Supervisor, or senior management of the Company shall be deemed to be interested in such contracts, transactions or arrangements in which his/her related person or associate is interested.

Where a Director, Supervisor and senior management of the Company gives to the Board a notice in writing stating that, by reason of the facts specified in the notice, he/she is interested in contracts, transactions or arrangements which may subsequently be entered into by our Company, so far as the content stated in such notice is concerned, such Directors, Supervisor, and senior management shall be deemed to have made the disclosures required by the aforesaid provision of the Articles, provided that such notice have been given before the date on which the question of entering into the contracts, transactions or arrangements is first taken into consideration by the Company. The Company shall arrange appropriate insurance coverage in respect of possible legal action against the Directors.

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(4) Qualifications

No person shall serve as our Director, Supervisor, or senior management if he/she is:

- i. a person who is unable or has limited ability to undertake any civil liabilities;
- ii. a person who has been convicted of an offense of bribery, corruption, embezzlement or misappropriation of property, or the destruction of socialist market economy order; or who has been deprived of his political rights due to his crimes, in each case where less than five years have elapsed since the date of completion of the sentence;
- iii. a person who has been a Director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise;
- iv. a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law and has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation;
- v. a person who is liable for a relatively large amount of debts that are overdue;
- vi. a person who is investigated by the judicial agencies for violation of criminal law and such case is pending;
- vii. a person who is not eligible for enterprise's leadership under laws, administrative regulations and the listing rules of the place where the Shares of the Company are listed;
- viii. a person who is not a natural person;
- ix. a person judged by the competent agencies to have violated the provisions of relevant securities laws, being involved in deceptive or dishonest acts and is within five years of the date on which the judgment was made;
- x. other circumstances as stipulated by relevant laws and regulations of the place where the Company's Shares are listed.

The election, appointment of Director, Supervisor, or senior management shall be invalid if such election, appointment or employment is in violation of the above provisions. If a Director, Supervisor, and senior management falls into the situations provided in this Article during his/her term of office, he/she shall be dismissed by the Company.

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The validity of the act of a Director, or senior management on behalf of the Company to bona fide third parties shall not be affected by any irregularities in his/her appointment, election or qualifications.

(5) Duties

Directors, Supervisors, and senior management of the Company shall bear the obligations towards the Company. The Company shall have the right to take the following measures in addition to various rights and remedial measures stipulated in laws, administrative regulations and the listing rules of the place where the Shares of the Company are listed:

- i. claim damages from the Director, Supervisor and senior management in compensation for losses sustained by the Company as a result of such breach;
- ii. rescind any contract or transaction entered into by the Company with the Director, Supervisor and senior management or by the Company with a third party (where such third party knows or should know that there is such a breach of duties by such Director, Supervisor and senior management);
- iii. account for the profits made by the Director, Supervisor and senior management in breach of his/her duties;
- iv. recover any funds received by the Director, Supervisor and senior management that should have been received by the Company, including (but not limited to) commissions;
- v. demand payment of the interest earned or which may have been earned by the Director, Supervisor and senior management on the funds that should have been paid to the Company.

When performing their duties, Directors, Supervisors and senior management of the Company must comply with the principle of good faith and shall not put themselves in situations where their own interests may conflict with the obligations they have undertaken. This principle includes but not limited to performing the following obligations:

- i. to act honestly in the best interests of the Company;
- ii. to exercise his/her power within but not exceeding the scope of authority;
- iii. to exercise the discretion vested in him personally without being manipulated by others; not transferring discretionary powers to other persons, unless and to the extent permitted by laws, administrative regulations, the listing rules of the place where the Shares of the Company are listed or with the informed consent given in a general meeting;
- iv. to treat Shareholders of the same class equally and Shareholders of different classes fairly;
- v. to enter into contract, transaction or arrangement with the Company is not allowed, unless in line with the Articles of Association or otherwise by the approval at a general meeting on an informed basis;
- vi. to seek private gain using the properties of the Company in any manner is not allowed, unless agreed at a general meeting on an informed basis;

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- vii. not to exploit his/her position to accept bribes or other illegal income or expropriate properties of the Company by any means, including (but not limited to) opportunities beneficial to the Company;
- viii. to accept commissions associated with transactions of the Company is not allowed unless agreed at a general meeting on an informed basis;
- ix. to comply with the Articles of Association, faithfully execute his/her duties and protect the Company's interests, and not to exploit his/her position and power in the Company to advance his/her own private interests;
- x. not to take advantage of any duties to seek any business opportunities which should have been the Company's for himself or others, operate himself or for other person in same business as that of the Company and not to compete with the Company in any kind without informed consent of the general meeting;
- xi. not to misappropriate the Company's funds or lend such funds to others, or deposit the Company's capital or funds into accounts under his own name or the name of other individuals; and not to loan the Company's funds to others or provide guarantees in favor of others supported by the Company's assets for the Company's shareholders or other individuals;
- xii. not to disclose confidential information relating to the Company obtained during employment without informed consent of the general meeting; unless in the interest of the Company, not to use such information; however, under the following circumstances the information may be disclosed to a court or other competent government agencies:
 - a) required by the provisions of the law;
 - b) for the public interests;
 - c) for the interests of Directors, Supervisors, or senior management.

Directors, Supervisors and senior management may not direct the following persons or institutions ("**Related Parties**") to do what they are prohibited from doing:

- i. spouses or minor children of the Directors, Supervisors and senior management of the Company;
- ii. trustees of the Directors, Supervisors and senior management of the Company or of the persons mentioned in (i) above;
- iii. partners of the Directors, Supervisors and senior management of the Company or of the persons mentioned in (i) and (ii) above;

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- iv. any company under the de facto control of the Directors, Supervisors and senior management of the Company individually or jointly with the persons or other directors, Supervisors and senior management of the Company mentioned in (i), (ii) and (iii) above; and
- v. the Directors, Supervisors and senior management of the controlled companies mentioned in (v).

The good faith obligation of the Directors, Supervisors and senior management of the Company may not necessarily cease with the termination of their terms; their obligation to keep the trade secrets of the Company in confidence shall survive the termination of their terms. Other duties may continue for such period as fairness may require depending on the time lapses between the termination and the act concerned and any circumstance and condition under which the relationships between them and the Company are terminated.

Unless otherwise provided in the Articles of Association, the liabilities of the Directors, Supervisors and senior management of the Company arising from the violation of specific duties may be dissolved by the general meeting on an informed basis.

In addition to the obligations set forth in laws, administrative regulations or the listing rules of the stock exchange where the Shares of the Company are listed, the Directors, Supervisors and senior management shall assume the following obligations for each of the Shareholders when exercising their authorities:

- i. they shall not cause the Company to operate beyond the scope of business indicated on our business license;
- ii. they shall sincerely act for the best interests of the Company as the starting point of any action;
- iii. they may not deprive the Company of its assets in any manner, including but not limited to, opportunities beneficial to the Company;
- iv. they shall not deprive the Shareholders of personal rights and interests, including but not limited to the distribution rights and voting rights, except for restructuring of the Company approved at the general meeting pursuant to the provisions of the Articles of Association.

The Directors, Supervisors and senior management of the Company have the responsibilities when exercising their rights or carrying out their obligations to act with the care, diligence and skill due from a reasonably prudent person under similar circumstances.

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3 AMENDMENTS TO ARTICLES OF ASSOCIATION

The Company may amend the Articles of Association according to the provisions of laws, administrative regulations, the listing rules of the place where the Shares of the Company are listed and the Articles of Association. The amendment to the Articles of Association shall not contravene the provisions of laws and administrative regulations or the relevant provisions of the securities regulatory authority in the place where the shares of the Company are listed.

Any amendments to the Articles of Association shall be made through the relevant decision-making procedures and the necessary procedure in accordance with the relevant laws, administrative regulations and the provisions of the Articles of Association. Any amendment to the Articles of Association in relation to the Mandatory Provisions will only be effective after being approved by the company's approval department authorized by the State Council and the CSRC; in relation to matters involving the Company's registration, the changes shall be registered in accordance with law.

4 VARIATION OF RIGHTS OF EXISTING SHARES OR ANY CLASS OF SHARES

Should the Company proposes to change or abolish the rights conferred to any class of Shareholders, approval by special resolution at the general meeting and from the Shareholders of the affected class at the general meeting convened separately shall be obtained before the proposal is implemented.

The rights of a particular class of Shareholders shall be deemed as changed or abolished under the following circumstances:

- i. increase or decrease the number of Shares of the class, or increase or decrease the number of Shares of the class with equal or more voting rights, distribution rights, other privileges than Shares of the class;
- ii. convert all or part of the Shares of a class into other classes, or convert another class of Shares, partly or wholly, into Shares of such class or authorize such conversion rights;
- iii. remove or reduce the rights of Shares of the class to accrued dividends generated or rights to cumulative dividends;
- iv. reduce or remove the senior rights attached to Shares of such class for dividends or for distribution of properties during liquidation of the Company;
- v. add, remove or reduce the rights of Shares of the class, including share conversion rights, options rights, voting rights, transfer rights, pre-emptive rights, and the rights to acquire the securities of the Company;
- vi. remove or reduce the rights of Shares of the class to receive payables from the Company in specified currencies;
- vii. create new classes of shares entitled to equal or more voting rights, distribution rights, or other privileges than Shares of the class;

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- viii. restrict the transfer or ownership of Shares of the class or increase such restrictions;
- ix. issue subscription or conversion rights for Shares of such or other classes;
- x. increase the rights and privileges of other classes of Shares;
- xi. the restructuring plan of the Company may constitute different classes of Shareholders to assume responsibilities disproportionately in restructuring;
- xii. amend or abolish the clauses stipulated in the Articles of Association.

Whether or not the Shareholders of the affected class have voting rights at the general meeting, in the event of involving the matters described from (ii) to (viii) and (xi) to (xii) in the above paragraph, they have voting rights at the class meeting, but the interested Shareholders shall have no voting rights at the class meeting.

The interested Shareholders include:

- i. where the Company makes an offer to all the Shareholders at the same ratio in accordance with the Articles of Association or purchases their own Shares through public transaction in the stock exchange, "interested Shareholders" refer to Controlling Shareholders as defined in the Articles of Association;
- ii. where the Company purchases its own Shares through an agreement outside the stock exchange in accordance with the Articles of Association, "interested Shareholders" refer to the Shareholders who are relevant to such agreement;
- iii. in the Company's restructuring plan, "interested Shareholders" refer to the Shareholders who assume liabilities at a proportion less than other Shareholders in the same class or who hold interests different from other Shareholders in the same class.

