
BUSINESS

OVERVIEW

We are a China-based medical device company focused on providing novel solutions for the treatment and integrated management of metabolic diseases. Founded in Hangzhou in 2016 and by developing the first medical device approved for the digestive endoscopic treatment of obesity in China, we have established ourselves as an early entrant advancing clinical applications in the metabolic disease field, providing novel solutions that offer therapeutic features distinct from pharmacotherapy and invasive bariatric surgery in metabolic diseases treatment. We envision a future where our minimally invasive technologies deliver clinical benefits for metabolic diseases, benefiting patients worldwide.

We have strategically focused our product portfolio on metabolic diseases, a therapeutic area characterized by vast, growing patient populations and significant unmet medical needs. Driven by global lifestyle changes, urbanization, and aging populations, metabolic diseases, including obesity, metabolic dysfunction-associated steatohepatitis (MASH), and type 2 diabetes mellitus (T2DM), have become a pervasive global health challenge, creating one of the largest and fastest-growing opportunities in the medical device sector.

- **Obesity:** Obesity is a complex, relapsing chronic disease associated with a range of metabolic complications. In China, where obesity is defined as a BMI of ≥ 28.0 kg/m², the population of patients with obesity has reached 233.7 million in 2025 and is projected to expand to 329.8 million by 2034, according to Frost & Sullivan.
- **MASH:** MASH represents a critical therapeutic void with limited effective treatment options globally. The prevalence of MASH in patients with obesity in China was 57.9 million in 2025, according to Frost & Sullivan. As MASH can progress to cirrhosis and liver cancer, there is an urgent clinical need for interventions that address the underlying metabolic drivers of the disease.
- **T2DM:** The increase of body weight or waist circumference can aggravate insulin resistance. In China, the number of patients with obesity living with T2DM reached 57.5 million in 2025, according to Frost & Sullivan. Conventional pharmacotherapies often face challenges regarding long-term adherence and side effects, creating a substantial demand for non-pharmacologic interventions that can deliver durable glycemic control.

Against the backdrop of this vast prevalence, endoscopic bariatric and metabolic therapy (EBMT) has emerged as an effective, minimally invasive solution, offering an alternative to address the unmet clinical needs in treatment of obesity and metabolic diseases. According to Frost & Sullivan, the global market size of EBMT devices is projected to grow from US\$148 million in 2025 to US\$1,248 million by 2030, representing a CAGR of 53.1%. In China, the market size of EBMT devices is projected to grow from RMB32 million in 2025 to RMB1,352 million by 2030, representing a CAGR of 111.1%, driven by the introduction of innovative, less invasive solutions like ours.

To seize these market opportunities and address the unmet medical needs associated with metabolic diseases, we initiated the development of our Core Product, the gastric bypass stent system (the “GBS”) in 2017, led by a senior management team with extensive experience and deep insights in the medical device industry. We have strategically built a product pipeline that spans from the treatment devices for obesity and metabolic diseases, to compatible devices and integrated management products, all of which focusing on the treatment and management of metabolic diseases, addressing indications including overweight, obesity, MASH complicated with obesity, and T2DM complicated with obesity. As of the Latest Practicable Date, we have successfully developed and commercially launched one EBMT treatment device product, being our Core Product, and obtained registration approval on two compatible products that are designed to facilitate the operations of treatment devices and one digital health management platform for full-cycle management. In addition, we are developing the GBS-Low BMI and independently developing various other pipeline product candidates at different stages, targeting mainstream viable EBMT options for metabolic diseases, enabling us to penetrate this vast but underserved market.

BUSINESS

The following diagram summarizes the development and registration status of our in-house developed products and product candidates in key regions as of the Latest Practicable Date.

Product Pipeline

Portfolio	Product code name	Treatment Indication	Region	Pre-clinical	Clinical Trial	Registration	Upcoming Key Milestone (Expected)	Source	Risk Classification	Competent Authorities
Treatment Devices for Obesity and Metabolic Diseases	★ GBS	Obesity	China			Approved in China (January, 2024)	N/A	Self-developed	III	NMPA
		Obesity	Other Regions*			Submitted in Hong Kong, Indonesia, Thailand, Vietnam, Singapore and Brazil	N/A	Self-developed	Multiple ¹	Multiple ²
		Obesity	EU*			In CE marking review	Expects obtaining CE marking from the relevant notified body in H2 2026	Self-developed	IIb	UDEM (NB: CE22696)
		Obesity and Overweight	China		Clinical Trial in process		To complete pivotal clinical study in Q4 2027	Self-developed	III	NMPA
	● GBS-SH	MASH	Global *	IDE-Enabling studies			To initiate early feasibility study in Europe in Q3 2026	Self-developed	Multiple ³	Multiple ²
	● GBS-DM	T2DM	China	FIIH study			To complete FIIH study in Q4 2027	Self-developed	III	NMPA
	● DGB	Obesity	China		Clinical trial in process ²		To complete the pivotal clinical study in Q4 2027	Self-developed	III	NMPA
	● RCB	Obesity	EU*			In CE marking review	Expects obtaining CE marking from the relevant notified body in Q1 2028	Self-developed	IIb	BSI (NB: CE2797)
	● RCB	Obesity	China	Registration testing in preparation			To complete registration testing in Q4 2026	Self-developed	III	NMPA
	*Videa Gastroscope	/	China			Approved in China (December, 2025)	N/A	Self-developed	II	Shanghai NMPA
Devices Compatible	/	/	EU			In CE marking review	Expects obtaining CE marking from the relevant notified body in Q2 2027	Self-developed	IIa	SGS BELGIUM NV (NB: CE 1639)
	*Agitation/ Deflation Catheter	/	China	Registration testing completed			To submit NMPA registration in Q4 2026	Self-developed	II	Zhejiang NMPA
	*Endoscope retrieval kit	/	China			Approved in China (July, 2025)	N/A	Self-developed	II	Zhejiang NMPA
Integrated management software	● Dmx	/	China			Approved in China (December, 2024)	N/A	Self-developed	II	Tianjin NMPA

★ Core Product ● Key Product

BUSINESS

- * Denotes devices or product candidates exempted from mandatory or additional local clinical trial requirements in the specified jurisdictions. The specific regulatory bases are as follows:
 - (i) For GBS (in the EU, Indonesia, Thailand, Hong Kong, Vietnam, Saudi Arabia, Malaysia, Ecuador, Colombia, the Philippines, Singapore and Brazil) and DIGB (in the EU): Exempted from conducting local clinical trials. The respective Notified Bodies and competent authorities accept clinical evaluation reports supported by clinical trial data generated in China, which have been assessed to comply with applicable regulations, including the EU Medical Device Regulation (MDR, Regulation (EU) 2017/745).
 - (ii) For GA (in the EU): Exempted from clinical trials as it is a Class IIa device and does not fall within the scope of Article 61(4) of the EU MDR that mandates clinical trials. Its registration is supported by clinical evaluation data pursuant to Article 61 of the EU MDR.
 - (iii) For GA, RTK, and Drx (in China): Exempted from clinical trials as they are Class II devices included in the Catalogue of Medical Devices Exempted from Clinical Evaluation (《免於進行臨床評價醫療器械目錄》) promulgated by the NMPA, and meet the relevant exemption criteria under the Measures for the Administration of Registration and Recordation of Medical Devices (《醫療器械註冊與備案管理辦法》).
- # Mainly includes China, US, EU, and Southeast Asia
 - MASH denotes metabolic dysfunction-associated steatohepatitis
 - T2DM denotes Type 2 diabetes mellitus
- 1 We have completed FIH study in patients with obesity and MASH in China, and plan to conduct further clinical research across different ethnicities.
- 2 We initiated a prospective, multicenter, randomized controlled pivotal clinical trial in China in August 2025, with the aim of completing the trial by 2027.
- 3 Video Gastroscope consists of endoscopic video image processor and electronic upper gastrointestinal endoscope.
- 4 The risk classification for the GBS is Class C in Indonesia, Thailand, Vietnam, Saudi Arabia, Malaysia, the Philippines and Singapore; Class III in Hong Kong, Ecuador and Brazil; and Class IIb in Colombia.
- 5 The competent authorities for the GBS are the MOH in Indonesia, MOH in Vietnam, the Thai FDA in Thailand, the MDD in Hong Kong, the SFDA in Saudi Arabia, the MDA in Malaysia, the ARCSA in Ecuador, the INVIMA in Colombia, the FDA in the Philippines, the HSA in Singapore, and the ANVISA in Brazil.
- 6 The risk classification for GBS-SH is Class III in China and the U.S.; Class IIb in the EU; and Class C in Indonesia, Thailand, Vietnam, Malaysia, the Philippines, and Singapore.
- 7 The competent authorities for GBS-SH are the NMPA in China, the FDA in the U.S. and the Philippines, the MOH in Indonesia and Vietnam, the Thai FDA in Thailand, the MDA in Malaysia, and the HSA in Singapore. For the EU, the competent authority will be a Notified Body (NB) which is yet to be determined.

Note: Design stage refers to the designing and developing of the sample product. IDE-enabling studies refer to the requisite preclinical research conducted to support an IDE application for clinical trials.

BUSINESS

Our Core Product

GBS is a minimally invasive medical device developed for the treatment of obesity, inspired by the weight loss and metabolic benefits of Roux-en-Y gastric bypass (RYGB) surgery. It functions as a flexible, retrievable sleeve placed endoscopically to establish an impermeable barrier between gastric chyme and the intestinal mucosa of the duodenum and proximal jejunum, in order to reduce nutrient absorption and promote hormone modulation to achieve weight loss.

Our Core Product represents an evolution in treatment weight loss and the management of metabolic disorders. It was the world’s first commercializing approved intestinal interventional medical device for obesity, and received NMPA approval as a Class III Innovative Medical Device in January 2024, becoming the first medical device approved for digestive endoscopic treatment of obesity in China. The device was approved under the special review green path procedures for innovative medical devices (the “**Green Path**”), highlighting its novel mechanism and significant clinical value. We are actively developing the GBS-Low BMI, aiming to address a broader population with unmet clinical needs, and to introduce new specification of the GBS. We received ethics approval from the leading institution of the study in January 2026 and had initiated patient enrollment and recruitment for its pivotal trial, and had reached approximately 50.0% of the target patient enrollment as of the Latest Practicable Date, targeting completion of the clinical study by the end of 2027.

In addition, we are actively advancing the global expansion of GBS. As of the Latest Practicable Date, it had also received regulatory approvals in 11 other countries and regions, including Hong Kong, Indonesia, Thailand, Vietnam, Saudi Arabia, Malaysia, Ecuador, Colombia, the Philippines, Singapore and Brazil. Additionally, we are in the process of obtaining registration for the GBS in other regions such as the European Union.

Our Core Product has demonstrated a proven track record of rapid product commercialization and market penetration. In the year ended December 31, 2024 and 2025 and the six months ended June 30, 2025 and 2026, the GBS was used in 239, 2,066, 817 and 1,955 commercial implantation procedures, respectively, representing an over eight-fold increase from 2024 to 2025 and an 139.3% increase from the six months ended June 30, 2025 to the same period of 2026. Since the commercial launch of the GBS in China in April 2024 and up to the Latest Practicable Date, it had been successfully used in over 5,200 commercial implantation procedures. As of the same date, endoscopic procedures using the GBS have been launched at 490 hospitals across China, and we have completed training for physicians at over 650 hospitals. We have established a dedicated in-house sales and marketing team with deep industry expertise, primarily focusing on academic promotion and physician education. Supported by the demonstrated efficacy and safety clinical performance of the GBS in weight loss, our value-based pricing strategy, strong endorsements from leading KOLs in metabolic surgery, gastroenterology, and endocrinology, and our extensive distributor network, we believe we are well-positioned to capture the significant opportunities in China’s underpenetrated endoscopic weight loss market and further expand our market share.

Our Key Products

We are developing a gastric bypass stent system product candidate targeting MASH complicated with obesity (the “**GBS-SH**”), developed based on the same platform with the GBS. It is designed to utilize a longer sleeve and an optimized retrieval system for an expected six-month implantation period. In recognition of its potential to address significant unmet medical needs, GBS-SH was granted Breakthrough Device Designation by the FDA in October 2024, making us the only Chinese company to obtain such designation as of the Latest Practicable Date. This designation is reserved for devices that offer significant advantages over existing alternatives, and it facilitates prioritized review by the FDA throughout the regulatory process. We plan to initiate an international multi-center registration trial by the end of 2027.

BUSINESS

Leveraging the same platform, we are also developing a gastric bypass stent system product candidate targeting T2DM complicated with obesity (the “**GBS-DM**”). Initial observations from our FIH study on GBS-DM indicated significant improvements in glycemic control, including in FPG and HbA1c, in patients with T2DM complicated with obesity. We are currently in the small-scale exploratory clinical research phase to validate the device for an estimated six to nine-month implantation period.

Based on the intragastric balloon platform, we are developing two product candidates designed to reduce gastric volume and induce satiety. Our key innovation of the platform is a polyurethane thin-film forming technology, designed to significantly reduce adverse events compared to competitor products. The degradable intragastric balloon (the “**DIGB**”) is engineered with a degradable valve that allows the inner fluid to be released from the balloon after three to four months, improving patient experience by innovatively eliminating the need for endoscopic retrieval. The retrievable intragastric balloon (the “**RIGB**”) is built on the same technological platform as the DIGB with similar components, which is designed as a non-degradable balloon for a six-month implantation period requiring endoscopic removal. The pivotal clinical trial of DIGB has initiated patient enrollment, reaching nearly 70% of the targeted size as of the Latest Practicable Date. We have submitted applications for the CE marking in Europe for the DIGB in February 2026. As of the Latest Practicable Date, we have commenced feasibility verification studies of RIGB.

Other Product and Product Candidates

We have developed a diversified product portfolio to complement our core offerings. Our Core Product, GBS, is supplied as a comprehensive system that includes both a delivery system and a retrieval system. The GBS procedure can be performed using standard, third-party video gastrointestinal endoscopes commonly available in hospitals. While our proprietary compatible devices, such as the GA, CA and RTK, are not mandatory for the use of our Core Product, we have developed these specialized accessories to further optimize the procedural experience and provide physicians with a complete portfolio. The RTK, in particular, serves as an optional, specialized retrieval tool that offers enhanced operational flexibility.

- *Candidates for weight loss:* Our pipeline includes minimally invasive endoscopic and ingestible products and product candidates for weight management and weight loss. Our endoscopic suturing system (the “**ESS**”) enables endoscopic sleeve gastropasty, a procedure that reduces stomach volume through a series of sutures to promote weight loss. Additionally, our super space-occupying gel capsule (the “**SOC**”) represents a novel, non-surgical approach. The SOC is designed to expand into a biocompatible gel within the stomach to physically induce a feeling of fullness, offering a temporary intervention. Together, these candidates provide a spectrum of varied therapy options.
- *Candidates for T2DM complicated with obesity:* Our lead candidate aside from GBS-DM is the ablation catheter (the “**RAC**”), designed for duodenal mucosal resurfacing. This endoscopic procedure remodels the superficial lining of the duodenum, aiming to positively alter nutrient-sensing and hormone secretion pathways, such as GLP-1, thereby improving glycemic control and insulin sensitivity with a potentially durable effect. This positions the RAC as a differentiated, interventional option between daily pharmacology and metabolic surgery.
- *Compatible Devices and Accessories:* Our video gastroscope product (the “**GA**”) features an innovatively extended length designed to facilitate EBMT treatment procedures, providing visualization and operational reach for complex interventions. The GA was granted its Class II Medical Device Registration Certificate by the Shanghai NMPA in December 2025. As of the Latest Practicable Date, we have submitted application for CE marking for GA in Europe, and expect obtaining CE marking from the relevant notified body in Q2 2027. Complementing the

BUSINESS

GA, we are developing an electronic video colonoscope focusing on lower gastrointestinal endoscopy (the “CA”), for which we submitted the CE marking application in March 2026 and the NMPA registration application in April 2026. We expect to obtain approvals for such applications in the second quarter of 2027 and the fourth quarter of 2026, respectively. We are also developing a digestive endoscopy quality control software (the “EQS”), which applies image recognition technology to assist physicians in improving the quality and completeness of endoscopic procedures. We plan to submit NMPA registration application for the EQS in the fourth quarter of 2026.

- Our pipeline in this category also includes aspiration/deflation catheter (the “SIC”) specifically designed to puncture, deflate, and evacuate fluid from intragastric balloons. The innovative aspect of the SIC lies in its bullet-like ejection mechanism with a spring-loaded, trigger-activated design, which reduces the difficulty of puncturing intragastric balloon products, such as our RIGB, thereby facilitating easier operation for physicians. The SIC is planned for regulatory submission in 2026. Central to our retrieval safety is the endoscopic retrieval kit (the “RTK”), an upgraded system for the GBS designed to withdraw the entire stent into a retrieval tube, significantly enhancing procedural safety during device removal. The RTK obtained its Class II Medical Device Registration Certificate from the Zhejiang NMPA in July 2025. In addition, we are developing an impedance-based body composition analyzer (the “BCA”) and a dual-energy X-ray bone densitometer and body composition analyzer (the “BCS”). Body composition analyzers are bioelectrical devices commonly used in weight management outpatient departments, designed to assist the assessment of patients. BCA is typically used for preliminary assessment, while BCS assessment is preferred where a more precise evaluation is required, as it can provide relatively more accurate assessment of body composition. The BCA and BCS are currently at design stage.
- *Comprehensive Lifestyle Management:* Our Dtx is a digital health management platform designed to support weight management. This software enables clinicians to oversee patient weight management progress, serving as a bridge between patients and clinicians to enhance compliance through continuous engagement. Dtx was granted Class II Medical Device Registration Certificate by the Tianjin NMPA in 2024, marking a significant milestone. We also offer clinical nutrition food products (“CNT”) to provide targeted nutritional support as a key dietary intervention in medical weight management programs.

We have established five integrated, proprietary technology platforms that comprehensively support our product development, production, and quality control. These platforms, which encompass advanced stent engineering, film forming, polymer modification, sophisticated delivery systems, and stringent product quality control, are built upon deep expertise in materials science and engineering. The specialized know-how and patents underpinning them are the result of long-term accumulation and are difficult to replicate. We believe our technology platforms form a solid foundation for the R&D of our broad product pipeline of product candidates.

We have established an experienced management and R&D team that covers the entire value chain of interventional medical devices. Our team effectively integrates clinical insights with advanced engineering, allowing us to translate complex concepts into novel solutions. With extensive industry experience and specialized expertise in biomedical materials, we possess development capabilities spanning from fundamental materials science and engineering design to clinical validation and regulatory registration. Complementing our technical capabilities is our commercialization background. This multidisciplinary combination of insight, R&D, and commercialization serves as the cornerstone of our sustained research and development and commercialization.

BUSINESS

OUR STRENGTHS

We are a medical technology company, and a key contributor to the metabolic disease treatment and management ecosystem. We believe our competitive advantages are founded on the following core strengths:

The World’s First Commercializing Approved Intestinal Interventional Medical Device for Obesity, Offering a Differentiated and Competitive Treatment Option

Our Core Product, the GBS, is a novel solution that addresses the unmet clinical need in obesity. According to Frost & Sullivan, the GBS was the first globally commercializing approved intestinal interventional medical device for obesity. It was approved for commercialization for the treatment of obesity by the NMPA under the Green Path in January 2024, becoming the first medical device approved for digestive endoscopic treatment of obesity in China. The regulatory milestone validates our innovation and grants us a significant first-mover advantage in the massive and underserved Chinese obesity market. The GBS has also been acknowledged in authoritative clinical guidelines and expert consensus in China, including the Guideline for Diagnosis and Treatment of Obesity (2024 edition) issued by the NHC, the Expert Consensus on Digestive Endoscopic Treatment of Obesity in China, the Expert opinion on Endoscopic Duodenal-jejunal Bypass Liner Implantation for Weight Loss (2025 Edition), and the Expert Consensus on Weight Management Clinic Setting (2025 edition). Additionally, our Core Product GBS has already secured regulatory approvals in 11 other countries and regions as of the Latest Practicable Date, including Hong Kong, Indonesia, Thailand, Vietnam, Saudi Arabia, Malaysia, Ecuador, Colombia, the Philippines, Singapore and Brazil.

Unlike restrictive surgeries that permanently alter anatomy, the GBS mimics the weight loss and metabolic benefits of RYGB surgery through a reversible, minimally invasive approach. Distinct from most existing commercial treatments that mainly target the point of intake by limiting food consumption, the GBS primarily targets the point of reducing nutrient absorption. The GBS achieves its therapeutic effects through a unique dual-action mechanism. Mechanically, its sleeve creates a physical barrier in the duodenum and proximal jejunum to reduce nutrient absorption. Metabolically, this bypass triggers gut hormone secretion alteration, reducing GIP and stimulating GLP-1 to enhance satiety and improve blood glycemic control. Complemented by its ability to favorably modulate gut microbiota composition and preserves muscle mass, the GBS offers a multifaceted approach to long-term weight control.

The GBS demonstrates clinical profile characterized by high efficacy, a short treatment duration, and a favorable safety record. According to Frost & Sullivan, as the world’s first endoscopically delivered bypass therapy approved for a short three-month implantation, it achieves weight loss efficacy comparable to FDA-approved implants with longer durations (6 or 12 months). In contrast to invasive bariatric surgeries, the GBS offers a reversible, anatomy-sparing solution with a superior safety profile. Against pharmaceutical therapies, such as GLP-1 RAs, it provides distinct advantages by effectively preserving lean muscle mass and offering a short-term intervention rather than requiring chronic, long-term medication adherence.

Since the commercial launch of GBS, based on real-world data from over 5,200 patients as of the Latest Practicable Date, approximately 2,000 patients with available data and an implantation duration reaching three months achieved a mean TWL% of 12.0% at the time of stent removal. These patients demonstrated efficacy outcomes superior to those observed in our pivotal clinical trials. Specifically, the clinical response rate, defined as $\geq 5\%$ TWL, reached approximately 93.6% in this real-world setting, compared to approximately 80% in our pivotal clinical trials. According to Frost & Sullivan, this 5% TWL% level typically recognized as the clinically meaningful threshold in regulatory approvals and clinical guidelines in this field. Subsequently, after the retrieval of the GBS and as of the Latest Practicable Date, mean TWL% was approximately 13.0% at Month 6, based on data from approximately 1,600 patients available, the efficacy remained relatively stable at mean TWL% of 12.5% at Month 9, based on data from

BUSINESS

approximately 800 patients, 12.3% at Month 12, based on data from approximately 490 patients, and 13.3% at Month 15, based on data from approximately 260 patients. Notably, among the patients with certain body composition data available to us, approximately 90% achieved weight loss without muscle loss.

Moreover, our Core Product demonstrates sustained therapeutic benefit. Pivotal clinical trial shows that a significant proportion of patients continued to lose weight or sustain weight loss level for 24 weeks after device retrieval, and real-world evidence suggests efficacy can be maintained for up to nine months post-retrieval. Our Core Product also demonstrates a favorable safety profile, characterized by a low device-related rate of adverse events. Building upon this established efficacy and safety foundation of the GBS, we are strategically expanding the addressable patient population of our Core Product to include patients with a lower BMI. This expansion aims to address the significant unmet medical needs within this substantial demographic.

We believe the clinical performance and safety profile of the GBS are directly attributable to our innovative and unique design features, which establish high technical barriers to entry and underpins our market leadership. Our GBS features a unique anti-blockage design that leverages natural intestinal peristalsis to detach and clear potential blockage in the event of an obstruction, significantly mitigating a common failure mode of intestinal liners. The system is further distinguished by a biomimetic peristaltic distal release mechanism, which allows the sleeve’s natural deployment without X-ray guidance, thereby minimizing procedure time and radiation exposure.