The resolution of the class meeting shall be passed by votes representing more than two thirds of shareholding with voting rights attending the class meeting.

To convene a class meeting, the Company shall issue a written notice in accordance with the provisions of the Articles of Association on convening an extraordinary general meeting, informing all shareholders who are registered as holders of that class in the register of shareholders of the matters to be considered at the meeting as well as the date and venue of the meeting.

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In the event that the number of the voting shares represented by the shareholders intending to attend the meeting is more than one half of the total number of voting shares of that class, the Company may convene a class meeting. Otherwise, the Company shall within five days notify the shareholders once again, by way of public announcement, of the matters to be considered at the meeting and the date and venue of the meeting. Upon notification by public announcement, the Company may then proceed to convene the class meeting.

Where there are special requirements in the listing rules of the place where the shares of the Company are listed, the special requirements shall apply.

The notice of a class meeting shall be sent to the Shareholders entitled to vote at such meeting only. Insofar as possible, any class meeting shall be held in accordance with the same procedures as those of the general meeting, and unless otherwise provided herein, any clause relating to the procedures for convening the general meeting in the Articles of Association shall apply to class meeting.

Apart from the Shareholders of other class of Shares, Shareholders of Domestic Shares and Shareholders of unlisted Shares are deemed as same class of Shareholders, Shareholders of Domestic Shares and Shareholders of overseas listed foreign shares are deemed as different classes of Shareholders.

The special procedures for voting by class Shareholders shall not apply under the following circumstances:

- i. after approval by special resolution at shareholders' general meeting, the Company issue Domestic Shares and overseas listed foreign shares separately or at the same time at an interval of 12 months, and the proposed number of domestic shares and overseas listed foreign shares to be issued respectively will not exceed 20% of the outstanding issued shares of such class;
- ii. the plans to issue Domestic Shares and overseas listed foreign shares upon establishment of the Company are completed within 15 months from the date of approval by the securities regulatory authority of the State Council;
- iii. Upon approval obtained from the competent securities regulatory authorities of the State Council and consent given by the Hong Kong Stock Exchange, Shareholders of Domestic Shares of the Company transfer their shares to overseas investors or Shareholders of Domestic Shares of the Company are approved to convert all or part of their Domestic Shares into foreign shares, the listing and trading of which are made on overseas stock exchanges.

5 SPECIAL RESOLUTIONS NEEDED TO BE PASSED BY ABSOLUTE MAJORITY

The resolutions of the general meeting shall be divided into ordinary resolutions and special resolutions.

An ordinary resolution proposed at the general meeting shall be passed by simple majority of the votes held by the Shareholders (including proxies) attending the general meeting.

A special resolution proposed at the Shareholders' general meeting shall be passed by a two-thirds majority of the votes held by the Shareholders (including proxies) attending the general meeting.

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6 VOTING RIGHTS

Shareholders (including proxies) who vote at a general meeting shall exercise their voting rights in accordance with the number of shares with voting rights represented by them, and each share entitles the Shareholder one voting right at the general meeting. However, the Shares held by the Company itself do not carry voting rights, and such Shares shall not be included in the total number of Shares with voting rights held by Shareholders attending the general meeting. If the laws, administrative regulations, regulatory rules (including the Hong Kong Listing Rules) of the place where the Shares of the Company are listed stipulate that a Shareholder shall waive his/her voting right or limit any Shareholder to cast an affirmative or negative vote on a certain resolution, and in case of any violation of such relevant stipulation or limitations, votes casted by such shareholders or proxies thereof shall not be counted.

Any vote of Shareholders at a general meeting must be taken by poll except where the chairman of the meeting, in good faith, decides to allow a resolution that relates purely to a procedural or administrative matter to be voted on by a show of hands.

When voting, Shareholders (including proxies) entitled to two or more votes are not required to vote against or in favor with their total number of votes.

In case of an equality of votes, whether on a show of hands or on a poll, the chairman of the meeting is entitled to one additional vote.

7 RULES ON GENERAL MEETINGS

General meetings are divided into annual general meetings and extraordinary general meetings. A general meeting shall be convened by the Board. Annual general meetings shall be convened once every year and be held within six months after the end of the previous fiscal year.

8 ACCOUNTING AND AUDITS

(1) Financial and accounting policies

The Company shall formulate its financial accounting policies in compliance with laws, administrative regulations, the listing rules of the place where the Company's Shares are listed and the PRC accounting standards formulated by the state competent financial authorities.

The Board of the Company shall submit Shareholders at every annual general meeting such financial reports as required by relevant laws, administrative regulations, the listing rules of the place where the Company's Shares are listed and normative documents published by local governments and competent authorities.

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The financial statements of the Company shall, in addition to being prepared in accordance with the PRC accounting standards and regulations, be prepared in accordance with either international accounting standards or that of the overseas place where the Shares are listed. If there is any material difference between the financial statements prepared respectively in accordance with the two accounting standards, explanations shall be made in the notes to financial statements. When the Company distributes its after-tax profits of relevant accounting year, the lower of the after-tax profits as shown in such two financial statements shall prevail.

The Company shall make its financial reports available at the Company for Shareholders' inspection 20 days before the annual general meeting is convened. Each Shareholder of the Company shall be entitled to obtain a copy of the financial reports mentioned in this section.

The Company shall also publish the same by a way of announcements (including through posting at the Company's website, the website of the Hong Kong Stock Exchange and/or other websites as required by the Hong Kong Listing Rules and/or newspapers) permitted by laws, administrative regulations, departmental rules, normative documents and the relevant provisions of the securities regulatory authority in the place where the Company's Shares are listed.

The Company shall deliver or send by mail its annual report (including its annual accounts and the auditors' report thereon or the summary of financial reports) to each Shareholder at the registered address at least 21 days before the annual general meeting and within 4 months after the end of relevant financial year.

Interim results or financial information published or disclosed by the Company shall be prepared in accordance with the PRC accounting standards and regulations, and at the same time in compliance with international accounting standards or that of the overseas place where the Shares are listed.

The Company shall publish two financial reports in each accounting year, meaning that the interim financial reports shall be published within 60 days after the end of the first six months of the accounting year and the annual reports shall be published within 120 days after the end of the accounting year.

(2) Appointment and dismissal of accountants

The Company shall engage an independent accounting firm which is qualified under relevant national regulations to audit the Company's annual financial report and review the Company's other financial reports.

The first accounting firm of the Company may be appointed by the inaugural meeting before the first annual general meeting. Such accounting firm shall hold office until the conclusion of the first annual general meeting.

If the inaugural meeting fails to exercise its aforesaid powers, those powers shall be exercised by the Board.

The accounting firm appointed by the Company shall hold office from the conclusion of the annual general meeting at which they were appointed until the conclusion of the next annual general meeting.

The Shareholders may, by ordinary resolution at the general meeting, dismiss any accounting firm prior to the expiration of its term, notwithstanding the terms to the contract howsoever entered into

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between the accounting firm and the Company, but without prejudice to the right of the accounting firm to claim, if any, for damages in respect of such dismissal.

9 NOTICE AND AGENDA OF GENERAL MEETINGS

The general meeting is the authorized organ of the Company that performs duties and exercises powers in accordance with the law.

An extraordinary general meeting shall be convened by the Company within two months upon occurrence of the following circumstances:

- i. the number of Directors is less than the number specified in Company Law or less than two thirds of the number required in the Articles of Association;
- ii. the uncovered losses of the Company reach one third of its total paid-in share capital;
- iii. on a one-vote per share basis, the Shareholders holding more than 10% of the Company's outstanding Shares carrying voting rights request in writing to convene an extraordinary general meeting;
- iv. the Board considers it necessary;
- v. the Board of Supervisors proposes it;
- vi. more than two independent non-executive Directors propose to hold such meeting;
- vii. other circumstances as required by laws, administrative regulations, departmental rules, the listing rules of the place where the Company's Shares are listed and the Articles of Association.

In the event the Company convenes a general meeting, the Board, the Board of Supervisors or Shareholders individually or jointly holding more than 3% of the Company's Shares are entitled to submit proposals to the Company. Shareholders individually or jointly holding an aggregate of more than 3% of the Company's Shares with voting rights shall have the right to submit ad hoc proposals to the convener in writing 10 days prior to the general meeting. The convener shall issue a supplemental notice of the general meeting to other Shareholders within 2 days after receipt of such proposal, and place the matters of the proposal falling within the scope of authority of the general meeting on the agenda for such meeting and submit for consideration at the general meeting.

The Company shall give reasonable written notice to the Shareholders for holding a general meeting. Unless the Company can prove that its reasonable written notice can be issued within a shorter period, the Company shall inform each of the Shareholders in writing of time and place of and matters to be considered at the annual general meeting at least 21 days or 20 working days (whichever is longer) prior to the convening of meeting, and each of the Shareholders will be given notice in writing 15 days or 10 working days (whichever is longer) prior to the convening of the extraordinary general meeting. In calculating the aforementioned starting period, the date on which the notice is given and the meeting is held shall not be included. The "working days" referred to herein shall be the legal working days announced by the PRC and Hong Kong governments. Where otherwise provided by laws and regulations,

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relevant regulatory authorities and stock exchanges of the place where the shares of the Company are listed, the provisions thereof shall prevail.

An extraordinary general meeting shall not decide on the matters not stated in such notice.

Notice of a general meeting shall satisfy the following requirements:

- i. in written form;
- ii. specifying the venue, date and time of the meeting;
- iii. describing the matters to be discussed at the meeting;
- iv. providing information and explanations necessary for the Shareholders to make informed decisions on the matters to be discussed. It includes (but is not limited to) that, when the Company proposes a merger, repurchase of Shares, reorganization of share capital or other restructuring, it shall provide the specific conditions and contracts (if any) of the transaction under discussions and earnestly explain the cause and result of the transaction;
- v. where any Director, Supervisor and senior management member have a material interest in respect of the matters to be discussed, the nature and extent of that interest shall be disclosed; where the impact of the matters to be discussed on such Director, Supervisor and senior management member in their capacity as Shareholders is different from the impact on other Shareholders of the same class, the difference shall be illustrated;
- vi. containing the full text of any special resolution proposed to be passed at the meeting;
- vii. providing a conspicuous statement that Shareholders entitled to attend and vote have the right to appoint a proxy to attend and vote on their behalf and such proxies are not required to be Shareholders;
- viii. stating the deadline and venue for the delivery of voting proxy letter of the meeting.

Except as otherwise provided in the Articles of Association, notice of a general meeting shall be served on the Shareholders (whether or not entitled to vote thereat) by personal delivery or prepaid mail to the addresses registered in the register of Shareholders. Notice of the Company's general meeting may be given to the Shareholders of Domestic Shares in the form of an announcement.