To ensure safety during removal, the device also incorporates a dual-protection retrieval system with a patented protective cap and funnel design to shield the esophagus and gastric mucosa. Building on this, our second-generation retrieval system approved by Zhejiang NMPA as a Class II medical device in July 2025 enables full retraction into a protective sheath prior to removal, further enhancing procedural safety.

A Comprehensive, Multi-Modality Portfolio Strategically Targeting the Vast Metabolic Disease Market

We have strategically positioned ourselves to address the massive global challenge of metabolic diseases, including overweight, obesity, MASH complicated with obesity, and T2DM complicated with obesity. According to Frost & Sullivan, the global population with obesity is projected to reach 1,263.7 million by 2030. The need for intervention is further amplified in MASH, which affects approximately 34% of individuals with obesity. As of the Latest Practicable Date, only two pharmaceutical therapies have received FDA approval for MASH, underscoring a significant unmet medical need, particularly for interventional device treatments. Furthermore, the rising prevalence of T2DM among individuals with obesity creates a compounding health crisis, driving urgent demand for therapies that can achieve weight loss and glycemic control.

To capture this market opportunity, we have established a diversified in-house developed pipeline beyond our Core Product. This pipeline spans mainstream interventional modalities to address various patient needs. We are advancing treatments for complex metabolic conditions, as exemplified by our specialized candidate, GBS-SH, for MASH complicated with obesity. In a FIH study, GBS-SH demonstrated compelling efficacy in reduction (fibrosis improvement by one or more stages) in liver fibrosis with no worsening of steatohepatitis, which was in 44.4% of the patient with liver fibrosis stage 1 to stage 3 in FAS, and 57.1% in PPS. Notably, in a subgroup with liver fibrosis stage 2 or stage 3, 66.7% of patients achieved reduction in both MASH resolution and fibrosis improvement by ≥ 1 stage, highlighting its potential in difficult-to-treat cases. This transformative profile was validated by the FDA’s grant of Breakthrough Device Designation in October 2024.

For T2DM complicated with obesity, we are optimizing product candidate GBS-DM (together with GBS and GBS-SH, the “**GBS Series**”), with positive outcomes observed in a three-month early feasibility

BUSINESS

FIH study. Specifically, data showed that 12 weeks after implantation, the mean HbA1c was reduced from 9.0% to 7.1%, demonstrating significant glycemic improvement. Additionally, pre-clinical investigation is underway on our proprietary product candidate for T2DM complicated with obesity, RAC, a DMR system expected to minimize stenosis risk while ensuring effective mucosal ablation.

Based on the intragastric balloon platform, we are developing two product candidates designed to reduce gastric volume and induce satiety. Our key innovation of the platform is polyurethane thin-film forming technology, designed to significantly reduce adverse events compared to competitor products. The DIGB is engineered with a degradable valve that allows the inner fluid to be released from the balloon after three to four months, improving patient experience by innovatively eliminating the need for endoscopic retrieval. We have conducted FIH study on DIGB, which demonstrated compelling efficacy. Specifically, the mean TWL% was 10.2%, and 90.0% of patients achieved a weight loss of $\geq 5\%$ TWL. It is currently undergoing a pivotal clinical trial in China which is expected to complete in 2027, targeting NMPA approval in 2028. We plan to submit application for CE marking for DIGB in Europe in 2026. To serve diverse market needs, we are also developing a non-degradable version RIGB for international markets and the ESS to provide a comprehensive bariatric toolkit.

Beyond therapeutic devices, our comprehensive portfolio of commercialized products and product candidates is designed to cover the entire treatment lifecycle of metabolic diseases. A cornerstone is our proprietary obesity management software, Dtx, approved as a Class II medical device in China in December 2024, making it the first digital health management platform for obesity management in China, according to Frost & Sullivan. By integrating our interventional devices with this digital tool, we establish a closed-loop prevention, treatment, management ecosystem, supporting patients from device therapy through long-term maintenance.

Established Commercialization Capability with Efficient Market Rollout, Deep KOL Engagement and Training Infrastructure

We have achieved progress in commercialization, rapidly translating regulatory approval into significant market adoption. Admitted to the NMPA’s Green Path for innovative medical devices, the GBS has gained market acceptance among clinical experts for its unique minimally invasive and reversible therapeutic profile. This strong acceptance is reflected in our compelling commercial performance. In the year ended December 31, 2024 and 2025 and the six months ended June 30, 2025 and 2026, the GBS was used in 239, 2,066, 817 and 1,955 commercial implantation procedures, respectively, representing an over eight-fold increase from 2024 to 2025 and an 139.3% increase from the six months ended June 30, 2025 to the same period of 2026. As of the Latest Practicable Date, the GBS has been successfully implanted in over 5,200 procedures across 30 provinces in China. This growth validates the product’s strong market momentum and its ability to address the vast unmet clinical need for treatment of obesity in China.

Our commercialization strategy is centered on clinical value and broad patient access. Prior to launch, we conducted extensive consultations with top metabolic experts, hospital administrators, and health economists to establish a pricing model that reflects the product’s substantial clinical value while ensuring economic accessibility for hospitals and patients, a key driver of our rapid adoption. To secure sustainable volume growth, we are actively advancing market access and have successfully secured inclusion in 28 provincial-level medical insurance reimbursement directories as of the Latest Practicable Date, laying a critical foundation for long-term market expansion.

Our market penetration is driven by deep academic engagement and high-level collaborations. We strategically target national and regional medical centers of excellence in obesity and metabolic diseases. We have established strong partnerships with KOLs at these centers, involving them early in product design optimization and multicenter clinical trials. Despite the inherent challenges typically associated with establishing a novel therapeutic paradigm, the GBS has achieved rapid clinical consensus and market

BUSINESS

penetration. This endorsement has translated into exceptional market uptake. We achieved 1,000 implantations in five months from June to November 2025, with monthly volume surging to over 200 implantations in July 2025. As of the Latest Practicable Date, the procedure has been successfully launched in 490 hospitals. Notably, we have seen significant traction in our hospital network, with commercial volume in single benchmark institution reaching as high as approximately 550 implantations, demonstrating that the GBS has swiftly transitioned to a recognized, reproducible clinical therapy.

To sustain our business expansion, we are committed to cultivating a broad network of proficient hospitals capable of performing this innovative procedure. We systematically promote standardized endoscopic operation protocols for both implantation and integrated patient management through national academic conferences, specialized training workshops, and procedural demonstrations. As of the Latest Practicable Date, we have established three flagship procedural training bases in collaboration with leading hospitals and universities. Under these collaborative arrangements, one of our key roles is to support the operational aspects of the training programs, such as bearing logistical expenses. The hospitals and universities provide the training facilities and expert personnel to conduct procedural demonstrations and hands-on animal operation training for attending physicians. These collaborations do not involve the conduct of clinical trials, the collection of patient clinical data, or joint research and development activities. Our academic initiatives had over 400 training sessions and seminars conducted, and had completed training for physicians at over 650 hospitals as of the same date.

A Consistent, Integrated R&D and Production Platform Driving Continuous Product Iterations and High Clinical Standards.

Our success is underpinned by a powerful, integrated platform that combines innovation capabilities with a stringent and globally aligned quality control system. This platform focuses on three core pillars: technology innovation and material science advancement, efficient clinical trial design and execution, and production capabilities.

Research and Development Capabilities. Our R&D philosophy is driven by original innovation and rapid verification. During the Track Record Period and up to the Latest Practicable Date, we have conducted extensive preclinical studies, and have been maintaining a cohort of numerous swines, enabling an agile feedback loop for immediate concept testing and iteration. Our strong in-house expertise is reflected in a comprehensive and growing intellectual property portfolio. As of the Latest Practicable Date, we owned an aggregate of 220 granted patents and patent applications which consisted of 88 granted patents and 66 patent applications in China, and 23 granted patents and 43 patent applications overseas. 104 of the granted patents and patent applications as of the Latest Practicable Date were related to our Core Product. Leveraging our long-term focus on metabolic diseases, we have assembled a core R&D team with deep technical expertise in critical fields such as metabolic diseases, polymer materials, structural design, and processing technologies. This expertise is institutionalized within our proprietary technology platforms, which form the foundation of our innovation, encompassing advanced stent engineering, advanced film forming technology, polymer modification, sophisticated delivery systems, and stringent product quality control. These platforms, built upon long-term accumulation of specialized know-how and patents, are difficult to replicate and enable us to systematically tackle industry challenges. For instance, we developed a proprietary and unique anti-blockage design that leverages natural intestinal peristalsis to detach and clear potential blockage in the event of an obstruction to reduce blockage rates and early removal. Similarly, to address placement challenges, our polymer and processing teams collaborated to create a unique deployment technology and an optimized implantation process. We are committed to expanding our pipeline through continuous R&D to strengthen our long-term competitive edge. Our efforts are augmented by strategic external partnerships, including a joint development collaboration with a leading hospital in Shanghai focused on innovation in the field of stent technology. Additionally, we are backed by a scientific advisory board comprising top scientists and physicians in metabolic disease treatment, who provide critical insights into global technological progress and development trends.

BUSINESS

Clinical Development Expertise. With deep experience in Class III medical devices, we have developed a profound understanding of relevant laws and regulations in both China and overseas markets. As the developer of the first medical device approved for digestive endoscopic treatment of obesity in China, we have accumulated unique, practical know-how in the efficient management and execution of such complex trials. Our expertise covers the entire clinical lifecycle, including trial planning, protocol design, project execution, data management, and analysis. We have successfully designed and executed the pivotal clinical trial for the GBS in China by working closely with principal investigators (PIs) at top-tier domestic and international hospitals. We actively monitor the progress of our ongoing trials and leverage our high-quality clinical data from China to support global registrations. Specifically, we expect our Chinese clinical data to partially support our CE marking application, potentially accelerating the registration process in Europe.

Production and Quality Control. We have built a professional production team capable of ensuring a seamless transition from product development to commercial-scale production. As of the Latest Practicable Date, we operate our independent production facilities in Hangzhou with a total gross floor area of approximately 4,385 sq.m. To further scale our production capacity, we are constructing a new production base in Quzhou, mainly for the production of our Core Product, spanning approximately 5,000 sq.m. As of the Latest Practicable Date, we had obtained the medical device manufacturing license for the GBS at the Quzhou facility, and the facility is expected to be operational in the second half of 2026. We have established a comprehensive and strict quality control management system that operates in full compliance with the GMP standards of the NMPA and the ISO 13485:2016 international standard. Our production capabilities are powered and sustained by our proprietary technological platforms ensuring performance and safety. We have also implemented an ERP system to digitize our production and supply chain workflows. This system offers distinct advantages by ensuring full-lifecycle product traceability, while significantly enhancing operational efficiency and minimizing the risk of human error through digital management.

An Experienced Management Team with Deep Scientific Expertise and Keen Industry Insight

We are led by an experienced management team with a proven track record of success, combining deep clinical insight with exceptional industrial execution capability.

- ***Mr. Zuo Yuxing, Our Chairman and Founder:*** Leveraging his unique background as a former gastroenterologist, Mr. Zuo founded the company to bridge a critical clinical gap. His firsthand understanding of the limitations in metabolic disease treatment drove his mission to transform surgical principles into minimally invasive device therapies. As the principal inventor of the GBS and with over 20 years of medical device industry experience, he is the chief architect of our corporate vision and product philosophy.
- ***Dr. Li Wenyu, Our Technical Director:*** Our R&D efforts are spearheaded by Dr. Li, who possesses over a decade of specialized experience in biomedical materials and device development. Dr. Li has successfully led the research and development of our pipeline portfolio, including the GBS and related product candidates for various indications, as well as our DIGB and RIGB products, ensuring our technology remains at the forefront of innovation.
- ***Mr. Zhong Gaofeng, Our Director of Clinical and Registration Affairs:*** Mr. Zhong oversees our clinical and registration strategy with over 20 years of experience. He has successfully navigated our pipeline products and product candidates through critical milestones, including the NMPA approval of the GBS and the FDA Breakthrough Device Designation of the GBS-SH. He also maintains a network of over 30 leading hospitals and KOLs, which facilitates our efficient clinical trial execution.
- ***Mr. Chen Jiahao, Our Chief Marketing Officer:*** Mr. Chen executes our commercialization strategy with over 20 years of sales and marketing experience in the high-value medical device

BUSINESS

sector. His extensive tenure at global industry leaders such as Medtronic equips us with best-in-class commercial operational expertise, which is instrumental in scaling our market presence and driving adoption.

For further details of our senior management, see “Directors and Senior Management.”

OUR STRATEGIES

We plan to execute the following strategic initiatives to leverage our competitive advantages and fulfill our corporate mission:

Consolidate and Expand Our Leadership in China’s High-Growth Endoscopic Weight Loss Market

The endoscopic weight loss market in China represents substantial untapped potential. According to Frost & Sullivan, it remains currently significantly underpenetrated relative to developed markets, which stands in stark contrast to the scale of the addressable demographic. According to Frost & Sullivan, the number of patients with obesity in China grew from 187.7 million in 2020 to 233.7 million in 2025, representing a CAGR of 4.5% over the same period, and is expected to reach 285.1 million in 2030 and 329.8 million in 2034, representing a CAGR of 4.1% from 2025 to 2030, and a CAGR of 3.7% from 2030 to 2034, respectively. This vast patient pool creates an urgent demand for effective interventions, particularly for those requiring medical weight loss beyond lifestyle modification but for whom invasive bariatric surgery is either clinically unsuitable or personally unacceptable.

To capitalize on this growth, our immediate priority is to secure dominant adoption in China’s top metabolic surgery centers by leveraging the proven clinical profile and strong KOL endorsement of the GBS. We aim to establish a leading market share in these core hospitals, while simultaneously extending our coverage to a wider network of hospitals with the potential to perform these procedures. Our long-term roadmap targets broad coverage of majority of Grade IIIA hospitals and other capable Grade III hospitals in China. We will strategically penetrate key clinical departments such as endocrinology, gastroenterology, bariatric surgery, and specialized obesity treatment departments, thereby unlocking channel penetration potential which is further catalyzed by the NHC’s “Weight Management Year” initiative (2024–2026) mandating the establishment of weight management clinics in certain tertiary hospitals. To enable this expansion, we will expand our commercial team with talent experienced in medical devices and optimize our distribution network for nationwide coverage.

Strengthen Academic Promotion and Collaboration. We will continue to cultivate our network of KOLs and physicians in the metabolic surgery field while strategically expanding this network into clinical departments of digestive, gastroenterology and endocrinology, where we see strong demand for our therapies. We will maintain close communication with leading medical associations, societies and conferences, and capitalize on favorable industry policies and the momentum of the national health campaigns such as the three-year campaign on public weight management initiated by the NHC and other ministries in China. Moreover, we believe that broadening our coverage of KOLs and physicians will provide us with a significant competitive edge in promoting our products and establishing the GBS as a cross-disciplinary standard of care.

Conduct Long-term Post-operative Follow-up, Innovate through Evidence and Sustain Leadership. We are committed to evidence-based clinical validation and long-term patient outcomes. We will continue to conduct post-operative follow-up assessments following endoscopic weight loss procedures to further study the long-term safety and efficacy of the GBS. This high-quality evidence will directly inform future product iterations and support our partners in publishing influential studies, thereby reinforcing our academic standing. Ultimately, this evidence-driven approach will further strengthen our partnerships with physicians, enhance our brand reputation, and reinforce our position as the leader in metabolic intervention.

BUSINESS

Accelerate the Development of Innovative Treatments and Integrated Management Pipelines for Metabolic Diseases.

We are committed to strengthening our leadership in the endoscopic treatment of metabolic diseases by continuously advancing a broad and integrated product pipeline.

Accelerating Product Innovation and Extension of Clinical Indications. To maintain our technological edge, we are accelerating the development of our GBS Series. This includes conducting clinical research for the GBS-Low BMI and commercializing the 81 cm sleeve specification under our existing GBS registration. As of the Latest Practicable Date, we have received ethics approval from the leading institution of the study in January 2026 and had initiated patient enrollment and recruitment for its pivotal trial, and had reached approximately 50.0% of the target patient enrollment as of the Latest Practicable Date, targeting completion of the clinical study by the end of 2027.

Diversifying Product Portfolio through Internal R&D. Concurrently, we are accelerating our broader pipeline, including dedicated devices GBS-SH and GBS-DM, as well as the DIGB and RIGB. By integrating these therapies with our approved digital health management platform, we aim to create a diversified product portfolio of hospital treatment and home management, which will solidify our leadership in the metabolic treatment field. Leveraging our established market position and deep expertise, we believe that the experience and technical know-how gained from our existing portfolio will directly fuel and accelerate the development of future products.

Strategic Partnerships and Business Development. To complement our internal innovation, we will actively seek collaboration and investment opportunities with third parties, with a focus on the endoscopic metabolic and weight loss sectors. Our deep understanding and unique insights into metabolic diseases enable us to identify external technologies with significant clinical potential for the treatment of obesity, MASH complicated with obesity and T2DM complicated with obesity. We will prudently evaluate investment opportunities to expand our portfolio regarding these technologies through strategic acquisitions, collaborations, or in-licensing arrangements.

Continue to Advance Our International Development Strategy

We are committed to expanding our global footprint with a differentiated international promotion strategy tailored for our GBS, focusing on high-potential overseas markets. To execute this strategy efficiently, we plan to collaborate with a global network of partners, including medical device companies, research institutions, core hospitals, and distributors.

Global R&D and Regulatory Capabilities. Our international expansion is supported by an R&D platform built to meet the stringent global standards. We have made significant progress with the GBS, having already completed the Stage 2 of the quality management system (QMS) and technical audits for the CE marking. Leveraging our mature experience in development and production, we are striving to enter the European market, representing a market opportunity to introduce one of the first Chinese self-developed endoscopic weight-loss products in the region. Concurrently, our R&D team is strategically synchronizing product iterations with global regulatory timelines. For the extension of indication for the GBS, we plan to update overseas registrations upon completion of its pivotal trial. We are also advancing our intragastric balloon portfolio for international markets, with CE marking application submissions planned for the DIGB and the non-degradable RIGB in 2026, ensuring a diversified portfolio for global patients.

Commercialization and Strategic Partnerships. To ensure rapid market access, our sales and marketing teams are building a distribution ecosystem. Beyond Europe, Southeast Asia and the Middle East, we are advancing registration work in other key markets such as Mexico. We will conduct feasibility assessments for additional markets and may leverage localized clinical trials to accelerate entry. Our global partners will be instrumental in facilitating effective market access across diverse geographies.

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Localization Teams and Emerging Market Breakthroughs. We will build localized teams to navigate regulatory pathways and execute ground strategies in high-potential emerging markets. Our regulatory teams have demonstrated agility in markets recognizing NMPA approval, securing registration in 11 other countries and regions, including Hong Kong, Indonesia, Thailand, Vietnam, Saudi Arabia, Malaysia, Ecuador, Colombia, the Philippines, Singapore and Brazil, since the GBS’s NMPA approval in January 2024. We are working to obtain registrations in the European Union by the end of 2026. To maximize the value of these approvals, we will invest in localized academic promotion teams to build a strong brand presence and drive sales growth. Demonstrating our rapid execution, as of the Latest Practicable Date, we have already successfully completed physician training at 11 hospitals across Southeast Asia.

Improve Operational Efficiency and Achieve Economies of Scale to Support Long-Term Sustainable Growth

We are committed to optimizing our production and operational capabilities to underpin our commercial expansion and ensure long-term, sustainable growth.

Production Capacity Expansion. To support our projected sales growth, we are constructing a new production facility in Quzhou, mainly for the production of our Core Product. As of the Latest Practicable Date, we had obtained the medical device manufacturing license for the GBS at the Quzhou facility. This facility, with a total gross floor area of approximately 5,000 sq.m., is expected to commence operations in 2026. This expansion is poised to unlock economies of scale, driving down unit costs and improving operating efficiency. We will further enhance efficiency by continuously upgrading our production infrastructure and increasing the level of automation across our production processes.

Operational Efficiency. In terms of operations, we will continue to execute strategies focused on lean management and efficiency improvement. We intend to strengthen our supply chain coordination and streamline our internal management processes to support our growing scale of operations. Simultaneously, we are actively exploring and implementing methods to optimize our inventory management systems, thereby further elevating our overall operational efficiency and responsiveness to market demand.

Attract, Develop, and Retain Top-Tier Talent to Drive Innovation and Commercial Capabilities

We believe that talent is the cornerstone of our sustainable growth. To support our ambitious R&D and commercialization goals, we plan to execute a comprehensive talent strategy focused on attracting, developing, and retaining high-caliber professionals across all key functions.

We will continue to recruit outstanding R&D talent with multi-disciplinary expertise in material science, mechanical engineering, software and clinical medicine to expand our internal innovation capabilities. Beyond technical skills, we foster a collaborative environment where our R&D team maintains direct communication with KOLs and clinical experts. This ensures our innovations are grounded in clinical insights and aligned with market needs.

To drive rapid market penetration for the GBS and future pipeline product candidates, we will expand our sales and marketing team. We will provide systematic training to equip our commercial team with deep product knowledge and the skills to deliver high-quality, professional support to physicians and distribution partners.

To ensure long-term stability and motivation, we are committed to offering competitive compensation, comprehensive benefits, clear career paths, and continuous learning opportunities. We aim to create a dynamic, rewarding, and growth-oriented environment where employees can thrive and grow alongside the company.

BUSINESS

OUR PRODUCTS AND PRODUCT PIPELINE

We are a China-based medical device company focused on providing novel solutions for the treatment and integrated management of metabolic diseases. As of the Latest Practicable Date, we have successfully developed and commercially launched one EBMT treatment device product, being our Core Product, and obtained registration approval on two compatible products that are designed to facilitate the operations of treatment devices for obesity and metabolic diseases and one digital health management platform for management. In addition, we are expanding various in-house pipeline products at different stages of development. The chart below summarized our in-house developed product portfolio as of the Latest Practicable Date.

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Product Pipeline

Portfolio	Product code name	Treatment Indication	Region	Pre-clinical	Clinical Trial	Registration	Upcoming Key Milestone (Expected)	Source	Risk Classification	Competent Authorities
Treatment Devices for Obesity and Metabolic Diseases	★GBS	Obesity	China			Approved in China (January, 2024)	N/A	Self-developed	III	NMPA
		Obesity	Other Regions*			Approved in Hong Kong, Indonesia, Russia, Vietnam, Saudi Arabia, Malaysia, Ecuador, Colombia, the Philippines	N/A	Self-developed	Multiple ^d	Multiple ^e
		Obesity	EU*			In CE marking review	Expects obtaining CE marking from the relevant notified body in H2 2026	Self-developed	IIb	UDEM (NB: CE206)
		Obesity and Overweight	China		Clinical Trial in process		To complete pivotal clinical study in Q4 2027	Self-developed	III	NMPA
		MASH	Global ^f		IDE-faunding studies ^g		To initiate early feasibility study in Europe in Q3 2026	Self-developed	Multiple ^h	Multiple ⁱ
	●GBS-SH	MASH	Global ^f		IDE-faunding studies ^g		To complete FTH study in Q4 2027	Self-developed	III	NMPA
	●GBS-DM	T2DM	China		FTH study		To complete the pivotal clinical study in Q4 2027	Self-developed	III	NMPA
	●DIGB	Obesity	China		Clinical Trial in process ^j		Expects obtaining CE marking from the relevant notified body in Q1 2028	Self-developed	IIb	BSI (NB: CE2797)
	●RIGB	Obesity	China		Registration testing in preparation		To complete registration testing in Q4 2026	Self-developed	III	NMPA
	GA ¹	/	China			Approved in China (December, 2025)	N/A	Self-developed	II	Shanghai NMPA
Devices Compatible	*Agitation/Deflation Catheter	/	EU			In CE marking review	Expects obtaining CE marking from the relevant notified body in Q2 2027	Self-developed	IIa	SGS BELGIUM NV (NB: CE1659)
	*Endoscopic retrieval kit	/	China		Registration testing completed		To submit NMPA registration in Q4 2026	Self-developed	II	Zhejiang NMPA
	*Obesity management software	/	China			Approved in China (July, 2025)	N/A	Self-developed	II	Zhejiang NMPA
	Integrated management software	/	China			Approved in China (December, 2024)	N/A	Self-developed	II	Tianjin NMPA

★Core Product ●Key Product

- * Denotes devices or product candidates exempted from mandatory or additional local clinical trial requirements in the specified jurisdictions. The specific regulatory bases are as follows:
- (i) For GBS (in the EU, Indonesia, Thailand, Hong Kong, Vietnam, Saudi Arabia, Malaysia, Ecuador, Colombia, the Philippines, Singapore and Brazil) and DIGB (in the EU): Exempted from conducting local clinical trials. The respective Notified Bodies and competent authorities accept clinical evaluation reports supported by clinical trial data generated in China, which have been assessed to comply with applicable regulations, including the EU Medical Device Regulation (MDR, Regulation (EU) 2017/745).
 - (ii) For GA (in the EU): Exempted from clinical trials as it is a Class IIa device and does not fall within the scope of Article 61(4) of the EU MDR that mandates clinical trials. Its registration is supported by clinical evaluation data pursuant to Article 61 of the EU MDR.
 - (iii) For GA, RTK, and Drx (in China): Exempted from clinical trials as they are Class II devices included in the Catalogue of Medical Devices Exempted from Clinical Evaluation (《免于进行临床评价医疗器械目录》) promulgated by the NMPA, and meet the relevant exemption criteria under the Measures for the Administration of Registration and Recordation of Medical Devices (《医疗器械注册与备案管理办法》).