The above announcements shall be published in one or several newspapers designated by the competent securities authority of the State Council within 15 Business Days prior to the extraordinary general meeting or 20 Business Days prior to the annual general meeting. Once they are published, all Shareholders of Domestic Shares shall be deemed to have received the notice of the relevant general meeting. Notice of the general meeting served on the Shareholders of overseas-listed foreign shares may be published through the designated website of the Hong Kong Stock Exchange and the website of the Company. Once it is published, all Shareholders of overseas-listed foreign shares shall be deemed to have received the notice of the relevant general meeting.

The resolutions of the Shareholders' general meeting shall be divided into ordinary resolutions and special resolutions.

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An ordinary resolution made by the Shareholders' general meeting shall be passed by a simple majority of the votes held by the Shareholders (including proxies of Shareholders) attending the Shareholders' general meeting.

A special resolution made by the Shareholders' general meeting shall be passed by a two-thirds majority of the votes held by the Shareholders (including proxies of Shareholders) attending the Shareholders' general meeting.

The following matters shall be resolved by way of ordinary resolutions at a general meeting:

- i. work report of the Board and the Board of Supervisors;
- ii. plans of earnings distribution and loss make-up schemes proposed by the Board;
- iii. removal of members of the Board and non-employee representative supervisors and their remunerations and methods of payment;
- iv. annual budget and final accounts report, balance sheet, income statement and other financial statements of the Company;
- v. annual report of the Company;
- vi. resolutions to determine the Company's appointments, dismissals or discontinuance of appointment of accounting firms;
- vii. other matters which shall be approved by a general meeting other than those requiring approval by special resolutions in accordance with laws, administrative regulations, the listing rules of the place where the Company's shares are listed or the Articles of Association.

The following matters shall be resolved by way of special resolutions at a general meeting:

- i. the increase or decrease of share capital, issuance of any class of Shares, warrants and other quasi-securities by the Company;
- ii. issuance of corporate bonds;
- iii. division, merger, dissolution, liquidation (including voluntary liquidation) or change of corporate form of the Company;
- iv. amendment to the Articles of Association;
- v. the consideration of matters relating to the Company's purchases or disposals of material assets (including but not limited to land, building, equipment, production line, equity) or the amount of guarantees within one year, which is more than 30% of the latest audited total assets of the Company;
- vi. other matters as required by laws, administrative regulations, the listing rules of the place where the Company's Shares are listed or the Articles of Association, or as identified by ordinary resolutions at the general meeting to have a significant impact on the Company and to require approval by special resolutions.

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10 POWER OF THE COMPANY TO REPURCHASE OF ITS OUTSTANDING SHARES

The Company may, subject to the provisions of laws, administrative regulations, the listing rules of the place where the Company's Shares are listed and the Articles of Association and after obtaining the approval from the relevant competent national authorities, repurchase its outstanding shares through legal procedures under any of the following circumstances:

- i. cancelling shares for reducing the Company's registered capital;
- ii. merger with another company that holds the Shares in the Company;
- iii. using the Shares for the employee share ownership scheme or equity incentive scheme;
- iv. repurchase of the Shares held by the Shareholders as requested by them since they object the resolution for the merger or spinning-off of the Company proposed at a general meeting;
- v. conversion of the convertible corporate bonds issued by the Company into the Shares;
- vi. maintaining the corporate value and protecting the Shareholders' interests as necessary;
- vii. other circumstances permitted by laws, administrative regulations, the listing rules of the place where the Company's Shares are listed and regulatory authorities.

The Company shall not purchase or sell its Shares except under the aforesaid circumstances.

Upon obtaining an approval from relevant competent national authorities, the Company may repurchase its Shares by any of the following means:

- i. by making an offer to all of its Shareholders for the repurchase of Shares on a pro rata basis;
- ii. by on-market repurchase on a stock exchange;
- iii. by off-market repurchase through an agreement;
- iv. by any other means permitted by laws, administrative regulations, the securities regulatory authorities of the State Council and other relevant regulatory authorities.

The Company must obtain a prior approval from the Shareholders at a general meeting in the manner stipulated in the Articles of Association before it can effect an off-market repurchase through an agreement. The Company may, by obtaining a prior approval from the Shareholders at a general meeting in the same manner, rescind or vary any contract which has been so entered into or waive any right thereunder.

A contract for the repurchase of Shares includes, but not limited to, an agreement which causes the Company to become entitled or obliged to repurchase its Shares.

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The Company may not assign any contract for the repurchase of its Shares or any right contained thereunder.

With regard to the redeemable Shares that the Company has the right to redeem, if they are not bought back on the market or by way of tender, the purchase prices of these Shares shall not exceed certain maximum price; if they are bought back by way of tender, the tenders shall be available and proposed to all Shareholders in the same manner.

Unless the Company is in liquidation, it must comply with the following provisions in relation to repurchase of its issued Shares:

- i. where the Company repurchases its Shares at nominal value, payment shall be made out of the book balance of the distributable profits of the Company and out of the proceeds from a new issue of Shares made for that purpose;
- ii. where the Company repurchases its Shares at a premium, payment up to the nominal value may be made out of the book balance of the distributable profits of the Company and out of the proceeds from new issue of Shares made for that purpose. Payment of the premium shall be effected as follows:
 - a) if the Shares being repurchased were issued at nominal value, payment shall be made out of the book balance of the distributable profits of the Company;
 - b) if the Shares being repurchased were issued at a premium, payment shall be made out of the book balance of the distributable profits of the Company and out of the proceeds from new issue of Shares made for that purpose, provided that the amount paid out of the proceeds from the new issue shall not exceed the premium received by the Company on the issue of the repurchased Shares nor shall it exceed the book value of the Company's premium account (or capital common reserve fund account) (including any premiums on the new issue) at the time of the repurchase.
- iii. the Company shall make any payment for the following purposes out of the Company's distributable profits:
 - a) acquisition of the right to repurchase its own Shares;
 - b) variation of the contract for the repurchase of its Shares;
 - c) release of the Company's obligation(s) under the contract for the repurchase of Shares.
- iv. after the Company's registered capital has been reduced by the aggregate nominal value of the cancelled Shares in accordance with relevant provisions, the amount deducted from the distributable profits of the Company for payment of the nominal value of Shares which have been repurchased shall be recorded in the Company's premium account (or capital common reserve fund account).

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11 TRANSFER OF SHARES

All overseas listed foreign shares listed in Hong Kong for which full payment has been made may be transferred freely in accordance with the Articles of Association; save under the following conditions, the Board may refuse to recognize any instrument of transfer without providing any reason:

- i. The instrument of transfer and other documents relating to or affecting ownership of any shares shall be registered and the amounts shall not exceed the maximum amount as stated in the Listing Rules of the Hong Kong Stock Exchange from time to time;
- ii. The instrument of transfer only involves overseas listed foreign shares listed in Hong Kong;
- iii. Stamp duty payable has been paid for the instrument of transfer;
- iv. It is required to provide relevant share certificates and evidence reasonably required by the Board to prove that the transferor has the right to transfer the said shares;
- v. If the Shares are transferred to joint holders, the number of joint holders shall not exceed four;
- vi. The relevant shares are free from lien of any company; and
- vii. No Shares shall be transferred to any minors or mentally defective persons or any other legally incapacitated persons.

If the Board refuses to register the share transfer, the Company shall send the transferor and the transferee a notice of refusal to register the said share transfer within 2 months after the request for transfer is submitted. All instruments of transfer shall be kept at the Company's legal address or at such address as the Board may from time to time designate.

Any change or correction of any part of the share register shall comply with the law of the location where the said part is kept.

No changes in the Shareholders' register due to the transfer of Shares may be made within 30 days before the date of a general meeting or within 5 days before the record date for the Company's distribution of dividends.

12 FINANCIAL ASSISTANCE FOR APPLICATION FOR ACQUISITION OF SHARES IN THE COMPANY OR ANY OF ITS SUBSIDIARIES

The Company or its subsidiaries (including the Company's affiliated enterprises) shall not, at any time, provide any form of financial assistance to a person who is acquiring or intends to acquire the Shares. The aforesaid person acquiring shares of the Company includes any person who directly or indirectly assumes any obligations as a result of acquisition of the Shares in the Company.

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The Company or its subsidiaries (including the Company's affiliated enterprises) shall not, at any time, provide any form of financial assistance for the purposes of reducing or discharging such obligations assumed by such person.

For the purpose of the abovementioned provision, financial assistance includes, but not limited to, the following:

- i. gifts;
- ii. guarantee (including the assumption of responsibility or property to secure the performance of the obligations by the obligor), compensation (other than compensation arising out of the Company's own fault) or release or waiver of any right;
- iii. provision of a loan or entering into any other contract under which the obligations of the Company are to be fulfilled before the obligations of another party, and a change in the party to such loan or contract as well as the assignment of the rights under such loan or contract;
- iv. any other form of financial assistance given by the Company when the Company is unable to pay its debts, has no net assets or when its net assets would be reduced by a material extent.

Assumption of obligations as referred in this section includes the assumption of obligations by the obligor by way of contract or other arrangement (irrespective of whether such contract or arrangement is enforceable or not and irrespective of whether such obligations are borne individually or jointly with other persons) or by any other means which results in a change in his/her financial position.

The following actions shall not be deemed to be prohibited, except prohibited in accordance with the relevant laws, administrative regulations, departmental rules and normative documents:

- i. provision of financial assistance by the Company where the financial assistance is given in good faith and in the interests of the Company, and the principal purpose of which is not for the acquisition of the Shares in the Company, or the giving of the financial assistance is an incidental part of a master plan of the Company;
- ii. lawful distribution of the Company's assets as dividends;
- iii. distribution of dividends in the form of Shares;
- iv. reduction of registered capital, repurchase of the Shares or reorganization of the shareholding structure effected in accordance with the Articles of Association;
- v. provision of loans by the Company for its normal business activities within its scope of business (provided that this does not reduce the net assets of the Company or that financial assistance is provided out of the distributable profits of the Company, if it does reduce the net assets of the Company);
- vi. contributions made by the Company to the employee share ownership schemes (provided that this does not reduce the net assets of the Company or that financial assistance is provided out of the distributable profits of the Company, if it does reduce the net assets of the Company).

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13 THE RIGHTS OF ANY SUBSIDIARY OF THE COMPANY TO OWN THE SHARES OF THE PARENT COMPANY

No provision under the Articles of Association shall confer any right on any subsidiary of the Company to own the Shares of the parent company.