Mainly includes China, US, EU, and Southeast Asia

MASH denotes metabolic dysfunction-associated steatohepatitis

T2DM denotes Type 2 diabetes mellitus

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- 1 We have completed FIH study in patients with obesity and MASH in China, and plan to conduct further clinical research across different ethnicities.
- 2 We initiated a prospective, multicenter, randomized controlled pivotal clinical trial in China in August 2025, with the aim of completing the trial by 2027.
- 3 Video Gastroscope consists of endoscopic video image processor and electronic upper gastrointestinal endoscope.
- 4 The risk classification for the GBS is Class C in Indonesia, Thailand, Vietnam, Saudi Arabia, Malaysia, the Philippines and Singapore; Class III in Hong Kong, Ecuador and Brazil; and Class IIb in Colombia.
- 5 The competent authorities for the GBS are the MOH in Indonesia, MOH in Vietnam, the Thai FDA in Thailand, the MDD in Hong Kong, the SFDA in Saudi Arabia, the MDA in Malaysia, the ARCSA in Ecuador, the INVIMA in Colombia, the FDA in the Philippines, the HSA in Singapore, and the ANVISA in Brazil.
- 6 The risk classification for GBS-SH is Class III in China and the U.S.; Class IIb in the EU; and Class C in Indonesia, Thailand, Vietnam, Malaysia, the Philippines, and Singapore.
- 7 The competent authorities for GBS-SH are the NMPA in China, the FDA in the U.S. and the Philippines, the MOH in Indonesia and Vietnam, the Thai FDA in Thailand, the MDA in Malaysia, and the HSA in Singapore. For the EU, the competent authority will be a Notified Body (NB) which is yet to be determined.

Note: Design stage refers to the designing and developing of the sample product. IDE-enabling studies refer to the requisite preclinical research conducted to support an IDE application for clinical trials.

BUSINESS

Our Core Product, the Gastric Bypass Stent System for Obesity

Overview

Our Core Product, the GBS is a minimally invasive medical device developed by us for the treatment of obesity. According to Frost & Sullivan, the GBS was the first globally commercializing approved intestinal interventional medical device for obesity. The GBS is inspired by the proven weight loss and metabolic benefits of the RYGB surgery, an invasive bariatric surgery, and offers a non-surgical alternative by mimicking its core mechanism. Mechanically, its sleeve creates a physical barrier in the duodenum and proximal jejunum to reduce nutrient absorption. Metabolically, this bypass triggers gut hormone secretion alteration, reducing GIP and stimulating GLP-1 to enhance satiety and improve blood glycemic control. Complemented by its ability to favorably modulate gut microbiota composition and preserves muscle mass, the GBS offers a multifaceted approach to long-term weight control.

It had received NMPA approval as a Class III Innovative Medical Device in January 2024, becoming the first medical device approved for digestive endoscopic treatment of obesity in China. The device was approved under the NMPA’s Green Path, highlighting its novel mechanism and significant clinical value. As of the Latest Practicable Date, it has also received regulatory approvals in 11 other countries and regions, including Hong Kong, Indonesia, Thailand, Vietnam, Saudi Arabia, Malaysia, Ecuador, Colombia, the Philippines, Singapore and Brazil.

Approved by the NMPA for patients who have not achieved sufficient improvement with lifestyle interventions, non-invasive therapies, or pharmacotherapy, the current indication covers individuals meeting one of the following criteria: (i) BMI ≥ 32.5 kg/m² with simple obesity; (ii) BMI between 30.0 and 32.5 kg/m² with at least two components of metabolic syndrome; or (iii) BMI between 30.0 and 32.5 kg/m² with obesity-related comorbidities (the “**Approved Indication**”). We are actively developing the GBS-Low BMI, aiming to address a broader population with unmet clinical needs.

Product Structure

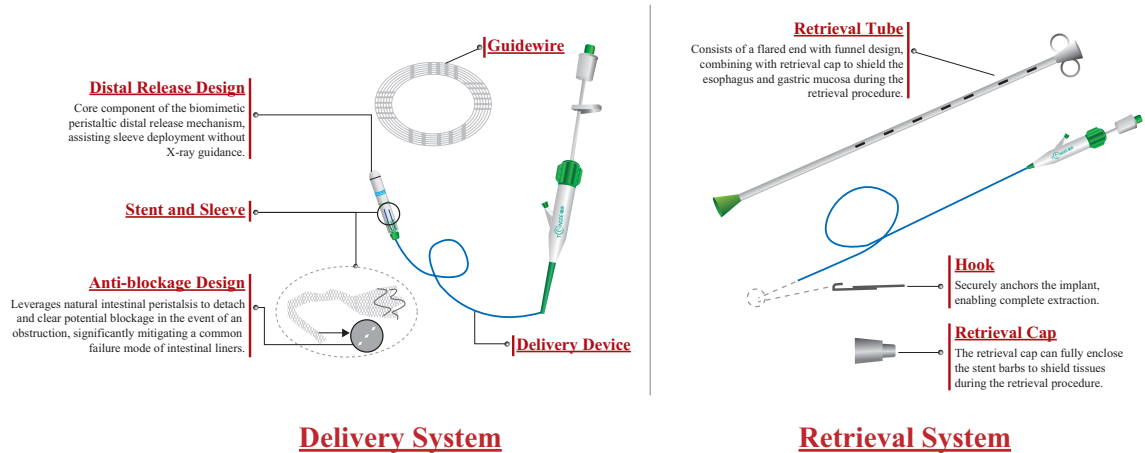
Our GBS system comprises a delivery system and a retrieval system.

The delivery system It consists of a delivery device, the GBS stent, and a guidewire, with the stent pre-loaded within the device’s storage tube. The GBS stent itself is an assembly of the following key components: a nitinol alloy stent with anchoring barbs, a sleeve made from linear low-density polyethylene (LLDPE) and low-density polyethylene (LDPE) film, an ultra-high-molecular-weight polyethylene (UHMWPE) retrieval suture, radiopaque tantalum marker rings, and release ball. The sleeve features a low coefficient of friction and non-permeable to ensure the smooth passage of food chyme. Our GBS also features a unique anti-blockage design that leverages natural intestinal peristalsis to detach and clear potential blockage in the event of an obstruction, significantly mitigating a common failure mode of intestinal liners. The delivery system is further distinguished by a biomimetic peristaltic distal release mechanism, which allows the sleeve natural deployment without X-ray guidance, thereby minimizing procedure time and radiation exposure.

The retrieval system It consists of a retrieval tube, a retrieval hook, and a retrieval cap, facilitating the complete endoscopic extraction of the implant. The retrieval tube consists of a flared end with funnel design, combining with retrieval cap to shield the esophagus and gastric mucosa during the retrieval procedure.

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Below is an illustration diagram of our GBS:



Operation Procedure

GBS Implantation Procedure The GBS implantation is a standardized, endoscopic procedure performed under anesthesia. It begins with the placement of a guidewire to establish gastric access. The integrated delivery system is then advanced to the stomach over the guidewire. The core deployment process is conducted under continuous endoscopic vision, ensuring precision and safety. The deployment process is simplified by color-coded marker lines that enable direct visual alignment with the pylorus, ensuring controlled and accurate stent release. Upon release, direct endoscopic observation confirms that the stent has fully expanded and the anchoring barbs have anchored in the duodenal bulb. A follow-up digital fluoroscopy is scheduled post-procedure on an as-needed basis, utilizing the stent's radiopaque markers to objectively verify that the device remains in the correct position and maintains full expansion.

GBS Removal Procedure The procedure is conducted under continuous endoscopic visualization. It begins with an endoscopic assessment of the stent's position. The key step involves using a specialized retrieval hook to engage the stent under visualization, collapsing it into a compact form, and then withdrawing the gastric stent entirely after it is retracted into a protective retrieval cap to cover all barbs before removal. This design aims to shield the patient's upper gastrointestinal tract and prevent tissue damage during extraction. The entire system is then entirely withdrawn, completing the procedure. Post-removal, a final endoscopic inspection is performed to confirm tissue integrity. The retrieved device is also examined to verify its structural completeness, confirming a successful and complete removal.

Market Opportunity and Competition

The GBS targets the gap in weight loss in patients with obesity, the large population of patients who are unresponsive to diet and/or drug therapy but are unwilling or unsuitable for invasive, irreversible bariatric surgery. Pharmacologic therapies, such as the GLP-1 RAs, are often constrained by high discontinuation rates, rapid weight regain upon cessation, and potential muscle mass loss, while traditional bariatric surgery, despite its efficacy, remains a niche solution due to its invasive nature and permanent anatomical alteration.

The unique positioning of the GBS unlocks a sizable addressable market. According to Frost & Sullivan, the number of patients with obesity worldwide reached 1,035.7 million in 2025 and is expected to increase to 1,263.7 million in 2030 and 1,440.4 million in 2034. In China, the number of patients with obesity reached 233.7 million in 2025. Correspondingly, the global market for EBMT medical devices is projected to grow from US\$148 million in 2025 to US\$1,248 million by 2030, representing a CAGR of 53.1%, respectively. In China, the market size for EBMT medical devices is projected to grow from RMB32 million in 2025 to RMB1,352 million by 2030, representing a CAGR of 111.1%.

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The market is expanding under the NHC’s “Weight Management Year” campaign (2024–2026), which mandates the establishment of weight management clinics in hospitals of certain tertiary. Simultaneously, the inclusion of our GBS in Guideline for Diagnosis and Treatment of Obesity (2024 edition) issued by the NHC establishes a standardized framework for adoption, validating the therapy’s role in mainstream obesity treatment. Furthermore, the inclusion of our GBS in medical insurance reimbursement programs in 28 provinces as of the Latest Practicable Date significantly enhances affordability, effectively converting the vast demographic of potential patients into an accessible commercial market.

Our GBS is the first NMPA-approved endoscopic bypass medical device for obesity, addressing the unmet clinical need. According to Frost & Sullivan, as of the Latest Practicable Date, there are no other domestic comparable products in China at the clinical trial submission or more advanced stages. Our primary known global competitor is Morphe Medical, whose RESET® device obtained the CE marking in Europe in 2025 for a narrower population of BMI ≥ 40 kg/m², or those with BMI ≥ 30 kg/m² accompanied by at least one concurrent cardiometabolic risk factor. We believe our GBS is competitively positioned with a potentially larger addressable market, with our development plan aiming to expand into the even larger BMI 25.0–30.0 kg/m² population. Technically, our GBS is designed to enhance patient safety and procedural efficiency. Its design enables deployment that operates without the need for X-ray guidance, thereby facilitating a short procedure time and eliminating patient radiation exposure. Furthermore, it utilizes a specialized structure engineered to significantly reduce the risk of blockage. Additionally, the competitive landscape of our GBS also includes intragastric balloon products. See “— Market Opportunity and Competition” for DIGB and RIGB.

Summary of Clinical Trial Data

Pivotal trial

We have completed a prospective, multi-center, randomized, controlled clinical trial in China (the “**Pivotal Trial**”) to evaluate the efficacy and safety of the GBS for the treatment of obesity. We evaluated these endpoints by comparing test group patients receiving the GBS plus dietary intervention against control group patients receiving dietary intervention alone. We used dietary intervention as the control as it is a standard of care for obesity management.

Trial Design

The Pivotal Trial was conducted in seven centers in China, designed to enroll 100 patients. From November 2020 to October 2022, 99 eligible patients were enrolled and randomly assigned to the test group or the control group, with 50 and 49 patients in the respective groups. The analysis populations comprised 98 patients in both the full analysis set (FAS) and the safety set (SS), and 81 patients in the per protocol set (PPS). One patient randomized to the test group was excluded from all analysis sets as the device could not be implanted due to the patient’s duodenal anatomy, and the patient did not receive any trial-related treatment. All patients met the following key inclusion criteria: (i) age between 18 and 60 years; (ii) BMI ≥ 30.0 kg/m²; (iii) American Society of Anesthesiologists (ASA) physical status classification of I-II; and (iv) voluntarily participated and signed the informed consent form.

The primary endpoint of the Pivotal Trial was the proportion of patients achieving $\geq 5\%$ TWL and the percentage of excess weight loss (EWL%) in three months. Secondary endpoints included: (i) change in waist circumference in three months; (ii) device performance evaluation in the test group; (iii) change from baseline in BMI at Months 1, 3, 4, 6, and 9; (iv) change in HbA1c at Months 3, 6 and 9; (v) the intensity of glucose-lowering medication usage at Months 1, 3, 4, 6, and 9; (vi) change from baseline in glycemic parameters, lipid profiles, and blood pressure at Months 1, 3, 4, 6, and 9. Safety endpoints comprised the incidence of clinically significant laboratory changes, device- or procedure-related complications, and adverse events.

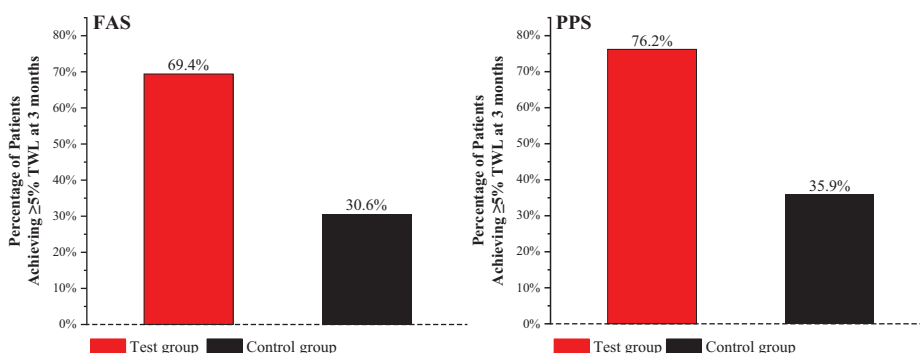
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Efficacy Results

The pivotal trial was designed as a superiority study. It successfully met all pre-specified primary endpoints and secondary endpoints, demonstrating statistically and clinically superior weight loss for the test group compared to the control.

For the endpoint of percentage of patients achieving $\geq 5\%$ TWL in three months, the results were as follows:

- In the FAS, the rate was 69.4% in the test group versus 30.6% in the control group, with a between-group difference of 38.78% (95% CI: 20.5%, 57.0%). The lower limit of the confidence interval exceeded the pre-specified superiority margin of 10%.
- In the PPS, the rate was 76.2% in the test group versus 35.9% in the control group, with a between-group difference of 40.3% (95% CI: 20.5%, 60.1%). The lower limit also exceeded the superiority margin of 10%.

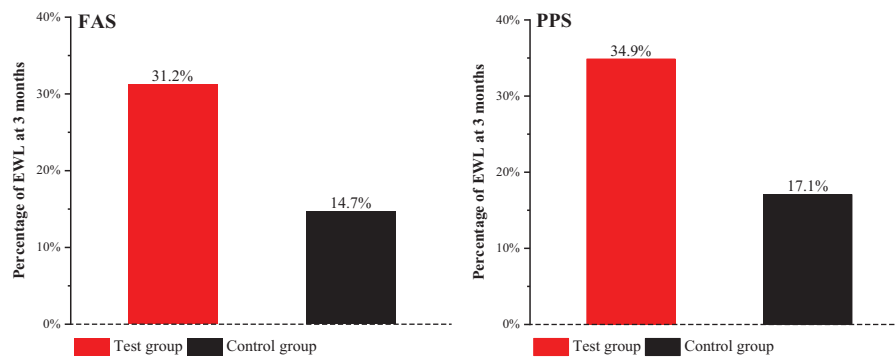


Percentage of patients achieving $\geq 5\%$ total weight loss at 3 months

For the endpoint of EWL% in three months, the results were as follows:

- In the FAS, the mean EWL% was $31.2\% \pm 21.5\%$ in the test group versus $14.7\% \pm 14.4\%$ in the control group, with a between-group difference of 16.5% (95% CI: 9.2%, 23.9%). The lower limit of the confidence interval exceeded the pre-specified superiority margin of 2%.
- In the PPS, the mean EWL% was $34.9\% \pm 20.4\%$ in the test group versus $17.1\% \pm 14.8\%$ in the control group, with a between-group difference of 17.8% (95% CI: 9.8%, 25.7%). The lower limit also exceeded the superiority margin of 2%.

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Percentage of excess weight loss at 3 months

In addition to the primary endpoints, the pivotal trial evaluated multiple secondary endpoints to comprehensively assess the efficacy of the GBS. The results for the secondary endpoints were as follows:

- *Change in waist circumference in three months:* At Month 3, the mean change in waist circumference from baseline in the FAS was -3.83 ± 4.14 cm in the test group and -2.50 ± 4.61 cm in the control group ($p=0.083$), and in the PPS, it was -4.22 ± 4.15 cm and -2.67 ± 4.94 cm, respectively ($p=0.055$). Although the differences did not reach statistical significance, the absolute mean reduction in the test group was greater than that in the control group. Furthermore, the percentage change in waist circumference from baseline at Month 3 showed a statistically significant difference between the two groups in the PPS ($p=0.041$), though not in the FAS ($p=0.068$).
- *Device performance evaluation in the test group:* In both the FAS and PPS, the device achieved a 100.0% success rate for delivery, deployment, and retrieval. Furthermore, no device inversion or detachment was observed at 30 and 90 days post-procedure.
- *Change from baseline in BMI at Months 1, 3, 4, 6, and 9:* The test group demonstrated a statistically significant greater reduction in BMI compared to the control group across all follow-up points. Specifically, in the FAS, the mean change in BMI from baseline at Months 1, 3, 4, 6, and 9 in the test group were -1.93 ± 0.93 kg/m², -3.07 ± 1.84 kg/m², -3.30 ± 2.34 kg/m², -3.18 ± 3.11 kg/m², and -3.10 ± 4.20 kg/m², respectively, all of which were statistically superior to the control group (all p-values < 0.05).
- *Change in HbA1c at Months 3, 6 and 9:* The differences between the test and control groups at Months 3, 6, and 9 did not reach statistical significance. This was because the indicator was analyzed across all subjects, but the number of subjects with a history of diabetes was small (8 in the test group and 9 in the control group), thus no statistical difference was established.
- *The intensity of glucose-lowering medication usage at Months 1, 3, 4, 6, and 9:* This indicator was analyzed only for subjects using glucose-lowering medications to treat diabetes. In the FAS, the differences between the two groups were statistically significant at Month 1 ($p=0.045$) and Month 4 ($p=0.018$), but did not reach statistical significance at Months 3, 6, and 9. The lack of statistical significance at other follow-up points and in the PPS was due to the small number of subjects using glucose-lowering medications to treat diabetes.
- *Change from baseline in glycemic parameters, lipid profiles, and blood pressure at Months 1, 3, 4, 6, and 9:* (i) glycemic parameters: In the FAS, the difference in fasting insulin at Month 1, and fasting C-peptide at Months 4 and 6 were statistically significant. However, the differences in

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fasting blood glucose at all time points, and other glycemic parameters at remaining time points did not reach statistical significance. This was attributed to the small number of subjects with a history of diabetes; (ii) lipid profiles (TC, TG, HDL-C, LDL-C): In the FAS, the difference in HDL-C at Month 3 was statistically significant. The differences in TC, TG, LDL-C at all time points, and HDL-C at remaining time points did not reach statistical significance; and (iii) blood pressure: The differences in the change from baseline in both systolic and diastolic blood pressure between the two groups did not reach statistical significance. Despite the lack of statistical significance, the absolute mean reductions in blood pressure in the test group were generally greater than those in the control group.

Safety Results

A total of 83 patients experienced adverse events (AEs), with 48 patients (245 events) in the test group and 35 patients (101 events) in the control group, indicating a between-group difference. Within the test group, 35 patients reported 83 events of device-related AEs, and 29 patients reported 67 events of procedure-related AEs. Serious adverse events (SAEs) occurred in six patients: four patients (four events) in the test group and two patients (two events) in the control group. In the test group, one SAE was assessed as device-related and one as procedure-related.

<i>Adverse Events (AEs)</i>	<i>Test group</i>	<i>Control group</i>
Patients with at least one AE, n (%)	48 (97.96%)	35 (71.43%)
Total number of AEs	245	101
Device-Related AEs, n (%)	35 (71.43%)	N/A
<i>Serious Adverse Events (SAEs)</i>		
Patients with at least one SAE, n (%)	4 (8.16%)	2 (4.08%)
Total number of SAEs	4	2
Device-Related SAEs, n (%)	1 (2.04%)	N/A

The safety profile of the GBS was characterized by a higher incidence of manageable AEs in the test group, consistent with the nature of an endoscopic implant procedure, with no increased risk of SAEs. As anticipated, the overall incidence of AEs was significantly higher in the test group (97.96%) than in the control group receiving only dietary intervention (71.43%). The majority of AEs in the test group were gastrointestinal and recoverable, without permanent injury. The reported adverse events in the test group were recoverable. There were no instances of irrecoverable adverse events or adverse events resulting in permanent injury or death during the pivotal clinical trial. Device-related AEs mainly include vomiting, abdominal pain, and gastrointestinal/duodenal ulcers. Importantly, the incidence of SAEs was not statistically different between the two groups ($p=0.678$). Specifically, of the four SAEs reported in the test group, one was assessed as device-related, being stent migration, one as procedure-related, and the remaining two were deemed unrelated to the device or procedure.

In conclusion, the pivotal trial demonstrated that the GBS provides statistically superior weight loss efficacy compared to dietary intervention alone, with a well-characterized and acceptable safety profile appropriate for an interventional device.

Pivotal trial for the GBS-Low BMI

To drive the continuous commercial expansion of our Core Product, the GBS, we are initiating a new pivotal clinical trial intended to support a modification to our existing NMPA registration. The primary objective is to extend the approved indication to cover patients with a lower BMI. The trial also introduces, as an additional variant to the currently approved 60 cm version, an 81 cm sleeve specification. Since the GBS-Low BMI utilizes the similar device structure and therapeutic mechanism as the approved GBS,

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differing only in the target patient population’s BMI range, it is regulated as an indication expansion rather than a separate product. Furthermore, as the GBS does not fall within the specific high-risk categories listed in the Catalogue of Class III Medical Devices Requiring Clinical Trial Approval (2020 Revision), we are not required to obtain a formal no objection letter from the NMPA to initiate this clinical trial.

The trial is expected to be designed as a prospective, multi-center, randomized, controlled study. We plan to enroll approximately 148 patients. Eligible patients should meet the following key inclusion criteria: (i) aged 18–60 years, (ii) diagnosis of obesity or overweight with inadequate weight loss response to prior lifestyle interventions, meeting one of the following sub-criteria: (a) BMI ≥ 32.5 kg/m²; (b) BMI ≥ 27.5 kg/m² with comorbid T2DM; (c) BMI between 27.5 kg/m² and 32.5 kg/m² with either inadequate response to medical treatment for obesity, or with other obesity-related comorbidities inadequately managed by medical therapy; or (d) BMI between 25.0 kg/m² and 27.5 kg/m² with T2DM and inadequate glycemic control following intensive medical therapy. Eligible patients should voluntarily participate in the trial and provide written informed consent.

Following initial screening, eligible patients will be randomized on a 1:1 basis into either a test group, receiving GBS placement plus lifestyle intervention, or a control group, receiving dietary intervention alone. The total trial duration is planned for nine months, comprising a three-month implantation period followed by a six-month post-retrieval follow-up.

The primary efficacy endpoint is expected to be the proportion of patients achieving $\geq 5\%$ TWL at three months compared to the control group based on key clinical indicators. Secondary efficacy endpoints will include, among others, device performance, weight loss outcomes at various follow-up time points, and changes in body composition and relevant metabolic parameters. Safety endpoints will assess the incidence of device deficiencies and adverse events.

We received ethics approval from the leading institution of the study in January 2026 and had initiated patient enrollment and recruitment for its pivotal trial, and had reached approximately 50.0% of the target patient enrollment as of the Latest Practicable Date, targeting completion of the clinical study by the end of 2027.

Development History and Development Plan

The R&D of our GBS commenced in 2017. The table below summarizes the key development milestones and future development plan for our GBS:

Time	Milestone
February 2017	Started pre-clinical investigation, including market research, and product design
November 2019	Completed the animal studies and type testing
September 2020	Obtained the NMPA approval to be reviewed under the Green Path
November 2020	Commenced the clinical trial in China
October 2022	Completed the clinical trial
March 2023	Submitted the NMPA registration application
January 2024	Obtained the NMPA approval as a Class III Innovative Medical Device
April 2024	Commenced sales in China

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According to Frost & Sullivan, the overall development timeframe of our Core Product is generally in line with industry norms for comparable Class III innovative medical devices. The future development and commercialization plan for the GBS mainly include the following:

- ***Extension of indication and new specifications:*** Based on our commercially approved 60 cm sleeve model, we are pursuing a registration modification with the NMPA to achieve the primary objectives of expanding the approved indication to cover patients with a lower BMI, while introducing an 81 cm sleeve specification to complement the existing 60 cm version. This update will allow for coverage of clinical needs across our expanded addressable population and selection of more specifications. We received ethics approval from the leading institution of the study in January 2026 and had initiated patient enrollment and recruitment for its pivotal trial, and had reached approximately 50.0% of the target patient enrollment as of the Latest Practicable Date, targeting completion of the clinical study by the end of 2027.
- ***Registration in new markets:*** To drive global growth, we are actively expanding our regulatory footprint. Having secured approvals in 12 markets including Chinese Mainland, we are now strategically pursuing registrations in other key jurisdictions. Specifically, we are in the process of obtaining registration for the GBS in other regions such as the European Union. Furthermore, we are actively progressing our application for the CE marking in Europe toward its approval. We submitted our application for CE marking under the Medical Device Regulation (MDR) in July 2024. According to relevant regulations, based on our conformity analysis and communications with our notified body, the clinical data obtained from our pivotal clinical trials in China is acceptable for the purpose of CE marking, and no separate local clinical trials or additional R&D work are required within the EU. We expect to obtain the CE marking in the second half of 2026.

Material Communication with Competent Authorities

We have maintained active and constructive engagement with the NMPA throughout the development and registration of the GBS. Our regulatory journey began in September 2020, when the GBS was formally accepted into and publicized under the NMPA’s Green Path review regime.

Following this, we commenced the pivotal clinical trial in China in November 2020, completed it in October 2022, and submitted the registration application in March 2023. The subsequent review process involved several key interactions with the NMPA. This collaborative process culminated in the NMPA’s approval of the GBS as a Class III Innovative Medical Device in January 2024.

Other than the above, we have not had any material regulatory communications with the competent authorities for GBS, and we are not aware of any material concern from the competent authorities in connection with GBS. As of the Latest Practicable Date, no material adverse change had occurred with respect to our regulatory status for GBS.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP EXTENSION OF INDICATION AND SPECIFICATIONS, AND EXPAND OVERSEAS MARKET FOR OUR GBS SUCCESSFULLY

Our Key Product, Gastric Bypass Stent for MASH Complicated with Obesity

Based on our established gastric bypass stent platform, we are developing a device candidate, GBS-SH, for the treatment of MASH complicated with obesity. As a product targeting a distinct indication and featuring differences in product design with a longer sleeve of approximately 80 cm, and implantation duration of six months compared to three months for the GBS, GBS-SH is expected to be regulated as a separate entity under the Guiding Principles for the Division of Medical Device Registration Units issued by the NMPA, requiring its own clinical development and registration pathway, as the guide mandates separate registration for products with distinct intended indication.

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We have completed a FIH study in China as of the Latest Practicable Date. Following our application submission in August 2024, this transformative profile was validated by the FDA’s grant of Breakthrough Device Designation in October 2024. Reserved for devices treating life-threatening or debilitating conditions, this status facilitates an expedited development path and prioritized regulatory review. We plan to initiate further FIH study across different ethnic group to ensure that the product design is optimized for global patient populations.

Product Structure

The GBS-SH leverages the same platform as the GBS. It consists of a disposable delivery system, an implant that mainly includes stent and sleeve, and a disposable retrieval system. The core implant utilizes the same fundamental components as our GBS but is being developed with modifications, such as longer sleeve similar to the planned introduction of new specification of the GBS, and more advanced retrieval system, to optimize its therapeutic effect for MASH with an expected longer implantation duration of six months.

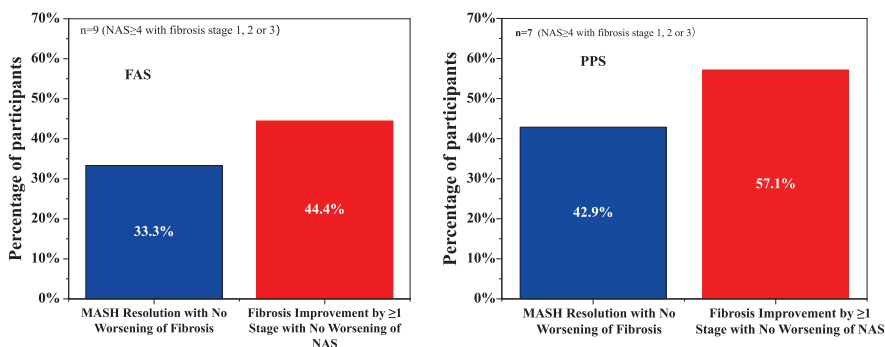
Operation Procedures

The operation procedure for GBS-SH is non-surgical, minimally invasive, and fully reversible. The placement and retrieval procedures are performed endoscopically, similar to our GBS. The key difference is the treatment period. Based on our exploratory studies, the implantation period for the MASH indication is expected to be primarily six months.

Summary of FIH Trial

An independent, small-sample clinical trial of the GBS-SH has been conducted at two centers in China. The trial was designed to provide a preliminary assessment of the efficacy and safety of the GBS-SH. Key primary efficiency points include MASH resolution, defined as a reduction in the nonalcoholic fatty liver disease activity score (NAS) by ≥ 2 points (NAS ranges from 0 to 8, with higher scores indicating more severe disease) with no worsening of fibrosis and an improvement in fibrosis by ≥ 1 stage with no worsening of the NAS. Key inclusion criteria included: (i) aged 18–65; (ii) clinical diagnosis of MAFLD; (iii) MRI-PDFF $\geq 10\%$; and (iv) BMI ≥ 25.0 kg/m². Nine eligible patients provided informed consent and were enrolled.

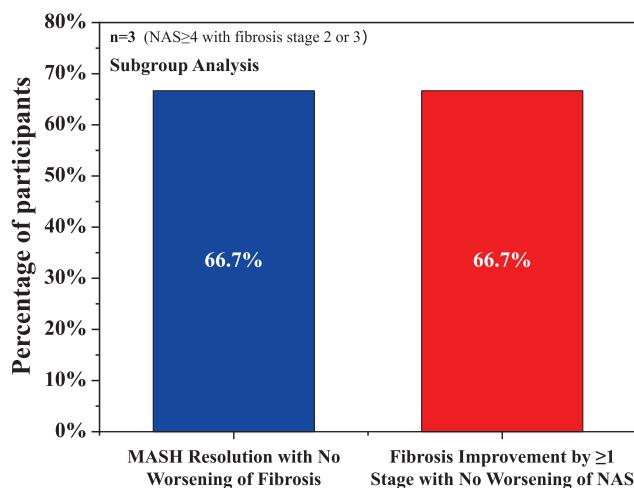
All enrolled patients successfully underwent GBS implantation and retrieval, completed the primary endpoint assessment, and received follow-up examinations. All the patients were with NAS ≥ 4 and fibrosis stage ≥ 1 and preliminary efficacy signals were observed. In the FAS (n=9), the proportion of patients with MASH resolution with no worsening of fibrosis was 33.3%. The proportion of fibrosis improvement by ≥ 1 stage with no worsening of NAS was 44.4%. In the PPS (n=7), the proportion of patients with MASH resolution with no worsening of fibrosis was 42.9%. The proportion of fibrosis improvement by ≥ 1 stage with no worsening of NAS was 57.1%.



Primary Endpoints of FIH study for GBS

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In our study, the data indicated that in the more advanced disease subgroup (NAS $\geq$ 4, fibrosis stage 2 or 3, n=3), two out of the three patients achieved both MASH resolution, and fibrosis improvement of at least one stage.



Subgroup Analysis of FIH Study for patients with NAS $\geq$ 4 and stage 2 or stage 3

Secondary endpoint assessments at 12- and 24-week post-implantation demonstrated significant improvements across multiple domains. For instance, mean liver fat content (MRI-PDFF) was reduced by 62.5% in the FAS. Liver stiffness in the FAS, demonstrated improvement, where 55.6% of patients achieved a reduction of $\geq$ 2 kPa, with no patients experiencing a worsening of $\geq$ 2 kPa. In the PPS, 71.4% of patients achieved a reduction of $\geq$ 2 kPa.

The safety profile was favorable. AEs during the initial implantation phase were limited to mild, transient gastrointestinal reactions such as nausea and vomiting. No device-related SAEs occurred. Both device implantation and retrieval procedures were successful in 100% of cases.

In summary, this exploratory trial provides preliminary evidence that the GBS-SH is a potentially effective and safe interventional therapy for patients with MASH complicated with obesity, successfully validating its clinical application concept.

Market Opportunity and Competition

According to Frost & Sullivan, the treatment of MASH is a global challenge. Specifically, the therapeutic landscape for MASH, historically referred to as NASH since 1980, has seen limited breakthroughs, with only two drugs having received FDA approval as of the Latest Practicable Date. Crucially, the clinical utility of these existing agents is constrained by their limited efficacy in fibrosis improvement by $\geq$ 1 stage. If further worsened, such persistent fibrosis can progress to cirrhosis and hepatocellular carcinoma, or eventually necessitate liver transplantation, critically associated with increased mortality rates. In China, the treatment gap is even more acute, as no pharmacologic therapy has yet obtained regulatory approval for the specific treatment of MASH. This underscores a significant unmet need and highlights the innovative potential of our GBS-SH.

This therapeutic void is magnified by the sheer scale of the affected population. According to Frost & Sullivan, the number of patients with MASH complicated with obesity is projected to grow from 349.0 million globally, including 57.9 million in China, in 2025 to 485.4 million, including 80.8 million in China, by 2034, representing a massive and expanding burden that requires urgent intervention.

BUSINESS

Further Development and Commercialization Plan

We plan to actively pursue the clinical application of GBS-SH. We plan to initiate an overseas exploratory FIH study in Europe to further evaluate the product for MASH complicated with obesity across different ethnicity. Subject to positive data, we plan to commence a global multi-center registration trial by the end of 2027, with subsequent regulatory filings aligned with the study’s timeline.

We are committed to the continual iteration of GBS-SH to optimize its long-term therapeutic profile. Key focus areas of our research and studies include increasing the sleeve length and implantation duration, as well as on improving MASH and liver fibrosis.

As a product with a distinct indication, GBS-SH will be regulated as a separate entity. We intend to leverage regulatory designations, including its existing FDA Breakthrough Device Designation, to facilitate efficient dialog with global health authorities and streamline the path to market.

Material Communication with Competent Authorities

Following our application submission in August 2024 that was supported by clinical data from our FIH study conducted in China, the FDA granted Breakthrough Device Designation to the GBS-SH in October 2024. In accordance with applicable PRC regulations, this study for the GBS-SH did not require to be pre-approved by the NMPA as it is not involved in the Index of Class III Medical Devices subject to Clinical Trial Approval (《需進行臨床試驗審批的第三類醫療器械目錄》).

In August 2025, we received written clarification via email from the FDA regarding key aspects of our clinical trial design. Building on this regulatory alignment, we aim to initiate a global multi-center clinical trial to further validate the GBS-SH.

Other than the above, we have not had any material regulatory communications with the competent authorities for GBS-SH, and we are not aware of any material concern from the competent authorities in connection with GBS-SH.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR GBS-SH SUCCESSFULLY

Our Key Product, Gastric Bypass Stent for T2DM Complicated with Obesity

Based on our GBS platform, we are developing a product candidate for T2DM complicated with obesity, GBS-DM. As it addresses a distinct indication and necessitates a different product design, with a longer sleeve of approximately 80 cm and a longer treatment duration up to nine months, GBS-DM is expected to follow its own regulatory pathway as a separate product under the Guiding Principles for the Division of Medical Device Registration Units issued by the NMPA, requiring dedicated clinical trials and approvals from the NMPA, as the guide mandates separate registration for products with distinct intended indication. This iteration retains the core mechanism of action of the approved GBS.

Product Structure

The GBS-DM leverages the same platform as our GBS. It consists of a disposable delivery system, an implant that mainly includes stent and sleeve, and a disposable retrieval system. The core implant utilizes the same fundamental components as our GBS but is being developed with modifications, including a longer sleeve, to optimize its therapeutic effect for T2DM complicated with obesity, such as a longer implantation duration.

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Operation Procedures

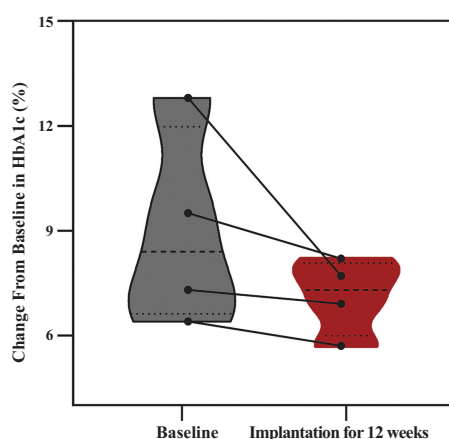
The operation procedure for GBS-DM is non-surgical, minimally invasive, and fully reversible. The placement and retrieval procedures are performed endoscopically, similar to our GBS. The key difference is the treatment period. Based on our exploratory studies, the implantation period for GBS-DM is not yet finalized but is estimated to be exceeding that of GBS.

Summary of FIH Trial

An independent, single-center, single-arm pilot study of the GBS-DM has been completed in compliance with applicable regulations in China. The study aimed to evaluate the preliminary efficacy and safety of the GBS-DM for treating patients with T2DM complicated with obesity.

Eligible patients were required to: (1) be aged 18–65; (2) have a BMI of 30–42 kg/m² with ineffective weight control via diet and exercise; (3) have an HbA1c $\geq 6.5\%$; (4) be classified as ASA I–II; and (5) provide informed consent and demonstrate willingness to comply with follow-up requirements.

All enrolled patients underwent GBS-DM implantation with follow-ups scheduled at weeks 1, 4, 8, and 12 (device removal), as well as 12- and 24-weeks post-removal. Results from the four-patient cohort demonstrated significant glycemic improvement: at 12 weeks post-implantation, the mean HbA1c decreased from 9.0% (range: 6.4–12.8%) at baseline to 7.1% (range: 5.7–8.2%), representing a mean reduction of 1.9%.



Change from Baseline in HbA1c

The safety profile was favorable. The most common AEs were mild-to-moderate gastrointestinal symptoms, such as abdominal pain, nausea, vomiting, constipation, occurring primarily in the first week post-implantation. No device-related SAEs were reported.

Market Opportunity and Competition

According to Frost & Sullivan, the intersection of obesity and T2DM represents a substantial and expanding public health burden characterized by a high baseline prevalence and sustained growth. According to Frost & Sullivan, globally, the number of patients with obesity living with T2DM is projected to rise from 361.9 million in 2025 to approximately 440.5 million by 2034, underscoring the persistent global demand for integrated metabolic interventions. Mirroring this global trend, the burden in China is similarly acute. The population of patients with T2DM complicated with obesity in China is projected to increase from 57.5 million in 2025 to approximately 66.6 million by 2034. This vast, concentrated patient pool presents a significant addressable market for therapeutic innovation.

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Despite this massive unmet clinical need, the market for device-based interventions remains significantly underserved. According to Frost & Sullivan, as of the Latest Practicable Date, there were no endoscopic medical devices in China that have received regulatory approval for the treatment of T2DM complicated with obesity. This absence of direct domestic competition highlights a market opportunity for our GBS to serve as a therapy addressing this critical therapeutic gap in the Chinese market. Globally, our competitive position is further differentiated against emerging therapies such as the DMR product, Revita. While DMR relies on energy-based mucosal ablation, a destructive process with outcomes subject to tissue regeneration variability, our GBS-DM employs a non-destructive mechanism. This distinction offers treatment controllability and reversibility. For patients, this non-permanent approach lowers the psychological barrier to treatment and ensures a more predictable safety profile, thereby enhancing patient compliance and willingness compared to irreversible tissue-altering procedures.

Further Development and Commercialization Plan

We plan to actively pursue the clinical application of GBS-DM. We have initiated a FIH study to further evaluate its potential for glycemic control and to refine the product design and expect to complete these studies in the second half of 2027. Building on the favorable data from these exploratory studies, we plan to initiate a registration clinical trial to support the regulatory approval for T2DM complicated with obesity. We aim to validate the device’s performance with an extended implantation period, which is estimated to be six to nine months, to ensure sustained therapeutic efficacy for T2DM management.

Given that the GBS-DM targets a distinct indication from our core product and necessitates a different treatment duration, we plan to advance its regulation as a separate product entity rather than as a modification to our existing registration. We intend to maintain close communication with regulatory authorities to define the optimal clinical pathway and data requirements for this specific indication.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR GBS-DM SUCCESSFULLY

Our Key Product, the Degradable Intragastric Balloon

Building on our intragastric balloon platform, we developed the DIGB, which is engineered with a degradable valve that allows the inner fluid to be released from the balloon after three to four months, improving patient experience by innovatively eliminating the need for endoscopic retrieval. It is currently undergoing a pivotal clinical trial in China, with completion targeted for 2027. To execute our global strategy, we are taking steps for international market entry. We have submitted the CE marking application for the DIGB in February 2026. This submission was supported by our existing data including pre-clinical data and FIH study. Subsequently, we will supplement this application with the results from our pivotal clinical trial in China, expected in 2027. This staged approach allows us to optimize the overall regulatory approval timeline.

Product Structure

The DIGB consists of, a capsule shell, a folded balloon pre-loaded inside the capsule shell, a delivery catheter, and an auxiliary guidewire pre-loaded inside the delivery catheter. The balloon features a degradable valve inside, engineered to degrade unaffected by the gastric acid environment, ensuring predictable performance and patient safety. Once deployed and filled with liquid, the valve is designed to disintegrate spontaneously after approximately three to four months. This triggers the automatic release of the fluid and the deflation of the balloon, allowing it to be naturally excreted through the gastrointestinal tract.

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Operation Procedure

The first procedure is delivering a capsule containing the deflated balloon. Once in the stomach, after a brief wait for dissolution of capsule, the balloon is filled with specific volume liquid via the delivery catheter. The delivery catheter is then swiftly withdrawn from the patient’s mouth, detaching from the inflated balloon. The treatment cycle concludes after three to four months when the integrated degradable valve disintegrates, allowing the balloon to empty and be expelled naturally without an endoscopic procedure.

Market Opportunity and Competition

The DIGB targets a vast market of patients seeking effective weight loss who are deterred by the highly invasive procedures of certain traditional therapies. For prevalence of patient with obesity globally and in China, see “— Our Products and Product Pipeline — Our Core Product, the Gastric Bypass Stent System for Obesity — Market Opportunity and Competition.”

The DIGB is designed with advanced polyurethane construction, which enables a thinner wall minimizes mechanical friction against the stomach wall, thereby aiming to reduce irritation and enhance patient tolerance. Meanwhile, the DIGB is designed to differentiate itself from traditional intragastric products by eliminating the need for endoscopic removal, thereby significantly lowering the threshold for treatment access. According to Frost & Sullivan, there were no comparable domestic products approved in China as of the Latest Practicable Date, representing a significant underserved market opportunity.

Summary of Clinical Trial Data

FIH Trial

A pilot study of our DIGB has been conducted at two sites in compliance with applicable regulations in China. The study aimed to provide a preliminary assessment of the efficacy and safety of the device in patients with obesity.

The primary efficacy endpoint was the mean TWL% at week 16. Secondary assessments included proportion of patients achieving $\geq 5\%$ TWL, EWL%, changes in body composition parameters, improvement in obesity-related comorbidities, and recording of device-related adverse events. Key criteria for patient enrollment included: (i) aged 18–65; (ii) BMI ≥ 27.5 kg/m², with or without obesity-related comorbidities; and (iii) history of insufficient weight loss with lifestyle modification or medical treatment. Ten eligible patients provided informed consent were enrolled.

All patients successfully underwent device implantation and received scheduled follow-up. As of the Latest Practicable Date, ten patients have completed follow-up of 16 weeks. These patients achieved TWL% of 10.2%, with 90.0% of patients attaining a clinically significant weight loss response of $\geq 5\%$ TWL. Significant improvements were also observed in secondary body composition parameters, including waist circumference and body fat percentage. The safety profile was favorable. Gastrointestinal symptoms occurring in the initial post-procedure period were managed symptomatically and resolved quickly. No device-related SAEs occurred during the study.

This pilot study provides initial evidence that our degradable intragastric balloon is a potentially effective and safe weight loss therapy for adults with obesity.

Pivotal clinical trial

We have initiated a prospective, multi-center, randomized, controlled pivotal clinical trial in China to evaluate the efficacy and safety of the DIGB for the treatment of obesity. We evaluated designed endpoints

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by comparing test group patients receiving the DIGB plus dietary intervention, against control group patients receiving dietary intervention alone. We used dietary intervention as the control as it is a standard of care for weight loss.

The pivotal trial is designed to take place in 13 centers in China, with a total of 336 enrolled patients. The protocol of the pivotal trial study was design based on the Guideline for Diagnosis and Treatment of Obesity (2024 edition).