14 DIVIDENDS AND OTHER METHODS OF DISTRIBUTION

The dividend distribution plans of the Company shall be resolved at the general meeting. After the Board takes into account the Company's financial position and subject to the relevant laws and regulations, Shareholders may authorize by ordinary resolution the Board to distribute and pay dividends.

The Company may distribute dividends in the following form of (or a combination of both):

- i. cash;
- ii. Shares;
- iii. any other means permitted by laws, administrative regulations, departmental rules and regulatory rules in the place where the Company is listed.

The Company shall pay cash dividends and other payments in RMB payable to the holders of Domestic Shares. Cash dividends and other payments payable to the holders of foreign shares shall be calculated and declared in RMB, and paid in foreign currency by the Company. As for the foreign currency needed by the Company for payment of cash dividends and other payments payable to the holders of the foreign shares, it shall be handled in accordance with applicable regulations on foreign exchange control of the PRC.

The Company shall appoint one or more receiving agents for holders of the overseas-listed foreign shares. Such receiving agents shall receive dividends which have been declared by the Company and all other amounts which the Company shall pay to the holders of the overseas-listed foreign shares on such Shareholders' behalf. Such amounts shall be kept by the receiving agents on such Shareholders' behalf, pending for paying such amounts to them.

The receiving agents appointed by the Company shall satisfy requirements under the laws of the place where the Shares of the Company are listed or the rules of relevant stock exchange. The receiving agents appointed for the holders of overseas-listed foreign shares listed on Hong Kong Stock Exchange shall each be a company registered as a trust company under the Hong Kong Trustee Ordinance.

15 PROXY/ PROXIES OF SHAREHOLDERS

Every shareholder entitled to attend and vote at general meeting shall be entitled to appoint in writing a person (whether a shareholder or not) as his/her proxy to attend and vote on his behalf. Where a shareholder is an institutional shareholder, it may appoint a proxy to attend and vote at any general meeting of the Company and such institutional shareholder shall be deemed to be present in person at any such meeting if it has appointed a proxy to attend thereat. Such institutional shareholder may execute a form of proxy by its duly authorized officer.

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A proxy so appointed may, pursuant to the instructions from that Shareholder, exercise the following rights:

- i. the Shareholders' right to speak at the meeting;
- ii. the right to demand, whether on his own or together with others, a poll;
- iii. the right to exercise voting rights on a show of hands or on a poll.

A Shareholder may appoint a proxy through a written power of attorney, which shall be signed by the appointer or the proxy he/she so appoints in writing. In the event that the appointer is a legal person, the power of attorney shall be affixed with the seal of the legal person or signed by its Director or its duly authorized officer or a duly appointed proxy.

The proxy form shall be lodged at the Company's premises or such other place designated in the notice convening the general meeting at least 24 hours prior to the relevant meeting for which the proxy is appointed to vote or 24 hours prior to the scheduled voting time. Where the proxy form is signed by a person authorized by the appointer, the power of attorney or other authorization documents shall be notarized. The notarized power of attorney and other authorization documents, together with the proxy form, shall be lodged at the Company's premises or such other place designated in the notice convening the meeting.

If the proxy is an institutional Shareholder, its legal representative (the person in charge) or any representative authorized by its Board or by other decision-making body may attend the general meeting of the Company on its behalf.

Any proxy form issued to a Shareholder by the Board for use by such Shareholder for the purpose of appointing a proxy to attend and vote at a general meeting of the Company shall enable the Shareholder, according to his/her free will, to instruct the proxy to vote in favor of or against a resolution, and in respect of each individual matter to be voted on at the meeting.

The proxy form shall contain a statement that, in the absence of specific instructions from the Shareholder, the proxy may vote as he/she thinks fit.

A vote made in accordance with the proxy form shall be valid notwithstanding the death or loss of capacity of the appointer or revocation of the proxy form or the authorization for executing such proxy form, or the transfer of the Shares in respect of which the proxy form is given, provided that the Company does not receive any written notice in respect of such matters before the commencement of the relevant meeting.

16 INSPECTION OF THE REGISTER OF SHAREHOLDERS AND OTHER RIGHTS OF THE SHAREHOLDERS

The Company shall make a register of Shareholders based on the vouchers provided by securities registries. The register of Shareholders shall record the following matters:

- i. the name (title), address (domicile), occupation or nature of each Shareholder;
- ii. the class and number of Shares held by each Shareholder;

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- iii. the amount paid-up or payable in respect of Shares held by each Shareholder;
- iv. the serial numbers of the Shares held by each Shareholder;
- v. the date on which each Shareholder is registered as Shareholder;
- vi. the date on which each Shareholder ceases to be a Shareholder.

The share register shall be the sufficient evidence for the Shareholders' shareholding in the Company unless there is evidence to the contrary.

The Company may, in accordance with the understanding and agreements made between the securities regulatory authorities of the State Council and an overseas securities regulator, maintain the register of Shareholders of overseas-listed foreign shares overseas and appoint the overseas agents to manage such register of Shareholders. The original register of Shareholders for the holders of overseas-listed foreign shares listed in Hong Kong shall be maintained in Hong Kong.

A duplicate register of Shareholders for the holders of overseas-listed foreign shares shall be maintained at the domicile of the Company and shall be open for inspection by Shareholders. The appointed overseas agents shall ensure the consistency between the original and the duplicate registers of Shareholders at all times.

Where the original and copies of the register of members of overseas listed foreign shares are inconsistent, the original shall prevail.

The Company shall keep a complete register of members. The register of members shall include the following:

- i. register of members kept at our Company's residence other than those specified in (ii) and (iii) below;
- ii. register of members of our Company's overseas listed foreign shares kept at the location(s) of the overseas stock exchange(s) where such Shares are listed;
- iii. register of members kept in other location(s) according to the decisions of the Board as required for the listing of the Shares of the Company.

Different parts of the register of members shall not overlap. The transfer of Shares registered in a certain part of the register of members shall not be registered elsewhere in the register of members as long as such Shares remain registered.

Any alteration or rectification to different parts of the register of members shall be made in accordance with the laws in the place where such part of the register of members is maintained.

No change of the register of members as a result of Share transfer shall be made within 30 days before the general meeting is convened or within five days prior to the record date on which the Company decides to pay dividends.

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When the Company convenes the general meeting, distributes dividends, puts into liquidation or is involved in other activities that require the determination of identity, the Board shall fix a date of record, upon expiration of which the Shareholders whose names appear on the register of members are entitled to such equity.

Any person who objects to the register of members and requests to register his/her/its name (title) in the register of members or to remove his/her/its name (title) from the register of members may apply to the court with jurisdiction to correct the register of members.

17 RESTRICTIONS ON RIGHTS OF CONTROLLING SHAREHOLDERS

Apart from the obligations required by laws, administrative regulations or the listing rules of the place where the Shares of the Company are listed, the Controlling Shareholders shall not make any decision that is prejudicial to the interests of all or part of the Shareholders on the following issues by exercising his/her/its Shareholder voting rights when exercising his/her/its power of Shareholders:

- i. releasing the responsibilities of the Directors and Supervisors to act honestly in the best interests of the Company;
- ii. permitting the Directors and Supervisors (for their own benefit or for the benefit of others) to deprive the Company's assets in any form, including but not limited to any opportunity beneficial to the Company;
- iii. permitting the Directors and Supervisors (for their own benefit or for the benefit of others) to deprive other Shareholders' personal rights and interests, including but not limited to any distributions or voting rights, but excluding the restructuring proposal of the Company submitted to the general meeting for approval pursuant to the Articles of Association.

18 LIQUIDATION PROCEDURES

Upon the occurrence of any of the following circumstances, the Company shall be lawfully dissolved and liquidated:

- i. where the term of operation expires as stipulated in the Articles of Association or other reasons for dissolution as stipulated in the Articles of Association occur;
- ii. where the general meeting resolves to dissolve by a special resolution;

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- iii. where dissolution is required for the purpose of merger or division of the Company;
- iv. where the Company has run into severe adversities in operation and management, under which circumstance its continuous existence may cause heavy losses to the Shareholders' interests, and such adversities may not be solved in other ways, the Shareholders holding more than 10% of the total number of Shares carrying voting rights may apply to the people's court to dissolve the Company;
- v. where the Company is legally declared bankrupt due to its inability to repay the debts as they fall due;
- vi. where the business license of the Company is suspended or revoked, or the Company is ordered to close down in accordance with the laws.

Where the Company is dissolved in accordance with the provisions set forth in (i), (ii) and (iv) above, a liquidation team shall be established within 15 days to carry out the liquidation upon the occurrence of any of the reasons for dissolution. The liquidation team shall consist of those persons determined by the Directors or the general meeting. In the event that no liquidation team is established within such period to carry out the liquidation, the creditor(s) may apply to the people's court to designate relevant persons to form a liquidation team and carry out the liquidation.

In the event that the Company is dissolved in accordance with the provision set forth in (v) above, the people's court will instruct the Shareholders, the related authorities and related professionals to form a liquidation team to carry out the liquidation pursuant to the provisions of relevant laws.

In the event that the Company is dissolved in accordance with the provision set forth in (vi) above, related authorities will instruct the Shareholders, the related authorities and related professionals to form a liquidation team to carry out the liquidation.

Where the Board decides to liquidate the Company for any reason other than the Company's declaration of its bankruptcy, the Board shall include a statement in the notice convening a general meeting for such purpose that, after performing a comprehensive investigation into the affairs of the Company, the Board is of the opinion that the Company will be able to pay its debts in full within 12 months from the commencement of liquidation.

Upon the passing of the resolution to liquidate the Company at the general meeting, the functions and powers of the Board of the Company shall cease immediately.

In accordance with the instructions of the general meeting, the liquidation team shall make a report at least once every year to the general meeting on the income and expenditure of the liquidation team, the business of the company and the progress of the liquidation process, and submit a final report to the general meeting upon completion of the liquidation process.

The liquidation team shall, within 10 days of its establishment, send notices to the creditors, and shall, within 60 days of its establishment, publish an announcement in newspapers.

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The creditors shall, within thirty days of receipt of the notices, or for those who have not personally received such notices, within forty-five days of the date of announcement, claims their rights to the liquidation team.

In claiming their rights, the creditors shall explain the relevant matters and provide supporting materials in respect thereof. The liquidation team shall carry out registration of such creditor's rights.

In the course of claiming of creditor's rights, the liquidation team shall not make any payment to the creditors.

After sorting out the assets of the Company and preparing the balance sheet and an inventory of assets, the liquidation team shall formulate a liquidation proposal and submit it to the general meeting or relevant competent authorities for confirmation.

In the event of liquidation due to dissolution of the Company and the liquidation team finds that, after sorting out the Company's assets and preparing the balance sheet and an inventory of assets, the assets of the Company are insufficient to pay the debts, it shall immediately petition to the people's court to declare the Company bankrupt.

After the people's court declares the Company bankrupt, the liquidation team shall hand over the liquidation matters to the people's court.

Following the completion of liquidation of the Company, the liquidation team shall prepare a liquidation report, a statement of income and expenditure and financial report for the liquidation period, which, after being verified by a PRC registered accountant, shall be submitted to the general meeting or relevant competent authorities for confirmation. The liquidation team shall, within 30 days after such confirmation by the general meeting or relevant competent authorities, file the above-mentioned documents to the company registration authority and apply for deregistration of the Company and publish an announcement relating to the termination of the Company.

19 OTHER IMPORTANT PROVISIONS FOR THE COMPANY OR THE SHAREHOLDERS

(1) General Provisions

The Company is a joint stock company with limited liability in perpetual existence and is an independent legal entity, subject to the jurisdiction and protection of the laws, administrative regulations and other relevant requirements of the PRC.

The Articles of Association are legally binding on the Company and its Shareholders, Directors, Supervisors, general manager and senior management, all of whom shall be entitled to claim their rights regarding matters related to the Company in accordance with the Articles of Association.

A Shareholder may take action against the Company pursuant to the Articles of Association, and vice versa. A Shareholder may also take action against another Shareholder, and may take action against the Director(s), Supervisor(s), manager(s) and other senior management of the Company.

The actions referred to in the preceding paragraph include court proceedings and arbitration proceedings.

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The Company may invest in other limited liability companies or companies limited by shares and its liability is limited to the amount of the shares of the companies which it has subscribed for.

(2) Shares and Transfer

Foreign Investors refer to those investors of foreign countries and regions of Hong Kong, Macau and Taiwan who subscribe for the Shares issued by the Company; domestic Investors refer to those investors within the territory of the PRC (except the above said regions) who subscribe for the Shares issued by the Company.

The Company may, to the extent that it is needed for its operation and development, approve an increase in capital in accordance with relevant provisions of the Articles of Association and the laws, regulations and the listing rules of the securities regulatory authority in the place where the Company's Shares are listed upon approval by resolution of the general meeting of Shareholders.

The Company may increase its share capital by following ways:

- (1) an offer of new shares to non-specific investors for subscription;
- (2) placing of new shares to existing Shareholders;
- (3) distribution of new shares to existing Shareholders;
- (4) issue of new shares to specific investors;
- (5) conversion of capital reserves into share capital;
- (6) other ways permitted by laws, administrative regulations and relevant regulatory bodies such as the securities regulatory authority of the State Council.

The increase in the Company's share capital, after being approved in accordance with the provisions of the Articles of Association, shall be conducted under the procedures prescribed by applicable laws, administrative regulations and the listing rules of the place where the Company's Shares are listed.

Unless otherwise provided by laws, administrative regulations, the securities regulatory authorities in the place where the Company's shares are listed or the Articles of Association, fully-paid Shares of the Company are freely transferable and free from all liens.

Transfer of the Company's Shares shall be registered with a securities registry entrusted by the Company.

When the Company reduces its registered capital, it shall prepare a balance sheet and an inventory of assets.

Subject to the approval of the securities regulatory authority of the State Council, the Company may issue the Shares to onshore and offshore investors.

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(3) Shareholders

The Shareholders of the Company are persons lawfully holding the Company's Shares and whose names (titles) are listed in the register of members.

Shareholders are entitled to rights and assume obligations according to the class of Shares they hold. Shareholders who hold the same class of Shares are entitled to the same rights and assume the same obligations.

Where a Shareholder of the Company is a body corporate, its rights shall be exercised by its legal representative or an agent of such legal representative on behalf of such Shareholder.

The holders of the Company's ordinary Shares shall be entitled to the following rights:

- i. to receive distribution of dividends and other forms of benefits in proportion to the number of Shares held by them;
- ii. to request, convene, preside over, attend or appoint a proxy to attend general meetings, and to exercise the corresponding voting rights according to laws;
- iii. to supervise and manage the Company's business and operational activities, put forward proposals or raise queries;
- iv. to transfer, grant or pledge the shares held by him/her in accordance with the provisions of the laws, administrative regulations, the listing rules of the place where the Company's Shares are listed and the Articles of Association;
- v. to obtain relevant information in accordance with the provisions of the Articles of Association, including:
 - A. to obtain a copy of the Articles of Association, subject to payment of the cost of such copy;
 - B. subject to payment of a reasonable charge, to inspect and make photocopies of:
 - a) all parts of the register of members;
 - b) personal particulars of the Director(s), Supervisor(s) and other senior management of the Company, including:
 - (a) their current and previous names and aliases;
 - (b) their primary address (residence);
 - (c) their nationality/nationalities;
 - (d) their full-time and all other part-time jobs and duties;
 - (e) their identification documents and document numbers.

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- C. reports on the state of the issued share capital of the Company;
- D. the latest audited financial statements of the Company, and the reports of the Board, auditors and Board of Supervisors;
- E. the special resolutions of the Company;
- F. reports listing the aggregate par value, number of shares, the highest and the lowest prices paid by the Company in respect of each class of Shares bought back by the Company since the end of the last accounting year and all the expenses paid by the Company therefor (classified as domestic shares and foreign shares);
- G. a copy of the annual report for the previous year that has been filed with the State Administration for Market Regulation or any other competent authorities;
- H. minutes of general meetings.

The Company shall maintain the aforesaid documents except item B at the Company's Hong Kong address as required by the Hong Kong Listing Rules, for inspection free of charge by the public and the holders of H Shares (Item (H) shall be available to the Shareholders of the Company only).

The Company may refuse to provide any document(s) for inspection or photocopying if such document(s) contain(s) information involving trade secrets of and insider information relating to the Company and personal privacy of relevant personnel.

- vi. to participate in the distribution of the remaining assets of the Company pro rata based on the number of Shares held by them in the event of termination or liquidation of the Company;
- vii. to have the right to dissent from the merger or division approved by resolution at the general meeting and be entitled to demand the Company to buy back their Shares;
- viii. to have the right, on a one-vote per share basis, for the Shareholders alone or in aggregate holding more than 3% of the Shares of the Company, to make a temporary proposal and submit it to the Board in writing 10 days before the general meeting is held;
- ix. to have other rights conferred by laws, administrative regulations, ministerial rules, listing rules of the place where the Shares of the Company are listed or the Articles of Association.

The Company may not exercise any power to freeze or otherwise infringe any right(s) attaching to the Shares held by any person or persons who are interested directly or indirectly therein only for the reason that they have not disclosed their interests to the Company.

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The Company's Share certificates shall be in registered form. In addition to the items set out in the Company Law, the items that should be specified in the Share certificates of the Company shall include other items required by the stock exchange where the Company's Shares are listed.

The Share certificates are signed by the chairman of the Board. Where the stock exchange on which the Shares are listed requires the Share certificates to be signed by senior management of the Company, they shall also be signed by related senior management. The Share certificates shall take effect after being affixed with the seal of the Company or machine-imprinted seal. The Share certificates shall only be affixed with the Company's seal under the authorization of the Board. The signatures of the chairman of the Board or related senior management on the Share certificates may also be in printed form.

Under the circumstance of paperless issuance and trade of the Shares of the Company, separate regulations of the securities regulatory authorities or the stock exchanges at the place where the Shares of the Company are listed shall apply.

Any Shareholders who is registered in, or any person who requests to have his/her/its name (title) entered in, the register of members may (if his/her/its Share certificate (the "**Original Share Certificate(s)**") is lost) apply to the Company for a replacement of new Share certificates in respect of such Shares (the "**Relevant Shares**").

In the event a holder of domestic shares loses his/her/its Share certificates and applies for a replacement, it shall be dealt with pursuant to related provisions of the Company Law.

In the event a Shareholder of overseas listed invested Shares loses his/her/its Share certificates and applies for a replacement, it shall be dealt with pursuant to the laws, regulations and rules of the stock exchange or other related provisions of the place where the original register of members of the overseas listed foreign Shares is maintained.

In the event a shareholder of overseas listed foreign Shares of a Hong Kong listed company loses his/her/its Share certificates and applies for a replacement, the issue of placement of Share certificate shall comply with the following requirements:

- i. An applicant shall submit the application in the form prescribed by the Company accompanied by a notarial certificate or statutory declaration, containing the grounds upon which the application is made and the circumstances and evidence of the loss of the Share certificate as well as stating that no other person shall be entitled to request to be registered as a Shareholder with respect to the relevant Shares.
- ii. No statement has been received by the Company from any person other than the applicant for having his name to be registered as the Shareholder with respect to the Shares before the Company came to a decision to issue the replacement Share certificate.
- iii. The Company shall, if it decides to issue a replacement new Share certificate to the applicant, publish an announcement of its intention to issue the replacement new Share certificate in such newspapers designated by the Board. The announcement shall be made at least once every 30 days in a period of 90 days.

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- iv. The Company shall, prior to the publication of its announcement of its intention to issue a replacement certificate, deliver a copy of the announcement to be published to the stock exchange on which the Shares are listed. The Company may publish an announcement upon receiving a confirmation from the stock exchange that the announcement has been exhibited at the stock exchange. The announcement shall be exhibited at the stock exchange for a period of 90 days.

If an application to issue a replacement Share certificate has been made without the consent of the registered Shareholders of the related Shares, the Company shall send a copy of the announcement to be published by post to such Shareholders.

- v. In the event that, upon expiration of the 90-day exhibition period of the announcement specified in (iii) and (iv) hereof, the Company has not received from any person any objection to the issue of replacement new Share certificate, the Company may issue a replacement new Share certificate to the applicant according to his/her/its application.
- vi. Where the Company issues a replacement new Share certificate under this Article, it shall forthwith cancel the Original Share Certificate(s) and enter the cancellation and issue in the register of Shareholders.
- vii. All expenses incurred by the Company for the cancellation of an Original Share Certificate and issue of the replacement new Share certificate shall be borne by the applicant. The Company shall have the right to refuse to take any action until a reasonable guarantee is provided by the applicant.

(4) Untraceable Shareholders

The Company shall have the right to cease sending dividend warrants by post to a holder of foreign shares listed overseas, but such right can only be exercised after the dividend warrants have been so left uncashed on two consecutive occasions. Such right may be exercised by the Company after the first occasion in which such a warrant is returned undelivered.