Eligible patients should meet the following key inclusion criteria: (i) aged 18–65 years, (ii) diagnosis of obesity with inadequate weight loss response to prior lifestyle interventions, meeting one of the following obesity or overweight: (a) BMI ≥ 32.5 kg/m²; (b) BMI ≥ 27.5 kg/m² with comorbid T2DM; or (c) BMI between 27.5 kg/m² and <32.5 kg/m² with either inadequate response to medical treatment for obesity, or with other obesity-related comorbidities inadequately managed by medical therapy. Eligible patients should voluntarily participate in the trial and provide written informed consent.

The two primary end points at Week 16 include mean TWL%, and proportion of patients achieving $\geq 5\%$ TWL from baseline. Secondary endpoints include device performance evaluation (test group only); mean TWL% and weight loss response rate at Weeks 8, 12, 24, and 40; EWL% at Weeks 8, 12, 16, 24, and 40; change from baseline in BMI, waist circumference, hip circumference, and body fat percentage at the same time points; and changes in obesity-related complications at Weeks 16 and 40, covering blood pressure, including systolic blood pressure and diastolic blood pressure, lipid profiles, including total cholesterol, triglycerides, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol, and glycemic parameters, including HbA1c, fasting plasma glucose, fasting plasma insulin, and fasting C-peptide.

Safety endpoints comprise the incidence of device deficiencies, device-related AEs and SAEs, as well as all other AEs and SAEs occurring during the study. The pivotal clinical trial has initiated patient enrollment, reaching nearly 70% of the targeted size as of the Latest Practicable Date.

Further Development and Commercialization Plan

We are actively advancing the global development and registration of our DIGB to strategically address diverse clinical preferences and market requirements. The DIGB is engineered with a degradable design that allows the balloon to empty and expel naturally without an endoscopic procedure. A pivotal registration clinical trial is currently underway in China. We have initiated patient enrollment, targeting approximately 336 patients across multiple centers. We are actively progressing the trial and aim to complete it in 2027, followed by the submission of a registration application to the NMPA.

We also intend to strategically leverage the clinical data generated in China as the primary evidence to support and accelerate our regulatory submissions in key international markets. We have submitted the CE marking application for the DIGB in February 2026. This submission was supported by our existing data including pre-clinical data and FIH study. Subsequently, we will supplement this application with the results from our pivotal clinical trial in China, expected in 2027. This staged approach allows us to optimize the overall regulatory approval timeline.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR DIGB SUCCESSFULLY

Our Key Product, the Retrievable Intra gastric Balloon

Our RIGB represents an intragastric balloon therapy designed to reduce gastric volume and induce satiety. Distinguished from traditional silicone balloons, the RIGB is constructed using our polyurethane thin-film forming technology. Furthermore, the RIGB features an ergonomic ellipsoid design tailored to fit the natural curvature of the stomach.

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Product Structure

The RIGB is built on the same technological platform as the DIGB, comprising a balloon folded within a capsule, a capsule shell, a delivery catheter, and a pre-loaded auxiliary guidewire. The core distinction is that the RIGB does not feature a degradable valve. Therefore, after the six-month treatment period, the device requires endoscopic retrieval. The removal procedure involves endoscopic puncture and aspiration of the balloon under general anesthesia with endotracheal intubation, followed by extraction of the deflated device.

Operation Procedure

The placement procedure for the RIGB mirrors the DIGB, involving delivering the capsule, subsequent filling via a catheter and separating delivery catheter from the inflated balloon. However, unlike the DIGB, the RIGB requires a specific retrieval procedure upon completion of the six-month treatment period. The removal procedure involves puncturing the balloon under visualization, aspirating the fluid using either our SIC device or needle with an aspiration channel, and then extracting the deflated balloon using grasping forceps.

Market Opportunity and Competition

Our RIGB is designed to align with existing clinical practices while offering a significant technological upgrade. Unlike legacy competitors that often rely on silicone materials, our RIGB utilizes polyurethane thin-film forming technology. This innovation allows us to provide a product that fits seamlessly into established physician workflows overseas, but with superior safety, durability, and patient tolerance. For prevalence of patient with obesity globally and in China, see “ — Our Products and Product Pipeline — Our Core Product, the Gastric Bypass Stent System for Obesity — Market Opportunity and Competition.”

Globally, the market for intragastric devices is currently populated by overseas silicone-based incumbents, including Boston Scientific’s Orbera, which was approved by the FDA in 2015, Spatz FGIA’s Spatz3, which was approved by the FDA in 2021, as well as Medsil and LexBal, both of which CE-marked. While these international products validate the clinical pathway for intragastric therapy, there were no comparable domestic products approved in China as of the Latest Practicable Date, according to Frost & Sullivan. We believe the RIGB’s advanced polyurethane construction positions it as a differentiated, next-generation alternative to these traditional silicone solutions. Specifically, this material enables a thinner wall which, coupled with an optimized oval design that better conforms to the natural gastric cavity, minimizes mechanical friction against the stomach wall, thereby aiming to reduce irritation and enhance patient tolerance.

Further Development and Commercialization Plan

The RIGB serves as a technologically advanced alternative within the established standard-of-care treatment paradigm, specifically tailored for international markets where physicians prefer retrievable devices. We are advancing the regulatory pathway for this product to capture opportunities in these established markets. We plan to submit the CE marking application for the RIGB in the second half of 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR RIGB SUCCESSFULLY

Our Other Product and Product Candidates

We are actively expanding our portfolio to establish a diversified product portfolio for the treatment and management of metabolic diseases. Beyond our Core Product and Key Products our diverse range of

BUSINESS

product and product candidates is designed to provide advanced therapeutic solutions, critical procedural support, and holistic lifecycle management, offering a total solution for metabolic diseases.

Product Candidates for Weight Loss

We offer a diversified portfolio of therapeutic candidates targeting distinct patient populations within the broad spectrum of obesity and metabolic disease.

- ***Endoscopic Suturing System (ESS):*** This system is designed to perform endoscopic sleeve gastropasty, a minimally invasive weight-loss procedure. It enables physicians to place a series of sutures along the greater curvature of the stomach using a gastroscope, effectively reducing gastric volume and capacity to weight loss. Our ESS is specifically engineered to address key challenges in endoscopic suturing. Its design prioritizes excellent device deliverability through the endoscope channel, superior tissue visualization for accurate suture placement, and an intuitive, efficient suture deployment mechanism. These features are expected to reduce the procedural learning curve, minimize operative time of the endoscopic sleeve gastropasty procedure for physicians.
- ***Super Space-occupying Gel Capsule (SOC):*** The SOC represents a novel approach to non-surgical weight loss. It is an ingestible capsule that expands into a biocompatible gel structure within the stomach to induce satiety and reduce food intake, serving as a temporary yet effective intervention for weight loss.

Product Candidates for T2DM

To address the growing demand for effective T2DM treatments, we offer an innovative duodenal mucosal ablation catheter (RAC) therapy for T2DM targets the significant unmet clinical need between pharmacotherapy and invasive surgery. This device is engineered for endoscopic duodenal mucosal resurfacing. Such targeted resurfacing is designed to alter the intestinal lining’s interaction with nutrients, thereby influencing enterohormone secretion, such as GLP-1, and improving metabolic parameters like glycemic control.

Compatible Devices and Accessories

Our Core Product, GBS, is supplied as a comprehensive system that includes both a delivery system and a retrieval system within its original packaging. Therefore, the RTK serves as an optional, specialized retrieval tool that provides physicians with enhanced operational flexibility for GBS and hospitals are not required to purchase additional retrieval devices when using GBS. Furthermore, the GBS procedure can be performed using standard, third-party manufactured video gastrointestinal endoscopes commonly available in hospitals. While our proprietary compatible devices, such as the GA, CA and RTK, are not mandatory for the use of our Core Product, we have, nevertheless, developed these specialized accessories to further optimize the procedural experience and provide a comprehensive portfolio for physicians.

- ***Endoscopic Products and Ancillary Products:*** Our proprietary gastroscope (GA) is a high-definition diagnostic and therapeutic endoscope developed specifically to support our interventional devices. GA features an innovatively extended length designed to facilitate EBMT treatment procedures, providing superior visualization and operational reach for complex interventions. The GA was granted its Class II Medical Device Registration Certificate by the Shanghai NMPA in December 2025. Complementing the GA, we are developing electronic video colonoscope focusing on lower gastrointestinal endoscope (CA), for which we submitted the CE marking application in March 2026 and the NMPA registration application in April 2026. We

BUSINESS

expect to obtain approvals for such applications in the second quarter of 2027 and the fourth quarter of 2026, respectively. We are also developing a digestive endoscopy quality control software (EQS), which applies image recognition technology to assist physicians in improving the quality and completeness of endoscopic procedures. The EQS has completed registration testing, and we plan to submit NMPA registration application for the EQS in the fourth quarter of 2026.

- ***Aspiration/Deflation Catheter (SIC)***: The SIC is a specialized catheter designed to puncture, deflate, and evacuate the fluid from intragastric balloons. The innovative aspect of the SIC lies in its bullet-like ejection mechanism with a spring-loaded, trigger-activated design, which reduces the difficulty of puncturing intragastric balloon products, such as our RIGB, thereby facilitating easier operation for physicians. We have completed registration testing for the SIC as of the Latest Practicable Date. The SIC is planned to submit for both CE marking and NMPA registration in 2026, with approval anticipated in 2027.
- ***Endoscopic Retrieval Kit (RTK)***: The RTK is an upgraded, dedicated retrieval system for our GBS Series products, designed to ensure the safe removal of implants. It features a lubricious coating that facilitates the smooth withdrawal of the entire stent into the retrieval tube, enhancing both procedural ease and safety during retrieval procedure. The RTK was granted Class II Medical Device Registration Certificate by the Zhejiang NMPA in July 2025. We registered the RTK as a separate medical device primarily as a strategic commercial decision to serve as a universal retrieval system for our GBS Series, including our pipeline products, GBS-SH and GBS-DM. These pipeline products will require retrieval systems but are registered separately from GBS. The standalone registration of RTK is not a regulatory requirement imposed by the NMPA and has no impact on the registration and approval status of our Core Product. Currently, the RTK is not sold separately.
- ***Body Composition Analyzer Products***: We are developing an impedance-based body composition analyzer (BCA) and a dual-energy X-ray bone densitometer and body composition analyzer (BCS). Body composition analyzers are bioelectrical devices commonly used in weight management outpatient departments, designed to assist the assessment of patients. They measure key body composition parameters, such as body fat percentage and lean muscle mass, providing clinicians with objective data to support treatment planning and the continuous management of patients’ overall condition. BCA is typically used for preliminary assessment, while BCS assessment is preferred where a more precise evaluation is required, as it can provide relatively more accurate assessment of body composition. The BCA and BCS are currently at design stage.

Comprehensive Lifestyle Management

Extending beyond interventional devices, we offer holistic solutions to support long-term patient outcomes through digital and nutritional interventions.

- ***Obesity Management Software (Dtx)***: Our Dtx is a digital health management platform designed to support weight management. This software enables clinicians to oversee patient weight management progress, serving as a bridge between patients and clinicians to enhance compliance through continuous engagement. Dtx was granted Class II Medical Device Registration Certificate by the NMPA in 2024, marking a significant milestone. Physicians utilize the Dtx software solely to monitor patients’ physiological data inputted by the patients themselves, rather than issuing medical diagnoses or prescriptions. Accordingly, we do not provide medical services or bear medical liability arising from the physicians’ use of the software. Dtx is in a trial operation phase and is provided free of charge to patients who have undergone the GBS procedure, and it currently does not operate on a SaaS subscription model. We did not generate any revenue from Dtx during the Track Record Period. Furthermore, as advised by our PRC Legal Advisors, the operation of the Dtx software does not fall under the restricted or prohibited businesses under applicable PRC laws and regulations.

BUSINESS

- **Clinical Nutrition Food Products (CNT):** Our CNT products are formulated with low-calorie nutrients, essential minerals, high-quality proteins, and dietary fiber. This composition is designed to provide targeted nutritional support as a key dietary intervention in medical weight management programs.

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KEY OPERATING DATA

The table below sets forth key operating data of our Core Product during the Track Record Period:

	For the year ended / As of December 31,		For the six months ended/ As of June 30,	
	2024	2025	2025	2026
Sales volume (set)	1,053	2,650	1,022	1,880
Number of implantation procedures supported	239	2,066	817	1,955
Number of hospitals newly covered ⁽¹⁾	67	287	163	100
Average terminal price (tax inclusive) ⁽²⁾	~36,600	~36,600	~36,600	~36,600

Notes:

- (1) Number of hospitals covered represents the total number of newly added hospitals where our products have successfully completed the hospital admission process and are officially listed as available for clinical procurement and use by physicians as of the end of the periods indicated.
- (2) Average terminal price represents the average price (tax included) at which our products are sold by distributors to the end-customers, which are primarily hospitals.

The significant increases in our sales volume, number of implantation procedures supported, and number of hospitals covered from 2024 to 2025 were primarily driven by our commercialization efforts. During this period, we expanded our distributor network and accelerated the hospital admission processes across various regions. Through our continuous academic promotion and other marketing efforts, the clinical acceptance of our products has significantly improved, evidenced by the exponential growth in the number of implantation procedures from 239 in 2024 to 2,066 in 2025, as well as the increase from 817 in the six months ended June 30, 2025 to 1,955 in the same period of 2026. The variance between our sales volume and the number of implantation procedures in each year during the Track Record Period primarily reflects the initial stage of our commercialization, during which our distributors procured products to establish necessary baseline inventory in anticipation of upcoming hospital admissions and scheduled surgeries. As our commercialization progressed, actual clinical consumption accelerated, leading to a narrower variance in 2025 and the six months ended June 30, 2026.

The price difference between the terminal price and our price to distributors primarily reflects the applicable taxes and the channel margin retained by our distributors to cover their substantial costs incurred. Our average terminal price (tax inclusive) remained relatively stable during the Track Record Period.

BUSINESS

During the Track Record Period, substantially all of our revenue was generated from sales of our Core Product with a minor portion derived from sales of other products such as CNT product, all of which were generated in China. The table below sets forth revenue in absolute amounts and as a percentage of total revenue, gross profit and gross profit margin for the sales of the GBS and other products during the Track Record Period:

	Year ended December 31,				Six months ended June 30,			
	2024		2025		2025		2026	
	RMB	%	RMB	%	RMB	%	RMB	%
(RMB in thousands, except for percentages)								
(unaudited)								
Revenue								
The GBS	12,706	99.9	32,086	99.6	12,326	99.6	23,628	99.7
Others	3	0.1	124	0.4	53	0.4	62	0.3
Total	12,709	100.0	32,210	100.0	12,379	100.0	23,690	100.0
	Gross Profit	Gross Profit Margin	Gross Profit	Gross Profit Margin	Gross Profit	Gross Profit Margin	Gross Profit	Gross Profit Margin
(RMB in thousands, except for percentages)								
(unaudited)								
Gross Profit								
The GBS	10,281	80.9	25,386	79.1	9,606	77.9	20,078	85.0
Others	1	33.3	37	29.8	28	52.8	32	51.6
Total	10,282	80.9	25,423	78.9	9,634	77.8	20,110	84.9

The table below sets forth our revenue in absolute amounts and as a percentage of total revenue by sales channel during the Track Record Period:

	Year ended December 31,				Six months ended June 30,			
	2024		2025		2025		2026	
	RMB	%	RMB	%	RMB	%	RMB	%
(RMB in thousands, except for percentages)								
(unaudited)								
Revenue								
Distributor	12,600	99.1	32,086	99.6	12,326	99.6	23,628	99.7
Direct sales	109	0.9	124	0.4	53	0.4	62	0.3
Total	12,709	100.0	32,210	100.0	12,379	100.0	23,690	100.0

During the Track Record Period, the vast majority of our revenue was derived from sales to our distributors, with only a minimal portion generated from direct sales.

BUSINESS

The table below sets forth our revenue from sales of the GBS by geographical region during the Track Record Period:

	Year ended December 31,		Six months ended June 30,	
	2024	2025	2025	2026
<i>(RMB in thousands)</i>				
<i>(unaudited)</i>				
Revenue				
North China ⁽¹⁾	2,097	6,162	3,226	5,671
East China ⁽²⁾	5,346	13,212	3,741	10,951
South China ⁽³⁾	1,673	3,450	1,525	2,612
Southwestern China ⁽⁴⁾	3,590	9,263	3,834	4,394
Total	12,706	32,086	12,326	23,628

Notes:

- (1) North China includes Beijing, Gansu, Hebei, Heilongjiang, Jilin, Liaoning, Inner Mongolia, Ningxia, Qinghai, Shaanxi, Tianjin and Xinjiang.
- (2) East China includes Anhui, Fujian, Jiangsu, Shandong, Shanghai and Zhejiang.
- (3) South China includes Guangdong, Guangxi, Hainan, Hubei, Hunan and Jiangxi.
- (4) Southwestern China includes Guizhou, Henan, Shanxi, Sichuan, Tibet, Yunnan and Chongqing.

OUR TECHNOLOGY PLATFORMS

We have established five integrated, proprietary technology platforms that underpin our R&D, production, and quality control capabilities. These platforms are strategically structured around the critical functional components of our Core Product and pipeline products and product candidates, encompassing medical stent engineering, advanced film forming, polymer modification, and sophisticated delivery and retrieval systems, all supported by a dedicated quality assurance framework. While each product is uniquely designed, these interconnected platforms maximize efficiency and accelerate innovation by leveraging shared core technologies and standardized processes.

We believe these platforms constitute a significant and sustainable competitive advantage. Continuous technical iteration and clinical insights, gained through both R&D and commercial-scale production, enable us to systematically optimize product performance and production processes. This synergistic approach ensures the efficient development of our pipeline and guarantees a seamless transition from prototype to commercial production, all within our stringent quality management system. As of the Latest Practicable Date, we owned 111 granted patents and 109 patent applications in relation to our technology platforms.

Advanced Medical Stent Technology Platform

This platform specializes in the R&D and precision production of high-quality medical stents. It synergizes our progress in material science, specifically room-temperature nitinol joining, ultra-low phase transition temperature forming, and advanced corrosion resistance treatments. By leveraging these distinct technical capabilities, we ensure our stents achieve accuracy, enhanced biocompatibility, and stable mechanical performance, meeting the demands of complex clinical applications.

This platform is primarily dedicated to the design, development, and production of our stent-based products, such as GBS Series. To support these operations, the platform utilizes a suite of specialized machinery and equipment, including circulating heat dissipation cooling systems, and micro-beam precision plasma welding machine.

BUSINESS

Advanced Film Forming Technology Platform

This platform is dedicated to the comprehensive research, development, and scalable production of advanced thin-film materials and film processing. It is distinguished by a suite of technologies, including large-diameter fluoropolymer or polyethylene-based polymer thin-walled soft sleeve forming, high gas-barrier ultra-thin polyurethane forming, continuous film forming, and specialized silicone film anti-adhesion solutions. By mastering these complex processes, we are able to transcend critical material limitations, enhancing the functional reliability and longevity of our medical devices.

This platform is primarily dedicated to the design, development, and produce of stent sleeves and critical components, including the sleeves for our GBS Series products and candidates and our DIGB and RIGB candidates. To support these operations, the platform utilizes a suite of specialized machinery and equipment, such as three-layer co-extrusion casting machines.

Polymer Modification and Processing Platform

This platform centers on the advanced engineering of polymers via physical and chemical modification, high-precision cross-linking, and surface treatment. Through these techniques, we can improve the functional characteristics of base polymer materials, in terms of, among others, friction, strength, and pushability. These modifications are essential for elevating the overall clinical performance and handling of our devices.

This platform is primarily dedicated to the design, development, and production of our products and key components, including the various bonding connectors for our GBS Series and the molding components for our DIGB and RIGB candidates. Key machinery and equipment utilized in this platform include activation instruments, high-frequency welding machines, and laminating machines.

Delivery and Retrieval Technology Development and Production Platform

This platform focuses on the R&D of sophisticated systems for device delivery and retrieval. It possesses core technologies including distal precise release, high-precision synchronous control, and non-destructive retrieval. A critical capability of this platform is high-precision synchronous control technology, which translates a physician’s external manipulation into complex, synchronized movements at the device’s distal end, representing one of the most advanced and complex technologies in our portfolio.

This platform is primarily utilized for the design, development, and production of our delivery and retrieval systems, specifically those for the GBS Series, as well as the ESS, RTK and RAC. To enable these complex functions, the platform employs a suite of specialized machinery and testing equipment.

Product Quality and Assurance Platform

Established to safeguard our innovative products, this dedicated platform ensures safety and reliability standards throughout the entire product lifecycle. We believe that the technical upgrades and clinical insights accumulated through our continuous R&D efforts, combined with the scale-up of our commercialized products, enable us to constantly optimize product performance and production processes. This virtuous cycle allows us to efficiently develop new product candidates to expand our portfolio. Furthermore, our technology platforms facilitate seamless synergy across R&D, pilot testing, and mass production, ensuring that our pipeline candidates transition smoothly from design to commercial production in full compliance with our quality management system.

BUSINESS

Leveraging these technology platforms, we have successfully developed a diverse portfolio of product candidates, including our Core Product and multiple first-in-China innovations. We are committed to continuous investment in R&D equipment and capacity expansion for each platform to further deepen our technical expertise and production capabilities, thereby supporting our long-term roadmap and meeting growing market demand.

RESEARCH AND DEVELOPMENT

Our R&D capabilities are anchored in our five core technology platforms, which drive ongoing initiatives focused on delivering clinically advanced products, enhancing the efficacy and safety of our existing portfolio, and expanding therapeutic applications. Since the NMPA registration approval of our GBS in January 2024, we have committed to its continual research and development, including follow-up studies based on real-world data for product optimization, as well as carrying out pivotal clinical studies for the GBS-Low BMI and introducing new specifications. Building upon this product’s development foundation, we also maintain a deep pipeline of candidates. This includes product candidates based on the same platform like the GBS-SH for MASH complicated with obesity, and the GBS-DM for T2DM complicated with obesity, as well as novel platforms such as the DIGB and the SOC.

We incurred research and development expenses of RMB41.1 million, RMB48.7 million, RMB22.0 million and RMB38.7 million for the years ended December 31, 2024 and 2025 and the six months ended June 30, 2025 and 2026, respectively. During the same periods, our research and development expenses incurred for our Core Product were RMB10.7 million, RMB19.3 million, RMB7.5 million and RMB11.4 million, respectively, accounting for 25.9%, 39.7%, 34.0% and 29.6% of our total research and development expenses for the corresponding periods.

Our In-House R&D Team

As of June 30, 2026, our in-house R&D team consisted of 56 members, 25 of whom had a master’s degree or above. Organized with dedicated process product design, and quality design functions, the team is highly experienced, with the majority of members possessing over five years of industry expertise. Our R&D team is led by our Technical Director, Dr. Li Wenyu, who has overseen our R&D efforts since June 2019. See “Directors and Senior Management — Senior Management” for his biography.

The team’s primary responsibilities encompass the full product development lifecycle, including initial concept generation, design planning and input, design realization and output, and design verification. Furthermore, our R&D personnel provide essential technical support for subsequent stages, including clinical trials, regulatory registration, and quality management. All key R&D personnel involved in developing our Core Product, including Dr. Li Wenyu, remained with us as of the Latest Practicable Date. The table below outlines the primary R&D and clinical personnel responsible for our Core Product:

Core Product R&D and Clinical Affairs	Personnel (Current Position with our Company)
Pre-clinical Development	Mr. Zuo Yuxing (Chairman and Founder) Dr. Li Wenyu (Technical Director)
Clinical Trial & Registration	Mr. Zhong Gaofeng (Director of Clinical and Registration Affairs)

Our R&D capabilities in China are reflected by our strong intellectual property portfolio. As of the Latest Practicable Date, we owned an aggregate of 220 granted patents and patent applications which consisted of 88 granted patents and 66 patent applications in China and 23 granted patents and 43 patent applications overseas. 104 of the granted patents and patent applications as of the Latest Practicable Date were related to our Core Product. We also owned six registered software copyrights in China as of the same date.

BUSINESS

We have entered into legally-binding confidentiality and non-compete agreements with our R&D team members. Pursuant to these agreements, any intellectual property conceived and developed during their employment belongs to us.

Product Design and Pre-Clinical Development

We have established and strictly follow an internal protocol that governs the design and development of our products, compliant with ISO-13485 standards. Our product design and development processes are summarized as below:

- *Design & Development Planning and Inputs:* We initiate the process by defining design inputs based on a comprehensive analysis of user needs, intended use, regulatory requirements, and risk management. These inputs establish clear, verifiable specifications for the product’s functional performance, safety, usability, and reliability.
- *Design and Development Outputs:* Our R&D team translates the approved design inputs into prototypes, detailed design specifications, and production procedures. Outputs are documented to enable verification and include product drawings, component specifications, and initial risk management files. A formal design review is conducted to assess outputs against inputs at this stage.
- *Design and Development Verification:* We perform systematic verification activities to objectively confirm through testing and analysis that the design outputs meet all specified design input requirements. This includes biocompatibility testing, mechanical/functional bench testing, and animal studies to validate safety, performance, and reliability before finalizing specifications for production.

To efficiently and safely evaluate our products and candidates, we conduct systematic preclinical animal studies prior to clinical trials. Working with qualified third-party institutions, we follow a structured, protocol-driven process: we first develop detailed study protocols defining objectives and specifications; these are then reviewed by the testing partner for feasibility and cost estimation. The partner institution is responsible for animal preparation, surgical execution, and postoperative monitoring. We believe this approach allows us to identify potential risks early and iteratively refine product design. Findings from these studies directly inform final design validation or trigger targeted enhancements to safety and efficacy profiles before advancing to human trials.

Clinical Trials

Our clinical and registration affairs team is led by Mr. Zhong Gaofeng. The team is structured into a clinical group and a registration group.

Our team is responsible for reviewing our clinical trial protocols to ensure compliance with NMPA guidelines and GCP standards. They manage all aspects of our clinical trials, including site selection, protocol execution, and data monitoring, and handle all communications and submissions with regulatory bodies. We conduct clinical trials primarily to secure regulatory approvals by demonstrating the safety and efficacy of our new products. Beyond this essential objective, solid clinical evidence serves to validate our innovations, enhance our brand credibility, and support market adoption.

Our dedicated regulatory affairs team are mainly in charge of regulatory approval, submitting clinical study reports together with other documents to the relevant authorities. Our clinical data and practices are designed to meet the standards of applicable regulations.

BUSINESS

Collaboration with Clinical Trial Institutions

We select clinical trial institutions from the NMPA’s catalog of approved GCP-compliant hospitals. The major factors we consider include their academic credentials and expertise, particularly the PIs, available patient volume, and their enthusiasm for innovative therapies.

We prepare a detailed clinical trial protocol that is submitted to each institution’s ethics committee (EC) for review and approval. Once approved, we enter into a clinical trial agreement with each institution. Pursuant to these agreements, the institution is obligated to conduct the trial strictly in accordance with the protocol, collect data, and issue case reports. We own all related intellectual property and results from the trial. We collaborate with leading clinical trial institutions for our product candidates.

Relationships with CROs and SMOs

We engage industry-leading contract research organizations (CROs) and site management organizations (SMOs) to manage, conduct, and support our clinical trials, including the pivotal trials for our GBS and DIGB.

We select our CROs and SMOs partners based on their qualifications, reputation, and specific experience with similar implantable devices and NMPA audits. Our CROs and SMOs are responsible for managing and monitoring trial implementation, and collecting data. We actively monitor our CROs and SMOs to ensure they perform their duties in line with our protocols and GCP standards. This includes holding weekly project meetings, conducting our own random on-site spot-checks, and retaining the right to replace personnel who do not meet our quality standards.

Relationships with CDMOs and Third-Party Service Providers

While we maintain a strategic focus on conducting the core production processes of our products in-house to safeguard our intellectual property and ensure stringent quality control, we engage specialized third-party service providers and contract manufacturers for specific production stages. Our collaboration with these external partners is primarily focused on non-core production steps where leveraging external expertise enhances efficiency. Specifically, we outsource the machining of certain molded components, such as handles and plastic parts, which are produced based on our proprietary technical drawings and designs. Additionally, we entrust the final ethylene oxide sterilization process to qualified third-party service providers.

To maintain the high standards of our final products, we implement a stringent selection and management process for these partners. We carefully select service providers based on their industry qualifications, production capacity, and strict compliance with GMP and ISO standards. We enforce stringent quality control measures over these outsourced processes; for instance, all externally machined components and sterilized products must undergo comprehensive incoming inspections and review of production records upon delivery to our warehouse before they can be released for final assembly or sale.

Relationships with PIs and KOLs

We believe that the quality, credibility, and academic value of our clinical trials depend significantly on the leadership and expertise of our PIs. We have established strong collaborative relationships with renowned experts in the fields of gastroenterology, digestive endoscopy, and metabolic surgery to lead our clinical studies. Our PIs bear the responsibility of supervising the clinical trials at their respective centers, ensuring that all study activities are conducted in strict adherence to the protocol and GCP guidelines, and safeguarding the safety and well-being of patients. They also provide critical academic input and feedback during the trial design phase, helping to optimize our clinical strategies.

BUSINESS

We select our PIs based on a comprehensive set of criteria, including their academic standing in the industry, their clinical experience with endoscopic interventions, and their ability to manage complex clinical trials. We designed and managed our clinical trials for the GBS, engaging distinguished KOLs in China, including senior executives and department heads from premier Grade IIIA hospitals specializing in digestive diseases. Furthermore, we collaborate with leading specialists from prominent medical institutions in our research initiatives on GBS-SH. These collaborations not only ensure the high quality of our clinical data but also facilitate the broader academic acceptance of our innovative therapies.

INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights are important to our business. We develop and use a number of patents, copyrights and other intellectual properties during our ordinary course of business.

As of the Latest Practicable Date, we owned an aggregate of 220 granted patents and patent applications which consisted of 88 granted patents and 66 patent applications in China and 23 granted patents and 43 patent applications overseas. 104 of the granted patents and patent applications as of the Latest Practicable Date were related to our Core Product. We also owned 100 registered trademarks and six registered software copyrights in China, as well as 17 registered trademarks overseas as of the same date.

The following table sets forth an overview of our material granted patents and pending patent applications in connection with our Core Product, the GBS, as of the Latest Practicable Date:

Product	Patent Name	Patent/ Application number	Patent Type	Holder	Jurisdiction	Patent Status	Date of Application	Date of Expiration
GBS	Gastric diverter and antibacterial digestive tract catheter thereof	ZL201710499034.3	Invention	Our Company	China	Granted	2017-06-27	2037-06-27
		EP3646827	Invention	Our Company	Europe	Granted	2017-10-13	2037-10-13
		IN478213	Invention	Our Company	India	Granted	2017-10-13	2037-10-13
		AU2017420550	Invention	Our Company	Australia	Granted	2017-10-13	2037-10-13
		JP6913825	Invention	Our Company	Japan	Granted	2017-10-13	2037-10-13
		RU2745080	Invention	Our Company	Russia	Granted	2017-10-13	2037-10-13
GBS	Duodenum built-in jejunum cannula releasing system and a use method therefor	ZL201810415050.4	Invention	Our Company	China	Granted	2018-05-03	2038-05-03
		US12303466B2	Invention	Our Company	United States	Granted	2019-04-30	2042-11-01
		EP3789003	Invention	Our Company	Europe	Granted	2019-04-30	2039-04-30
		IN507039	Invention	Our Company	India	Granted	2019-04-30	2039-04-30
		CA3094114	Invention	Our Company	Canada	Granted	2019-04-30	2039-04-30
		RU2759594	Invention	Our Company	Russia	Granted	2019-04-30	2039-04-30
		MX422441	Invention	Our Company	Mexico	Granted	2019-04-30	2039-04-30
GBS	Gastric diverter and release method thereof	BR112020019784-0	Invention	Our Company	Brazil	Granted	2019-04-30	2039-04-30
		ZL201810336514.2	Invention	Our Company	China	Granted	2018-04-12	2038-04-12
GBS	Gastric diverter and digestive tract stent thereof	ZL201810326731.3	Invention	Our Company	China	Granted	2018-04-12	2038-04-12
GBS	Gastric diverter and digestive tract support and release method thereof	US11517461B2	Invention	Our Company	United States	Granted	2018-10-24	2039-03-21
		EP3777784	Invention	Our Company	Europe	Granted	2018-10-24	2038-10-24
GBS	Intestinal barrier sleeve release system	ZL201710293809.1	Invention	Our Company	China	Granted	2017-04-28	2037-04-28
		US11622875B2	Invention	Our Company	United States	Granted	2017-06-28	2038-10-29
		EP3560463	Invention	Our Company	Europe	Granted	2017-06-28	2037-06-28
		IN485512	Invention	Our Company	India	Granted	2017-06-28	2037-06-28
		AU2017412054	Invention	Our Company	Australia	Granted	2017-06-28	2037-06-28
		JP6840270	Invention	Our Company	Japan	Granted	2017-06-28	2037-06-28
		RU2722311	Invention	Our Company	Russia	Granted	2017-06-28	2037-06-28

BUSINESS

Product	Patent Name	Patent/ Application number	Patent Type	Holder	Jurisdiction	Patent Status	Date of Application	Date of Expiration
GBS	Extendable digestive tract cannula and use thereof	ZL202311159684.5	Invention	Our Company	China	Granted	2023-09-08	2043-09-08
		US19/514787	Invention	Our Company	United States	Pending	2024-04-12	N/A
		JP2026513949	Invention	Our Company	Japan	Pending	2024-04-12	N/A
		EP24861493.5	Invention	Our Company	Europe	Pending	2024-04-12	N/A
		KR1020267007507	Invention	Our Company	South Korea	Pending	2024-04-12	N/A
GBS	Digestive tract stent recovery device and endoscope cannula	TW1928771B	Invention	Our Company	Taiwan Region	Granted	2025-05-15	2045-05-14
		CN202410618308.6	Invention	Our Company	China	Pending	2024-05-17	N/A
		PCT/CN2024/097364	Invention	Our Company	WIPO (PCT)	Pending	2024-06-04	N/A
		EP24938359.7	Invention	Our Company	Europe	Pending	2024-06-04	N/A
		US19/528937	Invention	Our Company	United States	Pending	2024-06-04	N/A
GBS	Release ball inner core for distal release of digestive tract cannula and preparation method and application thereof	CN202311152577.X	Invention	Our Company	China	Pending	2023-09-07	N/A
		US19/514389	Invention	Our Company	United States	Pending	2024-03-20	N/A
		JP2026513734	Invention	Our Company	Japan	Pending	2024-03-20	N/A
		CA3303552	Invention	Our Company	Canada	Pending	2024-03-20	N/A
		EP24861465.3	Invention	Our Company	Europe	Pending	2024-03-20	N/A
		KR1020267006672	Invention	Our Company	South Korea	Pending	2024-03-20	N/A
GBS	Graded detachable digestive tract implant cannula and digestive tract implant kit	CN202410126018.X	Invention	Our Company	China	Pending	2024-01-29	N/A
		PCT/CN2024/083188	Invention	Our Company	WIPO (PCT)	Pending	2024-03-22	N/A
		EP24921153.3	Invention	Our Company	Europe	Pending	2024-03-22	N/A
		US19/528950	Invention	Our Company	United States	Pending	2024-03-22	N/A
GBS	Automatic fracture type digestive tract cannula and kit	CN202410125123.1	Invention	Our Company	China	Pending	2024-01-29	N/A
		PCT/CN2024/082937	Invention	Our Company	WIPO (PCT)	Pending	2024-03-21	N/A
		EP24921152.5	Invention	Our Company	Europe	Pending	2024-03-21	N/A
		US19/528561	Invention	Our Company	United States	Pending	2024-03-21	N/A

As of the Latest Practicable Date, all of our material patents and patent applications, including those related to our Core Product, were independently invented and developed by our employees during the normal course of their employment with us. These inventions are deemed as service inventions and the intellectual property rights associated with these patents and patent applications are fully, validly and legally controlled by us. None of these material patents or patent applications involves any co-development with or contributions from external consultants, hospitals, universities, or other third parties, and we have not experienced any material disputes, claims, or litigation regarding the inventorship or ownership of our intellectual properties.

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 or region and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued 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 owned patents, or any such granted patents that may be issued in the future will be commercially useful in protecting our product candidates and the methods of manufacturing the same.

We may rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our product candidates. We seek to protect our proprietary products and product candidates, in part, by entering into confidentiality agreements with scientific partners and contractors, and including invention assignment clauses in agreements with our employees. We have included confidentiality covenants in employment agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard

BUSINESS

employment contract, which we use to employ each of our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee’s work.

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 secret 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 physical security of our premises and 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.

Based on the freedom-to-operate (FTO) analysis conducted covering China and Europe of our Core Product, the GBS, we were not aware of any granted patents that may materially affect our rights to conduct R&D or commercialization of the GBS in these jurisdictions as of the Latest Practicable Date. FTO analysis is a patent investigation, based on a search of patent databases, that is commonly used to determine whether any existing patents cover a company’s product, and to assess whether making, using, offering to sell, or selling the product would infringe any existing patents. However, we cannot provide any assurance that all relevant third-party patents were identified or that conflicting patents will not be issued in the future. See “Risk Factors — Risks Relating to Our Intellectual Property Rights.”

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement, misappropriation or other violations of third-party intellectual property and we are not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on its R&D for any product or product candidate in which we may be a claimant or a respondent. See “Appendix IV — B. Further Information about Our Business — 2. Intellectual Property Rights — Patents.”

BUSINESS

OUR CUSTOMERS

Our Major Customers

Our major customers mainly comprise our distributors during the Track Record Period. For salient terms of contracts with our distributors, see “— Sales, Distribution and Marketing — Sales to Distributors.” Revenue generated from our largest customer in the year ended December 31, 2024 and 2025 and the six months ended June 30, 2026, accounted for 19.6%, 17.8% and 22.4% of our revenue, respectively. Revenue generated from our five largest customers in the year ended December 31, 2024 and 2025 and the six months ended June 30, 2026, accounted for 60.8%, 56.2% and 44.8% of our revenue, respectively. We generally require payment in advance before delivery, and credit terms are granted only in exceptional circumstances. The table below sets out certain details of our five largest customers for the periods indicated:

Six months ended June 30, 2026

Rank	Customer	Background	Major products sold	Approximate transaction amount (RMB'000)	Percentage of total revenue (%)	Year of commencement of business relationship with us
1.	Customer A*	Customer A comprises two entities controlled by the same beneficial owner. The two entities are both limited liability companies registered in Shandong Province, specializing in distribution and sales of medical devices.	The GBS	5,310	22.4	2024
2.	Customer G	A limited liability company registered in Gansu Province, primarily engaged in the sales of medical devices and medical technology services.	The GBS	1,659	7.0	2025
3.	Customer H	A joint stock company registered in Chongqing, primarily engaged in the wholesale and distribution of pharmaceuticals and medical devices.	The GBS	1,327	5.6	2026
4.	Customer B	A limited liability company registered in Jiangsu Province, primarily engaged in the wholesale of medical devices.	The GBS	1,195	5.0	2024
5.	Customer I	A limited liability company registered in Shanghai, primarily engaged in the sales of medical devices and disinfection equipment.	The GBS	1,128	4.8	2024
Total				10,619	44.8	

BUSINESS

Year ended December 31, 2025

Rank	Customer	Background	Major products sold	Approximate transaction amount (RMB'000)	Percentage of total revenue (%)	Year of commencement of business relationship with us
1.	Customer C	A limited liability company registered in Shanghai, primarily engaged in the distribution of medical devices and the sale of disinfection equipment.	The GBS	5,732	17.8	2024
2.	Customer A*	Customer A comprises two entities controlled by the same beneficial owner. The two entities are both limited liability companies registered in Shandong Province, specializing in distribution and sales of medical devices.	The GBS	5,162	15.9	2024
3.	Customer B	A limited liability company registered in Jiangsu Province, primarily engaged in the wholesale of medical devices.	The GBS	3,858	12.0	2024
4.	Customer E	A limited liability company registered in Hunan Province, primarily engaged in the distribution of medical devices and pharmaceuticals.	The GBS	1,724	5.4	2024
5.	Customer D	A limited liability company registered in Yunnan Province, primarily engaged in the wholesale of medical devices.	The GBS	1,633	5.1	2024
Total				18,109	56.2	

BUSINESS

Year ended December 31, 2024

Rank	Customer	Background	Major products sold	Approximate transaction amount (RMB'000)	Percentage of total revenue (%)	Year of commencement of business relationship with us
1.	Customer B	A limited liability company registered in Jiangsu Province, primarily engaged in the wholesale of medical devices.	The GBS	2,496	19.6	2024
2.	Customer C	A limited liability company registered in Shanghai, primarily engaged in the distribution of medical devices and the sale of disinfection equipment.	The GBS	1,904	15.0	2024
3.	Customer A*	Customer A comprises two entities controlled by the same beneficial owner. The two entities are both limited liability companies registered in Shandong Province, specializing in distribution and sales of medical devices.	The GBS	1,858	14.6	2024
4.	Customer F	A limited liability company registered in Beijing, primarily engaged in the distribution of medical devices.	The GBS	743	5.9	2024
5.	Customer D	A limited liability company registered in Yunnan Province, primarily engaged in the wholesale of medical devices.	The GBS	730	5.7	2024
Total				<u>7,731</u>	<u>60.8</u>	

* Calculated on a consolidated basis.

To the best of our knowledge, during the Track Record Period and up to the Latest Practicable Date, all of our five largest customers in each year or period during the Track Record Period were Independent Third Parties. As of the Latest Practicable Date, none of our Directors, their associates or any of our shareholders (who or which to the knowledge of the Directors owned more than 5% of our issued share capital) had any interest in any of our five largest customers in each year or period during the Track Record Period.

OUR SUPPLIERS

Our Major Suppliers

Our major suppliers comprise CRO services provider, and provider of labor outsourcing and travel management and booking services. Purchase costs from our largest supplier in the year ended December 31, 2024 and 2025 and the six months ended June 30, 2026, accounted for 5.0%, 6.3% and 11.7% of our total purchases, respectively. Purchase costs from our five largest suppliers in the year ended December 31, 2024

BUSINESS

and 2025 and the six months ended June 30, 2026, accounted for 16.2%, 22.0% and 33.5% of our total purchases, respectively. The table below sets out certain details of our five largest suppliers for the periods indicated:

Six months ended June 30, 2026

Rank	Supplier	Background	Major products/ services purchased	Approximate transaction amount (RMB'000)	Percentage of total purchases (%)	Year of commencement of business relationship with us	Typical credit term
1.	Supplier C	A limited liability company registered in Beijing, specializing in medical device registration consulting and clinical trial services.	CRO services	4,749	11.7	2019	Within 10 working days after completion of each milestone
2.	Supplier B*	Comprises entities controlled by the same group, primarily engaged in human resources management and enterprise services.	Human resources and labor outsourcing services	3,976	9.8	2024	No typical credit term
3.	Supplier J	A limited liability company registered in Sichuan Province, primarily engaged in technology development and consulting services.	Financial advisory services for equity financing	1,782	4.4	2026	30 business days after receipt of financing proceeds
4.	Supplier K*	Comprises two entities controlled by the same beneficial owner. The two entities are both limited liability companies registered in Beijing, primarily engaged in travel services and internet ride-hailing platform operations.	Travel management and booking services	1,736	4.3	2025	No typical credit term
5.	Supplier L	A limited liability company registered in Zhejiang Province, primarily engaged in biomedical technology development, technical consulting services and the sales of medical devices.	Technical and project development services	1,340	3.3	2025	Payable upon achievement of each milestone
Total				13,583	33.5		

BUSINESS

Year ended December 31, 2025

Rank	Supplier	Background	Major products/ services purchased	Approximate transaction amount (RMB'000)	Percentage of total purchases (%)	Year of commencement of business relationship with us	Typical credit term
1.	Supplier B*	Comprises entities controlled by the same group, primarily engaged in human resources management and enterprise services.	Human resources and labor outsourcing services	3,216	6.3	2024	No typical credit term
2.	Supplier C	A limited liability company registered in Beijing, specializing in medical device registration consulting and clinical trial services.	CRO services	2,981	5.8	2019	10 business days upon achieving payment milestone
3.	Supplier A	A limited liability company registered in Zhejiang Province, primarily engaged in technology and corporate advisory services.	Financial advisory services for equity financing	2,400	4.7	2024	30 business days upon receipt of financing proceeds
4.	Supplier D	A limited liability company registered in Zhejiang Province, primarily engaged in travel and tourism services, and travel information consultation.	Travel management and booking services	1,457	2.8	2018	No typical credit term
5.	Supplier I	A limited liability company registered in Beijing, specializing in intellectual property agency and consulting services.	Intellectual property services	1,255	2.4	2019	No typical credit term
Total				11,309	22.0		

BUSINESS

Year ended December 31, 2024

Rank	Supplier	Background	Major products/ services purchased	Approximate transaction amount (RMB'000)	Percentage of total purchases (%)	Year of commencement of business relationship with us	Typical credit term
1.	Supplier D	A limited liability company registered in Zhejiang Province, primarily engaged in travel and tourism services, and travel information consultation.	Travel management and booking services	<u>1,581</u>	<u>5.0</u>	<u>2018</u>	No typical credit term
2.	Supplier F	A Grade A tertiary hospital located in Guangdong Province.	Clinical trial center services	1,094	3.5	2023	No typical credit term
3.	Supplier E	A limited liability company registered in Zhejiang Province, primarily engaged in property management.	Property management	884	2.8	2017	No typical credit term
4.	Supplier G	A limited liability company registered in Beijing, specializing in medical device registration consulting and clinical trial services.	CRO services	800	2.5	2022	Five days upon achieving payment milestone
5.	Supplier H	A limited liability company registered in Shenzhen, specializing in the research, development, and production of electronic endoscope products.	Endoscope parts	752	2.4	2023	One month
Total				<u>5,111</u>	<u>16.2</u>		

Note: The calculation of percentage of total purchase amounts disclosed above exclude purchase amounts incurred in connection with the [REDACTED].

* Calculated on a consolidated basis.

When we procure laboratory instruments and consumables using our standard contract template, we place specific orders on an as-needed basis specifying the quantity and delivery timeline. We typically settle payments on a monthly basis. Suppliers are required to warrant that the products meet original factory standards and our quality requirements, subject to our quality control inspection.

To the best of our knowledge, during the Track Record Period and up to the Latest Practicable Date, all of our five largest suppliers in each year or period during the Track Record Period were Independent Third Parties. As of the Latest Practicable Date, none of our Directors, their associates or any of our shareholders (who or which to the knowledge of the Directors owned more than 5% of our issued share capital) had any interest in any of our five largest suppliers in each year or period during the Track Record Period.

BUSINESS

Raw Materials and Procurement

Our principal raw materials primarily consist of nickel-titanium wires, metal and polymer components, electronic modules and packaging materials. We generally procure raw materials only from suppliers on our qualified supplier list. For R&D purposes, we prioritize qualified suppliers or validate new ones through stringent quality confirmations. For mass production, we implement a demand-driven procurement policy and formulate procurement plans based on rolling sales forecasts, maintaining a safety stock to ensure production continuity. We utilize an ERP system to manage the entire procurement life cycle.