The Company shall have the right to sell the shares held by a holder of foreign shares listed overseas who is untraceable in a manner which the Board deems appropriate, but the following conditions must be observed:

- i. the Company has distributed dividends on such shares for at least three times in a period of 12 years and the dividends are not claimed by anyone during such period; and
- ii. upon expiry of the 12-year period, the Company makes an announcement of its intention to sell the shares in one or more newspapers, and notifies the securities regulatory authority in the place where the shares of the Company are listed.

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(5) The Board

The Board shall be accountable to the general meeting, and exercise the following functions and powers:

- i. to convene general meetings and report on its work to the general meetings;
- ii. to implement resolutions passed at the general meetings;
- iii. to decide on the Company's business plans and investment plans;
- iv. to formulate the Company's annual financial budgets and final accounting plans;
- v. to formulate the Company's profit distribution proposals and loss recovery proposals;
- vi. to formulate proposals for the increase or reduction of the Company's registered capital, the issuance of Shares and the issuance of corporate bonds or other securities and listing plans;
- vii. to formulate proposals for substantial asset acquisition or disposal, the repurchase of the Company's Shares, or the merger, division, dissolution or change of corporate form of the Company;
- viii. to determine on the Company's internal management structure;
- ix. to appoint or dismiss the general manager, the board secretary and the company secretary of the Company and appoint or dismiss deputy general managers, financial controller and other senior management of the Company based on the general manager's nominations and determine their remuneration;
- x. to formulate the Company's basic management system;
- xi. to formulate proposals for amendments to the Articles of Association;
- xii. to authorize the chairman to exercise certain duties and powers of the Board;
- xiii. to decide on the establishment, and elect the members, of the special committee(s) of the Board;
- xiv. to formulate the equity incentive scheme(s) of the Company;
- xv. to prepare a proposal on the amount and payment method of the emoluments of directors and to submit such proposal to the general meeting for decision;
- xvi. to manage the information disclosure of the Company;
- xvii. to propose to general meetings for the appointment or replacement of the auditors of the Company;

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- xviii. to debrief the work report of the general manager and other senior management and review the performances of the general manager and other senior management;
- xix. to carry out transactions that require decisions by the Board in accordance with the Listing Rules of the Hong Kong Stock Exchange such as making investment in, acquiring or disposal of assets, conducting financing activities and entering into connected transactions;
- xx. to decide on such substantial matters and administrative affairs other than those shall be decided by the general meeting of the Company as provided by the laws, administrative regulations, rules and regulations of competent authorities and the Articles of Association of the Company and enter into other material agreements;
- xxi. to exercise other functions and powers as granted by laws, administrative regulations, ministerial rules, listing rules of the place where the Shares of the Company are listed, or the Articles of Association.

Except for the matters specified in items (vi), (vii) and (xi) which shall be passed by the affirmative vote of more than two-thirds of all Directors, the resolutions of the Board in respect of all other matters may be passed by the affirmative vote of more than half of all Directors.

In the event that the exercise of aforesaid functions and powers by the Board, or any transaction or arrangement of the Company shall be considered and reviewed by a general meeting according to the listing rules of the stock exchange of the places where the Company's shares are listed, such matters shall be submitted to the general meeting for consideration and review.

The Board shall also be responsible for the following matters:

- i. to formulate, review and improve the corporate governance system and condition of the Company;
- ii. to review and monitor the training for and continuous professional development of the directors and senior management;
- iii. to review and monitor the systems formulated by the Company and the compliance thereof, and make relevant disclosures in accordance with the laws and relevant provisions of the securities regulatory authority of the place where the Company's shares are listed;
- iv. to formulate, review and monitor the code of conduct and relevant compliance manual of employees and directors.

The Board shall be responsible for the above corporate governance functions and may also assign such responsibilities to one or more special Board committees.

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(6) Secretary to the Board

The Company shall have one secretary to the Board, who is appointed or dismissed by the Board. The secretary to the Board shall be a senior management officer of the Company. The Company's secretary to the Board shall be a natural person who has requisite professional knowledge and experience.

(7) Board of Supervisors

The Company shall have a Board of Supervisors.

The Board of Supervisors consists of three Supervisors, one of whom shall be the chairman. A supervisor shall serve a term of three years and can be re-elected upon expiry of his/her term of office. The appointment or dismissal of the chairman of the Board of Supervisors shall be passed by more than two-thirds of the members of the Board of Supervisors by way of vote.

The Supervisors shall be the representatives of shareholders and employees of the Company. The proportion of the employee representative Supervisors shall be no less than one-third. The shareholder representatives in the Board of Supervisors shall be elected and removed by the general meetings while the employee representatives shall be elected through the employee representatives meetings, employee meetings or through other forms of democratic election.

The Directors and senior management shall not act concurrently as Supervisors.

Meetings of the Supervisor shall be held only if more than two-thirds of the members of the Board of Supervisors are present. A resolution of the Board of Supervisors shall be passed by the affirmative votes of more than two-thirds of the members of the Board of Supervisors.

The Board of Supervisors shall be accountable to the general meeting, and legally exercise the following functions and powers:

- i. to inspect the financial affairs of the Company;
- ii. to monitor the directors and senior management to perform their duties, and put forward proposals on the removal of any director or senior management who violates laws, administrative regulations, the listing rules of the place where the Company's shares are listed, the Articles of Association or any resolution of the shareholders' meeting;
- iii. to require the Directors and senior management to correct an act if such act is harmful to the interests of the Company;
- iv. to verify financial information such as financial reports, business reports, profit distribution plans that the Board intends to submit to the shareholders' general meeting and, if in doubt, to be able to appoint, in the name of the Company, a registered accountant or a practicing auditor to assist in reviewing such information;

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- v. to propose the convening of extraordinary general meetings and, in case the Board fails to convene and preside over the general meetings in accordance with Company Law, to convene and preside over the general meetings;
- vi. to submit proposals to the general meetings;
- vii. to represent the Company in negotiation with or initiate legal proceedings against a Director;
- viii. to investigate and, if necessary, to engage professional entities, such as accounting firms and law firms, to assist the Company in such investigation if it discovers any irregularities in the Company's operations. The expenses shall be borne by the Company;
- ix. to initiate legal proceedings against directors and senior management in accordance with Company Law;
- x. to exercise other functions and powers as specified by the laws, administrative regulations and the Articles of Association.

The Supervisors shall be present at the meetings of the Board.

(8) General Manager

The Company shall have a general manager, who shall be appointed or dismissed by the Board.

The general manager of the Company shall be accountable to the Board and shall exercise the following functions and powers:

- i. to be in charge of the production, operation and management of the Company, to organize the implementation of the Board's resolutions, and report to the Board;
- ii. to organize the implementation of the Company's annual business plan and investment proposals;
- iii. to prepare the annual financial budget and final accounts of the Company and make recommendations to the Board;
- iv. to draft the plans for the establishment of internal management structure of the Company;
- v. to draft the basic management system of the Company;
- vi. to formulate detailed rules and regulations for the Company;
- vii. to propose to the Board the appointment or dismissal of the deputy general manager and the financial controller of the Company in accordance with the Articles of Association and relevant internal control system of the Company;

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- viii. to appoint or dismiss executive officers other than those who should be appointed or dismissed by the Board;
- ix. to determine the salaries, benefits, rewards and disciplinary actions of the employees, and to decide on the appointment and dismissal of the employees;
- x. to exercise other powers conferred by the Articles of Association and the Board.

(9) Provident Fund

The capital reserve fund consists of the following:

- i. the premium from issuance of Shares at a price in excess of their par value;
- ii. other incomes to be transferred to the capital reserve fund as required by the competent finance department under the State Council.

The provident fund of the Company shall only be used for the following purposes:

- i. to cover the losses, except the capital reserve fund which shall not be used to cover the losses.
- ii. to increase the share capital. In the event of conversion of the statutory reserve fund into share capital by way of capitalization, the balance of the reserve fund shall not be less than 25% of the registered capital prior to capital increase of the Company.
- iii. to expand the production and operation of the Company.

(10) Dispute Resolution

The Company complies with the following principles for dispute resolution:

- i. Any dispute or claim arising between the Company and its Directors or supervisors or senior management; the shareholders of overseas listed foreign shares and the Company; the shareholders of overseas listed foreign shares and the Directors, supervisors, general manager or other senior management of the Company; the shareholders of overseas listed foreign shares and the shareholders of unlisted shares, as well as between the shareholders of domestic shares, in respect of any rights or obligations arising from the Articles of Association, the Company Law and other relevant laws, administrative regulations, the listing rules of the place where the Company's shares are listed concerning the affairs of the Company shall be submitted by the abovementioned parties for arbitration.

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When the aforesaid dispute or claim is submitted for arbitration, the entire claim or dispute shall be referred to arbitration. For any party who has a cause of action based on the same facts giving rise to the dispute or claim or who is required to participate in the settlement of the dispute or claim, if such party is the Company or a shareholder, a Director, a supervisor, general manager or any other senior management of the Company, he/she/it shall comply with the arbitration award.

Disputes relating to the definition of shareholders and register of members may be resolved without arbitration.

- ii. The claimant may elect for arbitration to be conducted at either the China International Economic or Trade Arbitration Commission in accordance with its arbitration rules, or the Hong Kong International Arbitration Centre in accordance with its arbitration rules.

Once the claimant submits a dispute or claim to arbitration, the other party must conduct arbitration at the arbitral body elected by the claimant.

If a claimant chooses for arbitration to be conducted at the Hong Kong International Arbitration Centre, either party may apply for a hearing to take place in Shenzhen in accordance with the securities arbitration rules of the Hong Kong International Arbitration Centre.

- iii. For any disputes or claims of rights as mentioned in sub-article (i) above to be settled by way of arbitration, the PRC (excluding Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan) laws shall govern, except as otherwise stipulated in laws and administrative laws and regulations.
- iv. The award of the arbitral body shall be final and conclusive and binding on all parties.
- v. For any agreement which includes this rule of dispute resolution to be reached by Directors, supervisors or senior management and the Company, the Company represents both itself and each of the shareholders.
- vi. Any submission for arbitration shall be as an authorization to arbitration tribunal for public hearing and announcement of its award.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of Our Company

Our Company was established in the PRC on March 15, 2013 with an initial registered capital of US\$2,000,000. On July 21, 2021, our Company was converted into a joint stock company with limited liability under the PRC Company Law. Accordingly, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. The relevant PRC laws and regulatory provisions and a summary of our Articles of Association are set out in Appendices IV and V to this document, respectively.