We select suppliers based on stringent criteria, including qualification audits and sample and batch validations, especially for critical raw materials. We conduct annual reviews of our qualified suppliers and have established stable relationships with our key suppliers, many of whom have collaborated with us since 2018. Upon delivery, materials undergo strict quality control sampling and verification.

During the Track Record Period, we procured a vast majority of our raw materials from domestic suppliers in China. We did not experience any material difficulties, shortages, or interruptions in procuring raw materials during the Track Record Period and up to the Latest Practicable Date.

SALES, DISTRIBUTION AND MARKETING

Our Sales Network

Our commercial infrastructure consists of an internal sales and marketing team and a network of distributors. As of June 30, 2026, our internal sales and marketing team is comprised of 27 professionals. Our sales network is structured geographically into four major regions: north China, south China, east China, and west China. Our regional sales leaders possess extensive industry experience in China’s high-value medical devices market, which we believe is critical for penetrating new markets and driving academic adoption. This sales team is supported by a centralized marketing team, responsible for academic promotion and market access, and a commercial team responsible for channel management, distributor contracting, and logistics.

Our Marketing Strategies

As our GBS is an innovative medical device, our marketing strategy is in strict compliance of the relevant laws and regulations and is heavily focused on academic promotion and physician education to build awareness and establish it as a standard of care. Our key marketing activities include: (i) academic conference participation, we actively participate in major national academic conferences across multiple relevant disciplines, including bariatric surgery, gastroenterology and digestion, and endocrinology, to present our clinical data and demonstrate our product’s efficacy and safety to KOLs; (ii) systematic physician training, we have established a multi-level physician training program that includes foundational training at our animal lab in Hangzhou, where physicians are required to successfully perform multiple placements and retrievals on animal models to receive certification, and advanced training courses conducted at a renowned digestive disease specialty clinical institution in Beijing; (iii) holistic therapy promotion, we conduct integrated management training to educate physicians on the critical pre-operative and post-operative management, in addition to the procedure itself; (iv) brand building, we engage in public relations and media outreach to build our brand, and we have received coverage from major media outlets, highlighting our status as a domestic developer.

BUSINESS

Sales to Distributors

We adopted a distributorship model to commercialize our products, which enables us to efficiently deepen our market penetration leveraging the resources of our distributors in a cost-effective manner. In the year ended December 31, 2024 and 2025 and the six months ended June 30, 2025 and 2026, we derived 99.1%, 99.6%, 99.6% and 99.7% of our revenue through a distributorship model, respectively. The table below sets forth number of distributors and movement analysis as of the periods indicated:

	Year ended December 31,		Six months ended June 30,	
	2024	2025	2025	2026
Number of distributors at the beginning of the period	—	44	44	70
Number of new distributors for the period	44	50	24	34
Number of terminated distributors for the period	—	(24)	(5)	(17)
Net increase in the number of distributors for the period	44	26	19	17
Number of distributors at the end of the period	44	70	63	87

Our distributors are legally established companies holding requisite medical device operation qualifications, primarily serving public hospitals and other medical institutions. Typically, our distributors cover major regional territories and they are entitled to engage sub-distributors to distribute our products, leveraging their localized capabilities and resources, ensuring efficient coverage in broad areas. As of the Latest Practicable Date, our distributors had engaged an aggregate of 91 sub-distributors with ongoing business relationships.

In 2024 and 2025 and the six months ended June 30, 2025 and 2026, we established relationships with 44, 50, 24 and 34 new distributors, respectively. The additions were primarily driven by our continuous efforts to commercialize our Core Product following its initial market launch in 2024, which required us to actively expand our distribution network to broaden our market coverage and accelerate hospital penetration. In 2024, 2025 and the six months ended June 30, 2025 and 2026, we terminated cooperation with nil, 24, five and 17 distributors, respectively, primarily taking into account their performances, specifically because they either failed to develop and gain admission to target hospitals according to the agreed-upon plans, or failed to meet their minimum sales targets.

Selection and Management

We select distributors based on their regional network, hospital coverage, and existing experience with our target hospital departments, such as gastroenterology, bariatric surgery, and endocrinology.

We maintain a buyer-seller relationship with our distributors. We actively manage our distributor network, as well as their inventory levels. Distributors place orders based on terminal hospital procurement plans, budget execution progress, and reasonable safety stocking needs. Pursuant to our framework agreements, distributors are required to provide monthly inventory reports upon our request and we retain the right to conduct on-site inventory inspections.

To effectively mitigate channel stuffing risks, we have implemented distributor management policies, including: (i) requiring full payment before delivery; (ii) only allowing product returns in the event of product quality defects; (iii) periodically monitoring our distributors’ inventory levels to ensure they maintain a reasonable stock level commensurate with their sales capabilities; and (iv) requiring distributors to provide sales materials on a monthly basis, such as invoices and distribution records, enabling us to track their actual sell-through data and monitor the alignment between their sales and genuine market demand. At the end of each period during the Track Record Period, our distributors generally maintained healthy inventory levels of equal to or less than two to three month of their average implantation consumption.

BUSINESS

To effectively prevent cannibalization and unauthorized cross-regional sales, we have implemented strict measures, including: (i) imposing geographic or hospital restrictions on our distributors and prohibit sales outside their designated regions or hospital; (ii) assigning a unique identification code to every single unit of our product, allowing us to trace the product; and (iii) reserving the right to enforce breach penalties or terminate the partnership in the event of non-compliance.

Specifically, we furnish guidelines in terms of price management of our products. In the event of non-compliance with our pricing guidelines, we reserve the right to hold such distributors liable for breach of contracts. We aim to continually optimize our distribution network.

Our distributors bear the duty to manage, guide, and supervise the sub-distributors they authorize within their designated territories, ensuring that these sub-distributors conduct operations in compliance with obligations and standards no less stringent than those we impose on the distributors. Pursuant to our framework agreements, distributors are required to file any sub-distributor arrangements with us within five working days since the commencement of such arrangements. We are entitled to hold our distributors liable for any market disruption caused by the misconduct of their sub-distributors, require them to indemnify us for any resulting losses.

Key Salient Terms

We typically enter into standard annual framework agreements with our distributors, which include annual sales targets and require a security deposit. The key salient terms of such framework agreements with our distributors include:

- *Duration:* The distribution agreements generally have a term of one year, subject to renewal upon mutual agreement.
- *Designated Territory and Scope:* We authorize distributors to sell our designated products within a specifically defined geographic area or to specific designated hospitals. Distributors are prohibited from selling or distributing our products outside the authorized territory or hospitals without our prior written consent.
- *Security deposit:* To ensure compliance with the agreement and performance of obligations, distributors are required to pay a refundable security deposit, the amount of which mainly depending on the scope of authorization.
- *Sales target and minimum purchase:* The agreement includes mutually agreed sales targets, and does not include minimum purchase requirements. We may consider terminating our cooperation with the distributor if it fails to meet such targets.
- *Return policy:* We typically only allow product returns related to product quality defects and subject to our prior written consent.
- *Payment:* We generally require distributors to make full payment in advance before the delivery of products.
- *Distributor’s obligations:* Distributors are generally obligated to promote our products, maintain a professional sales team, and provide necessary after-sales services within the authorized territory. They are also required to comply with all applicable laws and regulations, including those related to medical device operations and anti-bribery.

BUSINESS

- *Order execution:* The framework agreement is executed through separate customary sales contracts or purchase orders for each batch of products, which specify the product type, quantity, unit price, and delivery details.
- *Termination:* The agreements include termination clauses for fundamental breaches, such as selling outside authorized territories, handling counterfeit products, or infringing our intellectual property, among others.
- *Exclusivity:* Distributors are subject to strict exclusivity obligations and are prohibited from dealing in competing products or supplying our products to competing third parties. Any violation of these terms also constitutes fundamental breaches and grounds for termination.

According to Frost & Sullivan, our distributorship model and commercial arrangements with our distributors is in line with industry practices. To the best of our knowledge, all our distributors were Independent Third Parties, and none of our distributors were wholly owned or majority controlled by our former or current employees, during the Track Record Period and up to the Latest Practicable Date. We do not have any material concentration risk with respect to any single distributor.

Compliance with the Two-Invoice System

The “Two-Invoice System” (兩票制) is a regulatory initiative in China that generally limits the distribution chain to a single level of distributors, requiring one invoice to be issued from the manufacturer to the distributor and another from the distributor to the medical institution. While this system has been widely implemented for pharmaceutical products, its application to medical devices, particularly innovative high-value consumables like our GBS, remains fragmented and is determined on a province-by-province basis. During the Track Record Period, the vast majority of provinces where we operate did not mandate the Two-Invoice System for our product category, allowing us to adopt flexible distribution arrangements based on local market practices. In the limited regions, namely, Shaanxi and Fujian provinces, where the Two-Invoice System is also enforced for medical devices, we have proactively adapted our commercial arrangements by engaging distributors to supply directly to hospitals, thereby ensuring full compliance. As advised by our PRC Legal Advisors, we have complied with applicable laws and regulations relating to the Two-Invoice System in all material aspects in applicable provinces during the Track Record Period and up to the Latest Practicable Date. We will continue to monitor the evolving regulatory landscape and adjust our distribution structure in specific regions as necessary.

Direct Sales

We engage in direct sales on a strategic and limited basis. Our direct sales customers are primarily benchmark hospitals, such as certain private hospitals. We utilize a direct sales model in these specific cases where the high channel costs, such as higher margin expectations, of such institutions make a distributor-led model less efficient. By engaging with them directly, we can navigate their distinct admission procedures more efficiently, significantly accelerating the hospital entry process.

Pricing

Our pricing strategy is designed to reflect the significant clinical and innovative value of the GBS and other products, ensure fair margins for our distribution partners, and achieve broad market access. Under this strategy, the pricing of our Core Product was developed in consultation with metabolic disease experts, hospital administrators, and health economists, balancing clinical efficacy with economic accessibility. We offer varied price points and incentive structures to our provincial-level distributors compared to our regional distributors, typically in the form of volume-based incentives, such as providing one free unit for every ten units ordered, reflecting their different roles in channel management and market development.

BUSINESS

These incentives are accounted for as a reduction in revenue and do not materially distort our pricing strategy or gross margin profile. We set a separate price point for our strategic direct sales customers. While we rely on our distributors to leverage their local resources and networks for hospital admissions and market development, we determine the final pricing of our products. We establish the bidding and terminal prices for public procurement, and our distributors do not have the authority to independently adjust these established prices through their own negotiations with medical institutions.

We have established a terminal price for the GBS procedure in public hospitals, generally ranging from RMB36,600 to RMB39,100 for a complete set comprising one delivery system and one retrieval system. In practice, the total terminal cost for a patient undergoing the GBS procedure involves various other hospital charges. While actual overall costs vary depending on the specific hospital and regional pricing policies, to our best information, an illustrative breakdown of a typical GBS procedure includes the aforementioned medical device fee of approximately RMB36,600, alongside other estimated associated costs of approximately RMB8,000, which generally include medicine, examinations and lab tests, treatment and consultation, and bed fees.

A key component of our market access strategy is achieving broad reimbursement. As of the Latest Practicable Date, our GBS is included in the provincial-level medical insurance reimbursement lists in 28 of the 30 provinces and municipalities where we have established commercial coverage, including Sichuan, Shandong, Hebei, Henan, Shanghai, Guangdong and Jiangsu. We are actively engaging with local healthcare security administrations in the remaining regions. For instance, we are making continuous efforts for the inclusion of GBS in Tianjin catalog by 2027.

As our GBS is a NMPA Class III Innovative Medical Device, as of the Latest Practicable Date, it was not subject to national or regional volume-based procurement (VBP) policies and programs. Furthermore, under the ongoing DRG/DIP payment reforms, regional DRG innovation incentive policies for innovative medical devices like our GBS vary. Certain regions establish a three-year period for such incentives, while others do not set a fixed term and instead adopt dynamic management. We are also actively collaborating with leading hospitals to establish dedicated surgical procedure pricing codes for GBS treatment to optimize the overall hospital cost structure and mitigate potential DRG pressures.

PRODUCTION AND QUALITY CONTROL

Production Facilities and Production Capacity

Our primary production and R&D operations are based in Hangzhou, China. As of the Latest Practicable Date, we operate an independent production facility in Hangzhou with a total gross floor area of approximately 4,385 sq.m. The facility, featuring a GMP-compliant cleanroom facility, was dedicated to the production of our Core Product, the GBS. Designed with an aim of scalability, this facility incorporates reserved infrastructure and floor space to accommodate the future commercial manufacturing of our pipeline candidates, such as other GBS Series products, the DIGB and the RIGB.

We hold a Class III and Class II Medical Device Production License for our production facilities. Our quality management system has been certified as compliant with ISO-13485:2016 standards. Our facility commenced operations in 2017 with a designed annual production capacity of 8,000 units, where one unit refers to one complete set of the GBS, comprising a delivery system, and a retrieval system. For the year ended December 31, 2024, it produced 3,401 units, representing an 42.5% utilization rate. For the year ended December 31, 2025, production reached 4,823 units, with a utilization rate of 60.3%. For the six months ended June 30, 2025 and 2026, production reached 1,790 units and 2,905 units, respectively, representing utilization rate of 44.8% and 72.6% for the respective periods.

To support our strategic expansion and meet rising market demand, we are establishing a new production facility in Quzhou, Zhejiang, mainly for the production of our Core Product, with an aggregate

BUSINESS

gross floor area of approximately 5,000 sq.m. and is designed with an annual production capacity of 50,000 units. This facility is expected to fundamentally enhance our production scale and supply chain resilience. As of the Latest Practicable Date, we had obtained the medical device manufacturing license for the GBS at the Quzhou facility. We are currently carrying out final operational readiness procedures, in preparation for the commencement of production at our Quzhou facility, which is expected to commence in the second half of 2026.

In addition, we intend to establish two potential production facilities in Wuxi, Jiangsu and Mianyang, Sichuan, which are intended to support the sales and production of our CNT products. As of the Latest Practicable Date, these potential facilities were still at an early planning stage and no construction had commenced. We plan to use our operating cash and other internal cash resources to fund the development of these new facilities.

Production Process

Our production process is managed through our ERP system and is conducted in-house, with the exception of the final sterilization step. We commenced commercial production of our GBS in February 2024.

The process begins with the procurement of raw materials from our list of qualified suppliers. Upon receipt, all materials undergo incoming quality inspection before being released to the production line. Our GBS production is not highly automated but relies on a suite of proprietary, self-developed equipment, jigs, and fixtures, which we believe creates a significant technical barrier to entry. Key processes include the proprietary forming of the sleeve, anchor stent fabrication, and the final assembly of the implant, delivery, and retrieval systems.

After assembly and packaging in our cleanroom, the finished products are sent to a qualified third-party vendor for ethylene oxide (EO) sterilization. Following sterilization, the products are returned to our facility for final quality control testing and release to the finished goods warehouse.

Quality Control System

We have implemented a comprehensive quality control system to ensure our products are safe, effective, and compliant with NMPA regulations, GMP, and ISO 13485 standards. Our quality control system covers the entire product lifecycle, from design to post-market surveillance.

- *Design and development control:* Quality control is embedded in our R&D process to ensure product design meets all specifications and regulatory requirements before being transferred to production.
- *Supplier and raw material control:* We maintain a strict supplier management process. Potential new suppliers undergo a stringent qualification process, including sample testing by our quality department. Only after successful testing and evaluation are they added to our qualified supplier list for small-batch and, subsequently, mass procurement.
- *Production and finished product control:* Our production quality system mandates quality checks at every critical stage, including (i) incoming quality control, all raw materials from qualified suppliers are inspected and tested upon arrival; (ii) in-process quality control, which includes first and final article inspection to ensure process stability; (iii) final quality control, we conduct inspection of certain critical components such as the stent barbs and comprehensive testing of the finished product after in-house assembly; and (iv) outgoing quality control, a final inspection is performed after the product returns from outsourced sterilization to verify its final integrity and packaging before it is released for sale.

BUSINESS

- *Environment control:* We establish and enforce stringent environmental control protocols for our microbiology laboratory and production facilities. These protocols are designed to maintain critical parameters, such as cleanliness, temperature, and humidity, within defined specifications, and their implementation is continuously monitored to ensure ongoing compliance and product quality integrity.

We maintain full traceability for our GBS, with each device linked by its identifier code to the individual employees who performed the key production steps. We also operate a post-market surveillance system to monitor and report any adverse events, ensuring continuous compliance and product improvement.

Inventory Management

Our inventories consist of raw materials, work in progress and finished goods. We manage our inventory levels based on our production plans and maintain safety stock levels to ensure continuous operations while avoiding overstocking. We utilize a digitalized ERP system to monitor our inventory status in real-time. We believe our inventory control policies have been effective and we did not experience any material shortage or overstocking during the Track Record Period and up to the Latest Practicable Date.

SEASONALITY

During the Track Record Period, our operation was subject to certain seasonal fluctuations, with typically increased sales during the fourth quarter. This trend is primarily attributable to (i) the fact that we initiated the commercialization of our Core Product following its NMPA approval in January 2024, and the lower sales volume in the first half of 2024 reflected a natural ramp-up period as we progressively expanded our hospital coverage and established our distributor network; and (ii) the purchasing patterns of our distributors, who tend to increase their inventory levels toward year-end in anticipation of public holidays and potential logistics disruptions, to ensure continuous supply for clinical procedures.

COMPETITION

The biotechnology industries are characterized by rapidly advancing technologies and intense competition. Although we believe that our pipeline of products and product candidates, leading R&D capability, established technology platforms, and experienced management team provide us with competitive advantages, we acknowledge the potential for competition from various sources, including major medical device and biotechnology companies. For more information on the competitive landscape of our products and product candidates, see “Market Opportunity and Competition” in this section for each product and product candidate above.

EMPLOYEES

As of June 30, 2026, we had 164 employees in total. The following table sets forth the number of our employees categorized by function as of June 30, 2026:

<u>Function</u>	<u>Number of Employees</u>
Research and Development	56
Clinical and Registration Affairs	7
General and Administrative	28
Sales and Marketing	27
Production and Quality	46
Total	<u>164</u>

BUSINESS

We require fairness and transparency in our recruitment processes and place emphasis on diversity in our recruitment. We welcome talents from different backgrounds to join us in order to increase our workplace diversity. We adopt a hybrid recruitment process and recruit candidates through both online and traditional methods. We always strive to provide employees with comprehensive social benefits, a safe work environment and a wide range of career development opportunities. Furthermore, we are committed to strictly complying with applicable laws, regulations and standards related to workplace safety, providing a safe and healthy workplace for our employees and implementing an effective management system to help ensure employee safety and well-being. As required by laws and regulations in China, we participate in various employee social security plans, including, among other things, pension, medical insurance, unemployment insurance, maternity insurance, on-the-job injury insurance and housing fund plans. We are committed to establishing a competitive and fair remuneration. In order to effectively motivate our staff, we continually refine our remuneration and incentive policies. We conduct performance evaluation for our employees regularly to provide feedback on their performance. Compensation for our staff typically consists of base salary and a performance-based bonus. We typically enter into standard employment agreements. In addition to such employment agreements, we typically enter into separate confidentiality and non-compete agreements. These contracts include standard confidentiality and non-compete covenants that prohibit the employee from disclosing, using or otherwise misappropriating our trade secrets, proprietary information or technical know-how and joining companies that compete with us or our affiliates during their employment and for a certain period of time thereafter. We maintain a good working relationship with our employees, and have not experienced any material labor disputes.

INSURANCE

We maintain certain insurance policies as of the Latest Practicable Date. For example, we maintain insurance policies that cover our assets and losses arising from accidents in clinical trials. We consider that the coverage from these insurance policies to be adequate for our operations and in line with the industry norm. During the Track Record Period, we had not made, or been the subject of, any material insurance claims.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE MATTERS

We believe our sustained growth lies in our contribution to society. Since our inception, we have adopted as our long-term strategic goal to promote environmental sustainability, support and participate in socially responsible projects, and adhere to a high standard of corporate governance.

ESG Governance

We prioritize Environmental, Social, and Governance (ESG) practices and have implemented a comprehensive ESG reporting process. Our Board holds full responsibility for establishing ESG policies and strategies, evaluating risks associated with daily operations, and monitoring progress to ensure effectiveness. It also fosters a culture aligned with our core ESG values. To bolster sustainability, improve governance, and enhance ESG performance, we have established a working mechanism comprising designated representatives from various functional departments, who are designated to manage the ESG issues most relevant to their respective functional lines (“**ESG Team**”). Reporting directly to the Board, they execute the ESG strategies laid out by leadership. ESG Team continuously conducts the identification and assessment of our material ESG risks and issues pursuant to institutional requirements, and promptly reports the results to our Board. The Board reviews such results and identifies material ESG issues based on the materiality of their impact on our business development and sustainable operations.

BUSINESS

We have engaged external ESG consultants to conduct an assessment based on the importance of impact to us and financial materiality, thereby systematically identifying and evaluating ESG-related risks, development opportunities and their potential impacts. Key ESG matters are set out in the table below:

<u>Key ESG matters</u>	<u>Potential risk</u>	<u>Actions</u>
Waste Management and Contracted Party Monitoring	Non-compliant operations, delayed filings or unauthorized disposal of hazardous waste by contractors may trigger environmental pollution risks.	We entrust qualified entities for collection and annual centralized disposal, require contractors to assign dedicated personnel for waste management, and ask for rectification and accountability for non-compliance.
Clinical Trial Benefits	Non-compliant preclinical animal testing may compromise animal welfare; non-standard clinical trial protocols, ethical review and implementation may infringe patients’ rights.	We standardize preclinical research as a mandatory compliance step for medical device trials, standardize clinical trial operations, complete ethical approval and secure informed consent to safeguard patient rights.

The ESG Team’s duties include developing and implementing an ESG framework and policies aligned with our long-term strategies while regularly reviewing and adjusting them. They ensure compliance with evolving ESG related laws and regulations and promptly update policies accordingly. The ESG Team identifies, assesses, and manages material ESG risks on an ongoing basis and takes timely measures to reduce potential impacts. The ESG Team also evaluates stakeholder communication effectiveness and incorporates feedback to optimize strategies.

Moreover, the ESG Team closely monitors and evaluates our performance against ESG targets and provides regular reports to the Board. Through these coordinated efforts, we aim to embed responsible, sustainable business practices deeply into our corporate culture and operations, positioning the company for long-term success.

Environmental Protection

As a company focusing on the development, production and commercialization of medical device, we recognize the significant environmental responsibilities that come with our operations. Environmental responsibility is deeply ingrained in our corporate values, guiding our efforts to reduce ecological harm at every stage of the value chain. We are focused on ongoing improvement, striving to lower our environmental footprint while advancing sustainable growth in alignment with our commitment to planetary stewardship.

We have obtained the necessary environmental impact assessment report for our production facilities and construction completion and environmental protection acceptance reports for our R&D laboratories, demonstrating that our R&D and planned production facilities meet all relevant PRC environmental and regulatory standards concerning capacity, resource usage, and waste handling.

GHG Emissions and Resource Consumption Management

During the Track Record Period, our greenhouse gas (GHG) emissions were primarily generated from our R&D activities, production processes, and other ordinary business operations.

BUSINESS

We closely monitor energy and water consumption levels at our offices and facilities and have implemented various policies and measures to conserve resources. These include:

- **Energy management.** We have implemented a stringent energy management system monitoring equipment safety and power usage. All lighting across our offices uses energy-efficient LED fixtures, and motion-sensor controls are installed in common corridors to ensure lights turn off automatically when unoccupied. Our guidelines govern the use of electrical appliances to prevent unnecessary energy waste.
- **Water conservation.** Motion-sensor faucets are installed throughout our office premises. We conduct regular inspections of water supply pipelines and promptly repair any identified leaks to minimize water loss.
- **Other resources conservation.** We have deployed product lifecycle management and enterprise resource planning systems to support paperless operations and require double-sided printing for all documents unless exceptional circumstances apply. The use of single-use items is actively discouraged; employees are encouraged to use reusable tableware and drinkware.
- **Green office practices.** We utilize video conferencing to reduce business travel and associated emissions. Our environmental management system is certified to ISO 14001 standards, and we leverage cloud-based storage solutions to reduce reliance on on-premises physical servers, thereby lowering energy consumption.