Our principal place of business in Hong Kong is at Room 1901, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, Hong Kong. We were registered as a non-Hong Kong Company under Part 16 of the Companies Ordinance on February 9, 2022. Ms. LEUNG Wai Yan has been appointed as the authorized representative of our Company for the acceptance of service of process and notices in Hong Kong.

2. Changes in the Share Capital of Our Company

As of the date of our incorporation, our registered capital was US\$2,000,000, which was fully paid up upon establishment. On July 21, 2021, our Company was converted into a joint stock company with limited liability, and our registered capital was RMB228,000,000 divided into 228,000,000 Shares with a nominal value of RMB1.00 each. As of the date of this document, our registered capital was RMB228,000,000 divided into 228,000,000 Shares with a nominal value of RMB1.00 each.

Upon completion of the [REDACTED], our issued share capital will increase to RMB[REDACTED], made up of [REDACTED] Unlisted Shares and [REDACTED] H Shares fully paid up or credited as fully paid up, representing approximately [REDACTED]% and [REDACTED]% of our registered share capital, respectively.

Save as disclosed in “History, Development and Corporate Structure” in this document, there has been no alteration in our share capital within two years immediately preceding the date of this document.

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3. Changes in the Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in Note 1 to the Accountants’ Report as set out in Appendix I to this document. Save as disclosed in “History, Development and Corporate Structure” in this document and below, there has been no alteration in the share capital of our subsidiaries within two years immediately preceding the date of this document.

Cryofocus America Inc.

On December 15, 2020, the registered capital of Cryofocus America Inc. was increased from USD500,000 to USD1,000,000.

Ningbo Beijifeng Biotechnology Co., Ltd. (寧波北極豐生物科技有限公司) (“Ningbo Beijifeng”)

On November 16, 2022, Ningbo Beijifeng was incorporated in the PRC as a limited liability company with a registered capital of RMB20,000,000.

Ningbo Huifeng Biotechnology Co., Ltd. (寧波輝豐生物科技有限公司) (“Ningbo Huifeng”)

On November 14, 2022, Ningbo Huifeng was incorporated in the PRC as a limited liability company with a registered capital of RMB30,000,000.

4. Resolutions of the Shareholders of the Company Passed on December 2, 2021

Pursuant to the resolutions passed at a duly convened general meeting of our Shareholders on December 2, 2021, it was resolved, among others:

- (a) our H Shares to be [REDACTED] on the [REDACTED] be [REDACTED];
- (b) subject to the completion of the [REDACTED], the Articles of Association have been approved and adopted, which shall become effective on the [REDACTED], and our Board has been authorized to amend the Articles of Association in accordance with any comments from the [REDACTED] and the relevant PRC regulatory authorities; and
- (c) authorizing our Board and its authorized person to handle all relevant matters relating to, among other things, the implementation of [REDACTED] of H Shares and the [REDACTED].

5. Restrictions on Repurchase

See Appendix V to this document for details.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

B. FURTHER INFORMATION ABOUT THE BUSINESS OF THE COMPANY

1. Summary of Material Contract

The following contract (not being a contract entered into in the ordinary course of business) was entered into by our Group within the two years preceding the date of this document and is or may be material:

- (a) the [REDACTED].

2. Our Material Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, we had registered the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
1		Hong Kong	Our Company	305585518	10	April 6, 2031
2		PRC	Our Company	13102399	10	February 27, 2025
3		PRC	Our Company	42263081	10	July 20, 2030
4		PRC	Our Company	55383103	10	November 6, 2031
5		PRC	Our Company	55406827	10	November 6, 2031
6		PRC	Ningbo SensCure	17558054	10	May 13, 2027
7	SenPort	PRC	Ningbo SensCure	21295998	10	November 13, 2027
8	胜博刀	PRC	Ningbo SensCure	46448028	10	January 6, 2031
9	ArctiqueFocus	PRC	Ningbo SensCure	55955761	10	December 6, 2031

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(b) Patents

For a discussion of the details of the material patents and material patent applications by our Company in connection with our Core Products, see “Business—Intellectual Property Rights” in this document.

(c) Domain Names

As of the Latest Practicable Date, we owned the following domain names which we consider to be material to be or may be material to our business:

<u>No.</u>	<u>Domain names</u>	<u>Registrant</u>	<u>Date of registration</u>	<u>Expiry date</u>
1	Cryofocus.com	Our Company	February 15, 2017	February 15, 2023
2	Cryofocus.cn	Our Company	February 15, 2017	February 15, 2023
3	senscure.net	Ningbo SensCure	March 7, 2013	March 7, 2023
4	senscure.com.cn	Ningbo SensCure	March 7, 2013	March 7, 2023

Save as the above, as of the Latest Practicable Date, there were no other trade or service marks, patents, copyrights, domain names and other intellectual or industrial property rights which were material in relation to our business.

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C. FURTHER INFORMATION ABOUT DIRECTORS, SUPERVISORS AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of Interests

(a) *Interests and short positions of the Directors, Supervisors and chief executive of the Company in the Shares, underlying Shares and debentures of our Company and our associated corporations*

The following table sets out the interests and short positions of our Directors, Supervisors and chief executive of our Company immediately following completion of the [REDACTED] and the conversion of our Unlisted Shares to H Shares in our Shares, underlying Shares or debentures of our Company or any of our associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to us and the [REDACTED] pursuant to [REDACTED] (including interests and short positions in which they are taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to [REDACTED], to be entered in the register referred to therein, or which will be required to be notified to us and the [REDACTED] pursuant to the Model Code for Securities Transactions by Directors of [REDACTED] contained in the [REDACTED], once our Shares are [REDACTED]:

Name of Director/ Supervisor/ Chief Executive	Capacity/ nature of interest	Class of Shares	Number of Shares	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the total share capital of our Company upon completion of the [REDACTED] ⁽¹⁾
Mr. ZHU Jun (朱軍) ⁽²⁾	Beneficial owner; interest in a controlled corporation	Unlisted Shares	9,721,236	4.26%	[REDACTED]%
		H Shares	4,166,244	1.83%	[REDACTED]%
Mr. Lv ⁽³⁾	Beneficial owner; interest in a controlled corporation; interest held jointly with another person	Unlisted Shares H Shares	91,369,084 41,578,172	40.07% 18.24%	[REDACTED]% [REDACTED]%
Mr. SUN Xiaolu (孫曉路) ⁽⁴⁾	Interest in controlled corporations	Unlisted Shares	5,295,368	2.32%	[REDACTED]%
		H Shares	10,317,388	4.53%	[REDACTED]%

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Notes:

- (1) The calculation is based on the total number of [REDACTED] Shares in issue immediately after completion of the [REDACTED].
- (2) Mr. ZHU Jun (朱軍) (“**Mr. Zhu**”), our executive Director, beneficially owns 1,030,697 Unlisted Shares and 441,727 H Shares of our Company. As of the Latest Practicable Date, Mr. Zhu owned approximately 38.77% in Ningbo Hongyingkang as one of its limited partners. As such, under the SFO, Mr. Zhu is deemed to be interested in the 8,690,539 Unlisted Shares and 3,724,517 H Shares held by Ningbo Hongyingkang.
- (3) Mr. Lv beneficially owns 15,308,992 Unlisted Shares and 6,560,996 H Shares of our Company. As of the Latest Practicable Date, Mr. Lv owned approximately 37.22% in Ningbo Maishang as one of its limited partners. As such, under the SFO, Mr. Lv is deemed to be interested in the 8,972,712 Unlisted Shares and 3,845,448 H Shares held by Ningbo Maishang. Further, pursuant to a concert party agreement dated April 26, 2021 entered into by Ms. Li and Mr. Lv, the Concert Parties confirmed that they have been acting in concert in exercising Shareholders’ rights pertaining to our Group (including our Company and Ningbo SensCure) since January 1, 2014, and they have agreed to continue to act in concert and reach consensus on proposals related to the daily management and operation of our Group presented to general meetings of the Shareholders of our Company for voting. As of the Latest Practicable Date, Ningbo Linfeng was owned as to 65% by Shanghai Shidi which was in turn wholly owned by Ms. Li. Further, as of the Latest Practicable Date, Ms. Li controlled the executive partner of each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui, namely, Shanghai Shidi Biotechnology Co., Ltd. (上海仕地生物科技有限公司) (“**Shidi Biotechnology**”). Shidi Biotechnology is entitled to exercise the voting power held by each of Ningbo Maishang, Ningbo Hongyingkang and Ningbo Kangrui in our Company pursuant to their respective partnership agreements. As of the Latest Practicable Date, Tongshang Linfeng Equity Investment Partnership (Limited Partnership) (寧波通商麟豐股權投資合夥企業(有限合夥)) (“**Tongshang Linfeng**”) was owned as to approximately 49.02% by Ningbo Linfeng as a limited partner. As such, under the SFO, Ms. Li is deemed to be interested in the 76,060,092 Unlisted Shares and 35,017,176 H Shares held by Shanghai Shidi, Ningbo Linfeng, Ningbo Maishang, Ningbo Hongyingkang, Ningbo Kangrui and Tongshang Linfeng.
- (4) Each of Hangzhou Proxima Innovative Investment L.P. (Limited Partnership) (杭州比鄰星創新投資合夥企業(有限合夥)) (“**Hangzhou Proxima**”) and Suzhou Proxima Venture Investment L.P. (Limited Partnership) (蘇州比鄰星創業投資合夥企業(有限合夥)) (“**Suzhou Proxima**”) is a limited partnership established in the PRC and is managed by its general partner, Hangzhou Proxima Innovative Investment Management L.P. (Limited Partnership) (杭州比鄰星創新投資管理合夥企業(有限合夥)), whose general partner is Shanghai Proxima Asset Management Co., Ltd. (上海比鄰星資產管理有限公司), which is owned as to 90% by Mr. SUN Xiaolu (孫曉路), our non-executive Director. As such, under the SFO, Hangzhou Proxima Innovative Investment Management L.P. (Limited Partnership) (杭州比鄰星創新投資管理合夥企業(有限合夥)), Shanghai Proxima Asset Management Co., Ltd. (上海比鄰星資產管理有限公司) and Mr. SUN Xiaolu (孫曉路) are deemed to be interested in 5,295,368 Unlisted Shares and 10,317,388 H Shares held by Hangzhou Proxima and Suzhou Proxima.

(b) Interests of the substantial shareholders in the Shares

Save as disclosed in “Substantial Shareholders” in this document, immediately following the completion of the [REDACTED], our Directors are not aware of any other person (not being a Director or chief executive of our Company) who will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to us and the [REDACTED] under the provisions of [REDACTED], or who is, directly or indirectly, interested in 10% or more of the issued voting shares of our Company.

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(c) Interests of the substantial shareholders of other members of our Group

So far as our Directors are aware and save as disclosed in “Substantial Shareholders” and “History, Development and Corporate Structure” in this document, as of the Latest Practicable Date, no persons are, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other members of our Group.

2. Particulars of Directors’ and Supervisors’ Service Contracts and Letters of Appointment

Pursuant to Rules 19A.54 and 19A.55 of the Listing Rules, we have entered into a contract with each of our Directors and Supervisors in respect of, among other things, compliance with relevant laws and regulations, observance of the Articles of Association and provisions on arbitration.

Save as disclosed in this document, none of our Directors and Supervisors has or is proposed to have entered into any service contract with any member of our Group (excluding agreements expiring or determinable by any member of our Group within one year without payment of compensation other than statutory compensation).

3. Emoluments of Directors and Supervisors

The aggregate amounts of emoluments and benefits in kind (including any possible payment of discretionary bonus and equity-settled share award expense) which were paid to our Directors and Supervisors for the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022 were RMB852,000 (including RMB15,000 of equity-settled share award expense), RMB8,333,000 (including RMB5,219,000 of equity-settled share award expense) and RMB8,522,000 (including RMB6,493,000 of equity-settled share award expense), respectively.

It is estimated that emoluments and benefits in kind (including any possible payment of discretionary bonus and equity-settled share award expense) equivalent to RMB12,701,989 in aggregate will be paid and granted to our Directors and Supervisors by us in respect of the year ending December 31, 2022 under arrangements in force at the date of this document.

The aggregate amounts of remuneration and benefits in kind (including any possible payment of discretionary bonus and equity-settled share award expense) which were paid by the Group to our five highest paid individual (including both employees and Directors) for the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022 were RMB7,716,000 (including RMB2,589,000 equity-settled share award expense), RMB15,420,000 (including RMB9,282,000 equity-settled share award expense) and RMB13,201,000 (including RMB8,768,000 equity-settled share award expense), respectively.

None of our Directors or any past directors of any member of the Group has been paid any sum of money for each of the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022 as (a) an inducement to join or upon joining the Company; or (b) for loss of office as a director of any member of the Group or of any other office in connection with the management of the affairs of any member of the Group.

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There has been no arrangement under which a Director or a Supervisor has waived or agreed to waive any emoluments for each of the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022.

4. Disclaimers

Save as disclosed in this document:

- (a) none of our Directors, Supervisors or our chief executive has any interest or short position in the Shares, underlying Shares or debentures of us or any of our associated corporations (within the meaning of Part XV the SFO) which will have to be notified to us and the [REDACTED] pursuant to [REDACTED], or which will be required, pursuant to [REDACTED], to be entered in the register referred to therein, or which will be required to be notified to us and the [REDACTED] pursuant to Model Code for Securities Transactions by Directors of [REDACTED] once the H Shares are [REDACTED] on the [REDACTED];
- (b) none of our Directors or Supervisors is aware of any person (not being a Director or chief executive of the Company) who will, immediately following completion of the [REDACTED], have an interest or short position in the Shares or underlying Shares which would fall to be disclosed to us under the provisions of [REDACTED] or who is interested, directly or indirectly, in 10% or more of the issued voting shares of any member of our Group;
- (c) so far as is known to our Directors, none of our Directors, their respective close associates (as defined under the Listing Rules) or Shareholders who own more than 5% of the number of issued shares of the Company have any interests in the five largest customers or the five largest suppliers of the Group; and
- (d) save as disclosed in this document, none of our Directors, Supervisors or any of the parties listed in "8. Qualifications of Experts" of this Appendix is:
 - (i) interested in our promotion, or in any assets which have been, within two years immediately preceding the date of this document, acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to any member of our Group; or
 - (ii) materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to our business.

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STATUTORY AND GENERAL INFORMATION

D. OTHER INFORMATION

1. Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or our subsidiaries under the laws of the PRC.

2. Litigation

Except as disclosed in this document, as of the Latest Practicable Date, we were not engaged in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance is known to our Directors to be pending or threatened by or against any member of our Group, that would have a material adverse effect on our Group's results of operations or financial condition, taken as a whole.

3. Preliminary Expenses

As of the Latest Practicable Date, our Company has not incurred any material preliminary expenses for the purpose of the Listing Rules.

4. Promoter

Save as disclosed in this document, within the two years preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given or is proposed to be paid, allotted or given to any Promoter in connection with the [REDACTED] and the related transactions described in this document.

5. Taxation of Holders of H Shares

(1) *Hong Kong*

The sale, purchase and transfer of H Shares registered with our Hong Kong branch register of members will be subject to Hong Kong stamp duty. The current rate charged on each of the purchaser and seller is 0.13% of the consideration of or, if higher, of the fair value of our Shares being sold or transferred. For further details in relation to taxation, see Appendix III to this document.

(2) *Consultation With Professional Advisers*

Potential [REDACTED] in the [REDACTED] are urged to consult their professional tax advisers if they are in any doubt as to the taxation implications of [REDACTED], [REDACTED], holding or disposing of or [REDACTED] our Shares (or exercising rights attached to them). None of us, the Joint Sponsors, the [REDACTED], or any other person or party involved in the [REDACTED] accept responsibility for any tax effects on, or liabilities of, any person, resulting from the [REDACTED], [REDACTED], holding or disposal of, [REDACTED] or the exercise of any rights in relation to our Shares.

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6. Application for [REDACTED]

The Joint Sponsors have made an application on behalf of our Company to the [REDACTED] for the [REDACTED] of, and permission to [REDACTED], the H Shares [REDACTED] and [REDACTED] as mentioned in this document. All necessary arrangements have been made to enable the securities to be admitted into [REDACTED].

7. No Material Adverse Change

Save as disclosed in “Summary—Recent Developments and No Material Adverse Change” in this document, our Directors confirm that, as of the date of this document, there has been no material adverse change in the financial or trading position or prospect of our Group since August 31, 2022 (being the date to which the latest audited consolidated financial statements of our Group were prepared).

8. Qualifications of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given their opinion and/or advice in this document are as follows:

<u>Name</u>	<u>Qualifications</u>
Citigroup Global Markets Asia Limited	Licensed corporation under the SFO to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts), Type 6 (advising on corporate finance) and Type 7 (providing automated trading services) regulated activities (as defined under the SFO)
Huatai Financial Holdings (Hong Kong) Limited	Licensed corporation under the SFO to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 6 (advising on corporate finance) and Type 9 (asset management) regulated activities (as defined under the SFO)
Ernst & Young	Certified public accountants under the Professional Accountants Ordinance (Cap. 50) and Registered Public Interest Entity Auditor under the Accounting and Financial Reporting Council Ordinance (Cap. 588)
AllBright Law Offices	PRC legal adviser
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Independent industry consultant
JunHe LLP Shanghai Office	Legal adviser as to PRC intellectual property law

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in our Company or our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

9. Consents

Each of the experts named in “8. Qualifications of Experts” in this section has given and has not withdrawn their respective written consents to the issue of this document with the inclusion of their reports and/or letters and/or the references to their names included herein in the form and context in which they are respectively included.

10. Joint Sponsors’ Independence

The Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules.

The Joint Sponsors’ fees payable by us in respect of the Joint Sponsors’ services as sponsor for the [REDACTED] are US\$1 million.

11. Binding Effect

This document shall have the effect, if an application is made in pursuance of it, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

12. Bilingual Document

The English and Chinese language versions of this document are being published separately, in reliance upon the exemption provided under [REDACTED] of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

13. Miscellaneous

Save as otherwise disclosed in this document:

- (a) within the two years preceding the date of this document, our Company has not issued nor agreed to issue any share or loan capital fully or partly paid either for cash or for a consideration other than cash;
- (b) no Share or loan capital of our Company, if any, is under option or is agreed conditionally or unconditionally to be put under option;
- (c) our Company has not issued nor agreed to issue any founder shares, management shares or deferred shares;
- (d) our Company has no outstanding convertible debt securities or debentures;

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

- (e) within the two years immediately preceding the date of this document, no commission, discount, brokerage or other special term has been granted in connection with the issue or sale of any capital of our Company;
- (f) there is no arrangement under which future dividends are waived or agreed to be waived;
- (g) there has been no interruption in our business which may have or have had a significant effect on the financial position in the last 12 months;
- (h) our Company is not presently listed on any stock exchange or traded on any trading system;
and
- (i) our Company currently does not intend to apply for the status of a sino-foreign investment joint stock limited company and does not expect to be subject to the Sino-Foreign Joint Venture Law of the PRC.

APPENDIX VII DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND AVAILABLE ON DISPLAY

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to a copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) a copy of the [REDACTED];
- (b) a copy of the material contract referred to in “B. Further Information about the Business of the Company—1. Summary of Material Contract” in Appendix VI to this document; and
- (c) the written consents issued by each of the experts and referred to in “D. Other information—8. Qualifications of Experts” in Appendix VI to this document.

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the website of the Hong Kong Stock Exchange at www.hkexnews.hk and our website at www.cryofocus.com during a period of 14 days from the date of this document:

- (a) the Articles of Association;
- (b) the Accountants’ Report for the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022 prepared by Ernst & Young, the text of which is set out in Appendix I to this document;
- (c) the audited consolidated financial statements of our Group for the two years ended December 31, 2020 and 2021 and the eight months ended August 31, 2022;
- (d) the report received from Ernst & Young on the unaudited [REDACTED] financial information of our Group, the text of which is set out in Appendix II to this document;
- (e) the Frost & Sullivan Report;
- (f) the PRC legal opinion issued by AllBright Law Offices, our legal adviser on PRC law, in respect of our general matters and property interests;
- (g) the intellectual property due diligence report prepared by JunHe LLP Shanghai Office in respect of our intellectual property in the PRC;
- (h) the material contract referred to in “B. Further Information about the Business of the Company—1. Summary of Material Contract” in Appendix VI to this document;
- (i) the service agreements and letters of appointment referred to in “C. Further Information about Directors, Supervisors and Substantial Shareholders—2. Particulars of Directors’ and Supervisors’ Service Contracts and Letters of Appointment” in Appendix VI to this document;

APPENDIX VII

**DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND AVAILABLE ON DISPLAY**

- (j) the written consents referred to in "D. Other Information—9. Consents" in Appendix VI to this document; and

- (k) the PRC Company Law, the PRC Securities Law, the Special Regulations and the Mandatory Provisions together with unofficial English translations thereof.