Through these efforts, we aim to further promote resource-saving practices and reduce overall resource usage.

The following table sets forth the amount of our electricity and water consumption for the periods indicated:

	Unit	Year ended December 31,		Six months ended June 30,
		2024	2025	2026
Electricity Consumption	kWh	322,340	773,278	574,697
Water Consumption	cubic meters	2,959	2,601	1,399

The following table sets forth the amount of our GHG emissions for the periods indicated:

	Unit	Year ended December 31,		Six months ended June 30,
		2024	2025	2026
Scope 1	tCO ₂ e	10.38	10.38	— ⁽¹⁾
Scope 2	tCO ₂ e	172.97	414.94	308.38
Scope 3	tCO ₂ e	0.11	0.11	0.04
Total GHG emission	tCO ₂ e	183.46	425.43	308.43
Total GHG emission intensity	tCO ₂ e/RMB in millions	14.43	13.21	13.00

Notes:

- (1) Our Scope 1 emissions is related to fugitive refrigerant, calculated based on annual refill volumes. As no refrigerant refills were recorded for the first half of 2026, the Scope 1 emission for this period is reported as nil.

BUSINESS

Based on the trends in our historical GHG emissions and the current emission status of the industry, we have formulated emission reduction targets that, taking 2025 as the base year, we aim to reduce the total GHG emission intensity by 10% by 2028. To achieve these targets, we will implement the following measures: (i) for Scope 1 emission, we aim to establish regular emission reduction initiatives including routine refrigerant leakage inspections, compliant recycling and disposal, and detailed ledger management; (ii) for Scope 2 emission, we aim to strengthen internal energy-saving electricity management and actively procure green electricity; (iii) for Scope 3 emission, we will focus on medical hazardous waste incineration to enhance source classification and control, prioritize the selection of low-carbon disposal partners, and optimize the connection processes for waste transportation and transfer.

Waste Management and Contracted Party Monitoring

We implement comprehensive policies to minimize our environmental impact through responsible waste management, energy efficiency, and water conservation. Our hazardous waste is generated from laboratory testing and R&D trials. Qualified compliant entities conduct collection of the waste and arrange for its centralized disposal on an annual basis in accordance with contractual agreements. We require the contracted parties for hazardous waste disposal to designate dedicated personnel to be responsible for waste transfer, disposal, settlement, submission of relevant documentation, assisting us with disposal verification and other related matters. We exercise supervision over the hazardous waste disposal process, conduct regular on-site inspections, strictly prohibit unauthorized disposal, and require rectification within a specified timeframe and pursue accountability for any non-compliant acts.

Social Responsibility

Product Safety, Social Risks, and Access to Healthcare

We recognize the profound social responsibility associated with the commercialization of our products. We have adopted internal control policies to mitigate the following critical social risks:

- *Inappropriate use of products:* To prevent risks associated with the inappropriate use of our products post-approval, we implement stringent programs focusing on physician training. We provide comprehensive procedural guidance, clear clinical indications, and ongoing medical education to ensure our devices are only used in accordance with approved protocols.
- *Effects of product pricing on access to healthcare:* We are committed to developing innovative therapies that are accessible to patients. Our pricing strategy is designed to balance the significant investment required for medical device R&D and quality assurance with the critical need for affordability.
- *Product safety and recall system:* We maintain a formal, mandatory product recall system in strict compliance with the NMPA’s Rules for the recall of medical devices and international best practices. This system has clear procedures for the prompt identification, reporting, investigation, and execution of any necessary recall or corrective action. This ensures that any safety issue detected post-market is addressed immediately, minimizing risk to patients and maintaining product integrity.

BUSINESS

Workplace Safety and Diversity

We have established and maintain a comprehensive set of rules, standard operating procedures, and measures, to ensure a healthy, safe, and inclusive environment for our employees and clinical trial participants. Our safety program emphasizes three core pillars: implementing clear guidelines for safe workplace practices, maintaining accident prevention protocols, and establishing transparent reporting procedures. For clinical trials, we require participants to demonstrate their understanding of all safety considerations both during initial enrollment and throughout their continued participation. These systematic protections reflect our fundamental commitment to fostering both physical safety and psychological well-being across all aspects of our operations.

We have also adopted a board diversity policy, which sets out the approach to achieve diversity of the Board. We recognize and embrace the benefits of having a diverse Board, including gender diversity, as an essential element in maintaining our competitive advantage and enhancing our ability to attract, retain and motivate employees from the widest possible pool of available talent. As of June 30, 2026, 91, or 555% of our total employees were female.

Clinical Trial Benefits

In terms of animal welfare safeguards, we designate preclinical research as a prerequisite compliance step for clinical trials. By standardizing the implementation and review procedures for preclinical research, we ensure the compliant and procedural conduct of our preclinical animal testing activities, laying a procedural foundation for animal welfare protection.

In terms of patient welfare and rights protection, we are dedicated to safeguard the core rights and interests of trial participants: (i) clinical trial protocols are jointly formulated by multiple departments and experts and subject to professional demonstration; (ii) prior to trial initiation, we submit and revise materials for ethical review, obtain ethical approval, and include informed consent form samples in the core trial documents to safeguard participants’ right to information and informed choice; and (iii) we conduct standardized pre-trial procedures including personnel training and the standardized enrollment of patients to safeguard the safety and rights and interests of participants throughout the trial process.

Corporate Governance

We uphold corporate governance standards as the foundation of our sustainable growth and long-term success. Our governance framework is structured to ensure effective oversight, transparency in decision-making, and value creation for all stakeholders. The Board serves as the guiding force in shaping our strategic direction, overseeing comprehensive risk management, and maintaining accountability throughout the organization.

Patient Data Protection and Prevention of Data Manipulation

We are committed to protecting sensitive patient information and ensuring the confidentiality of clinical trial participant data in compliance with all relevant laws, regulations, and industry standards. We require our CROs to maintain strict confidentiality of all documents, data, and records generated during clinical trials, and to bind their employees and consultants to these same confidentiality obligations. Without our prior written consent, CROs are prohibited from sharing any confidential information with third parties. Additionally, all our employees sign confidentiality agreements to further secure sensitive information. To ensure data integrity and prevent manipulation, we have established comprehensive internal policies.

BUSINESS

Supply Chain Management

We have established a supplier management system covering classification, access review and dynamic management, with production environment cleanliness requirements incorporated into outsourced production supplier screening criteria. We conduct dynamic management and annual reevaluation of existing outsourced production supplier, perform a comprehensive multi-dimensional scoring, verify their continuous compliance with cleanliness and other standards, and strictly implement an exit mechanism for non-compliant suppliers. There has been no material fraud, bribery or other misconduct involving our employees, distributors, suppliers and other third parties during the Track Record Period and up to the Latest Practicable Date.

Business Ethics and Integrity

We are committed to upholding high standards of corporate governance and fostering a healthy corporate culture. We believe that strong governance and ethical values are essential to the well-being of our employees and the sustainable development of our business. To this end, we have put in place a series of internal regulations to set forth the guidelines for compliance with laws and regulations and promote honest and ethical conduct, prevent corruption practices and conflicts of interest, and maintain operational transparency and fairness, including our code of business conduct and ethics, anti-corruption compliance policy, and internal control manual. These measures foster an ethical and transparent business environment while safeguarding our interests and those of all stakeholders.

PROPERTIES

We are headquartered in Hangzhou, Zhejiang. As of the Latest Practicable Date, we did not own any real property. As of the same date, we leased 12 properties in Chinese Mainland, with an aggregate GFA of approximately 26,500 sq.m., which were primarily used for office functions and production facilities. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs.

LICENSES, PERMITS AND CERTIFICATES

We are required to obtain and renew certain certificates, permits, and licenses for developing and commercializing our products, including those essential for the entire lifecycle of our medical device products. See “Regulatory Overview” for more information about the material certificates, permits, and licenses required for our business operations in Chinese Mainland, and other relevant jurisdictions. During the Track Record Period and up to the Latest Practicable Date, we have obtained all requisite certificates, permits, and licenses that are material for our operation, and all of such certificates, permits, and licenses are valid and up-to-date to the extent that they are still needed.

BUSINESS

We did not experience any material difficulties in renewing such certificates, permits, and licenses during the Track Record Period and up to the Latest Practicable Date, and do not expect to face any material difficulties in renewing them upon their expiry, if applicable.

The following table sets forth the summary of the key licenses, permits and certificates which we have obtained as of the Latest Practicable Date in China and overseas:

License/Permit	Holder	Issue Authority	Valid Period
Manufacturing License (浙藥監械生產許 20220109 號)	Our Company	Zhejiang NMPA	2022.10 – 2027.10
Manufacturing License (津藥監械生產許 20250862 號)	Tianjin Tangji	Tianjin NMPA	2025.08 – 2030.08
Manufacturing License (浙藥監械生產許 20260060號)	Jikang Medical	Zhejiang NMPA	2026.06 – 2031.06
Class II Medical device Distribution Filing (第 二類醫療器械經營備案: 浙杭食藥監械經營 備20173153號)	Our Company	Hangzhou Market Supervision Bureau	Long term since 2017.12
Medical Device Distribution License (醫療器械經營許可證 書: 浙杭藥監械經營 許20210076號)	Our Company	Hangzhou Market Supervision Bureau	2026.01 – 2031.01
NMPA registration for GBS (國械註 准20243130104)	Our Company	NMPA	2024.01 – 2029.01
NMPA registration for RTK (浙械註 准20252021547)	Our Company	Zhejiang NMPA	2025.07 – 2030.07
NMPA registration for a consumable for GA (滬械註 准20252060558)	Shanghai Tangji	Shanghai NMPA	2025.12 – 2030.12
NMPA registration for Dtx (津械註 准20242210335)	Tianjin Tangji	Tianjin NMPA	2024.12 – 2029.12
NMPA registration for an accessory for the GBS (浙械註 准20222061126)	Our Company	Zhejiang NMPA	2022.09 – 2027.09

BUSINESS

License/Permit	Holder	Issue Authority	Valid Period
NMPA registration for the video image processor of GA (滬械註准20252060563) . . .	Shanghai Tangji	Shanghai NMPA	2025.12 – 2030.12
Indonesia registration for GBS (KEMENKES RI AKL 20805420529)	Our Company	Ministry of Health of Indonesia	2024.10 – 2029.08
Thailand registration for GBS (68-2-2-2-0001693) . .	Our Company	Thailand FDA	2025.02 – 2029.12
Hong Kong registration for GBS (250834)	Our Company	Hongkong MDD	2025.03 – 2030.03
Vietnam registration for GBS (2501463DKLH/ BYT-HTTB)	Our Company	Ministry of Health of Vietnam	Long term since 2025.04
Saudi registration for GBS (MDMA-2-2025-1941)	Our Company	Saudi FDA	2025.06 – 2028.06
Malaysia registration for GBS (GC4546725-207519)	Our Company	Malaysia MDA	2025.07 – 2030.07
Ecuador registration for GBS (18943-DME-0725) . .	Our Company	Ecuador ARCSA	2025.07 – 2030.07
Colombia registration for GBS (2026DM-0031993)	Our Company	Colombia INVIMA	2026.01 – 2036.01
The Philippines registration for GBS (CMDR-2026-07305A)	Our Company	The Philippines FDA	2026.03 – 2031.03
Singapore registration for GBS (MDPR260508F0003)	Our Company	Singapore HSA	Long term since 2026.05
Brazil registration for GBS (81504790573)	Our Company	Brazil ANVISA	2026.06 – 2036.06

BUSINESS

License/Permit	Holder	Issue Authority	Valid Period
Certificate of ISO 13485:2016 (EN ISO 13485:2016 / AC:2018, EN ISO 13485:2016 / A11:2021) Medical devices - Quality management systems - Requirements for regulatory purposes (No. Q5 102885 0003 Rev. 05)	Our Company	TÜV SÜD Product Service GmbH • Certification Body	2026.08 – 2028.09
Certificate of ISO 13485:2016 Medical devices - Quality management systems (No. CN26/00003090)	Shanghai Tangji	SGS United Kingdom Ltd	2026.04 – 2029.04
Environmental Management System Certificate (GB/T 24001-2016 / ISO 14001:2015)	Our Company	Beijing NGV Certification Center Co., Ltd.	2025.01 – 2028.01
Quality Management System Certificate (GB/T 19001-2016 / ISO 9001:2015)	Our Company	Beijing NGV Certification Center Co., Ltd.	2025.01 – 2028.01
Occupational Health and Safety Management System Certificate (GB/T 45001-2020 / ISO 45001:2018)	Our Company	Beijing NGV Certification Center Co., Ltd.	2025.01 – 2028.01
Certificate of GMP and Control of Medical Devices / Health Products	Our Company	Ministry of Health of Brazil	2026.04 – 2028.04

COMPLIANCE

We face certain non-compliance risks during our ordinary course of business.

Properties Related Compliance

As of the Latest Practicable Date, agreements for three of our leased properties in Chinese Mainland had not been registered with the relevant PRC government authorities. Under the Administrative Measures for Commodity House Leasing, we may be ordered by the relevant authorities to rectify such non-compliance within a prescribed period. If we fail to do so, we may be subject to a fine ranging from RMB1,000 to RMB10,000 for each unregistered lease, indicating a maximum potential fine of RMB30,000 for us as of the Latest Practicable Date. However, according to the Civil Code of the PRC, the failure to

BUSINESS

register or file a lease contract does not affect its validity. During the Track Record Period and up to the Latest Practicable Date, we have not been subject to any administrative penalties for such non-compliance. As advised by our PRC Legal Advisors, the non-registration does not affect the legal validity of the lease contracts and does not constitute a substantive legal impediment with respect to the [REDACTED]. During the Track Record Period and up to the Latest Practicable Date, no single property interest that formed part of non-property activities had a carrying amount of 15%, and no single property interest that formed part of property activities had a carrying amount of 1%, of our total assets. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Cap. 32L of the Laws of Hong Kong), 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 our Group’s interests in land or buildings.

Labor Related Compliance

During the Track Record Period, we did not make full contributions to the social insurance and housing provident fund with respect to certain employees as required by relevant PRC laws and regulations. For the years ended December 31, 2024 and 2025 and the six months ended June 30, 2026, the aggregate shortfall in our contributions to social insurance amounted to approximately RMB1.9 million, RMB2.6 million and nil, respectively. In the six months ended June 30, 2026, we made up for approximately RMB1.3 million of our social insurance contribution shortfalls. For the years ended December 31, 2024 and 2025 and the six months ended June 30, 2026, the aggregate shortfall in our contributions to housing provident funds amounted to approximately RMB0.8 million, RMB1.0 million and RMB1.5 million, respectively. We have made social insurance contributions and housing provident fund contributions in full since July 2026. As advised by our PRC Legal Advisor, an employer that has not made social insurance contributions in full and on time as prescribed by the law, may be ordered by relevant authorities to rectify and pay the required contributions within a stipulated deadline and be subject to a late payment fee of up to 0.05% per day. If the employer fails to rectify the failure to make social insurance contributions within the stipulated deadline, it may be subject to a fine ranging from one to three times the amount overdue. Accordingly, the aggregate maximum potential penalty that could be imposed on us for the aforementioned shortfalls during the Track Record Period is approximately RMB13.5 million.

The Interpretation (II) of the Supreme People’s Court on Several Issues Concerning the Application of Law in Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋（二）》), promulgated on July 31, 2025 and effective from September 1, 2025, clarifies that any agreement or undertaking to waive social insurance contributions is invalid. Our Directors are of the view that the new judicial interpretation will not have a material adverse impact on our business, financial condition or results of operations. Considering that (i) during the Track Record Period and up to the Latest Practicable Date, we were not aware of any administrative penalty imposed on us or our PRC subsidiaries by social insurance or housing provident fund authorities, nor did relevant enterprise credit reports evidence any such penalties, and we had not received any written notice from competent authorities ordering us to rectify any non-compliance in this regard; (ii) in the absence of employee complaints or third-party reports; (iii) we undertake that, in the event that competent government authorities require us or our PRC subsidiaries to make contributions or supplementary contributions within a stipulated time period, we will duly comply in a timely manner; (iv) based on the appropriate procedures performed by our PRC Legal Advisors; and (v) as advised by our PRC Legal Advisors, the new judicial interpretation does not expand the scope of penalties nor repeal the existing laws, our PRC Legal Advisors are of the view that the likelihood that we be subject to the centralized collection of historical arrears and material administrative penalties is remote.

We maintain compliance with all applicable laws and regulations governing our operations. During the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any

BUSINESS

material non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operation.

LEGAL PROCEEDINGS

During the Track Record Period and up to the Latest Practicable Date, we have not been involved in any material legal or administrative proceedings that could significantly impact our operations, financial position, growth prospects, or reputation. Although we are not currently a party to any material legal proceedings, we may be subject to claims and litigation arising in the ordinary course of business. See “Risk Factors — Risks Relating to Our General Operations — We may be involved in lawsuits, claims, administrative proceedings or other legal proceedings against us.”

RISK MANAGEMENT AND INTERNAL CONTROLS

Risk management is critical to our operations. We have established and continuously maintained a risk management and internal control framework, supported by comprehensive policies and procedures tailored to our business. We are committed to the ongoing enhancement of this framework.

In preparation for the [REDACTED], we have engaged an independent third-party consultant (the “**Internal Control Consultant**”) to perform a review of selected areas of our internal controls. The Internal Control Consultant performed procedures and put forward suggestions for improvement. We have further strengthened our internal control process based upon the Internal Control Consultant’s suggestions.

Financial Reporting Risk Management

To mitigate financial reporting risks, we have established a comprehensive internal control system for financial management. This system includes detailed procedures for managing internal processes, among others. Additionally, we conduct monthly cash and bank reconciliations to ensure the accuracy and integrity of our financial data.

Product Quality Risk Management

To manage risks in relation to product quality, we have implemented a comprehensive quality control system that spans the entire product lifecycle. We have a formal process to establish detailed product quality standards during the R&D and design phase, focusing on safety, functionality, reliability for our products. Our quality control extends to our supply chain, where we enforce strict procedures for incoming material inspection and multi-dimensional compliance verification to ensure the controllability of raw material quality. During production, we conduct in-process inspections and final inspection for all finished products. To address issues that may arise, we have also established systematic processes for defect analysis and supplier claims, ensuring a closed-loop approach to quality assurance.

Compliance Risk Management

Compliance risk management is the core of our risk management activities, the foundation for effective internal controls and an important aspect of our corporate culture. Our general manager’s office is responsible for establishing our internal control system and reviewing its effectiveness. We have implemented a series of internal procedures to ensure the compliance of our business operations with the relevant rules and regulations. Our material decision-making is undertaken by our senior management, the Board of Directors, and Shareholders’ Meeting, as the case may be. We have established internal procedures to ensure that we have obtained all material requisite licenses, permits and approvals for our business operations, and monitor the status and effectiveness of those licenses and approvals. Additionally, we have adopted various measures in connection with our data protection.

BUSINESS

Human Resources Risk Management

We provide different training to our employees in different departments. Through these training, we ensure that our staff’s skills remain up-to-date and enable them to discover and meet customers’ needs. We have in place an employee handbook, which contains internal rules and guidelines regarding topics such as best commercial practice, work ethics, and negligence. We make our internal reporting channel open and available to our staff for any reporting of wrongdoing or misconduct. Reported incidents and persons will be investigated and appropriate measures will be taken in response to the findings.

Data Privacy Protection

We have taken measures to protect the confidentiality of patients’ data, including during clinical trials, and protect the security and confidentiality of their personal information to ensure compliance with all applicable laws and regulations on data protection and privacy. We collect various types of data across our business operations, primarily including: (i) clinical trial data, such as patients’ basic personal information, medical history, and examination results, for regulatory filings; (ii) supplier and customer data, such as contact and corporate information, for procurement and sales management; and (iii) user and healthcare data such as identity and certain health conditions, for our DTx.

To prevent unauthorized access and safeguard data security, we have established a comprehensive internal control framework covering the following aspects:

- *Organizational governance:* We have established a Cybersecurity and Data Security Compliance Committee, appointed a Data Protection Officer, and formulated a series of internal security management policies.
- *Technical safeguards:* We utilize secure cloud servers located in the PRC and implement technical measures such as data classification, access control based on the principle of least privilege, data encryption, desensitization, and firewalls. For clinical trials, patient data in our electronic data capture systems is pseudonymized.
- *Personnel management:* Access is strictly limited to authorized personnel, including third-party SMOs, who are required to sign confidentiality agreements. We also provide regular data security training to our employees.
- *Incident response:* We have established emergency response mechanisms and conduct regular cybersecurity drills to handle potential data incidents.

Regarding cross-border data transmission, our activities are strictly limited to providing necessary registration filing materials, such as technical documentation and certificates of free sale, to overseas medical device registration agents or Notified Bodies to obtain overseas marketing authorizations. These materials do not contain any personal information or important data, and thus do not trigger cross-border data export regulatory procedures. Except for the above, we do not transfer any data collected or generated within the PRC to overseas jurisdictions.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any breach of confidential information or any other information-related incidents which could cause a material adverse effect on our business, financial condition or results of operations, and we had not been subject to any material penalty in relation to data privacy. Our PRC Legal Advisors have confirmed that, 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 in this regard.

BUSINESS

AWARDS AND RECOGNITIONS

During the Track Record Period, we received a number of awards and accolades in recognition of our brand and products. The following table sets out major awards and recognitions we received during the Track Record Period and up to the Latest Practicable Date:

Year	Award/Recognition	Issuing Authority/Organization
2026	Zhejiang Province Specialized, Refined, Distinctive and Innovative SME (浙江省專精特新中小企業)	Zhejiang Provincial Department of Economy and Information Technology
2026	Second Prize, 11th “Maker in China” Zhejiang Competition and “Zhejiang Good Projects” SME Innovation and Entrepreneurship Competition (第十一屆「創客中國」浙江省賽區暨「浙江省好項目」中小企業創新創業大賽)	Zhejiang Provincial SME Association
2025	National High-tech Enterprise (國家高新技術企業)	Zhejiang Provincial Department of Economy and Information Technology, Zhejiang Provincial Department of Finance, and Zhejiang Provincial Tax Service, State Taxation Administration
2025	Postdoctoral Workstation	Zhejiang Provincial Postdoctoral Work Office
2025	National Technology-based SME (Shanghai Tangji) (國家科技型中小企業)	Ministry of Science and Technology
2025	Hangzhou Industrial Design Center (杭州市工業設計中心)	Hangzhou Bureau of Economy and Information Technology
2025	2025 Hangzhou Innovative High-quality Pharmaceutical and Medical Device Catalog (2025年創新優質杭產藥械目錄)	Hangzhou Bureau of Economy and Information Technology, and Hangzhou Health Commission
2025	2025 Hangzhou High-quality Product Recommendation Catalog (2025年杭州市優質產品推薦目錄)	Hangzhou Bureau of Economy and Information Technology
2025	2025 International Medical Innovation Competition - Medical Innovation Award (2025國際醫療創新大賽 — 醫療創新獎)	CIIE Exhibition Union Medical Devices Committee
2025	2025 Yangtze River Delta Excellent Domestic Medical Equipment and Consumables - Recommended Products (2025年度長三角優秀國產醫療設備耗材醫用耗材類 — 推薦產品)	Shanghai Yangtze River Delta Medical Device Industry Development Promotion Association (上海長三角醫療器械產業發展促進會)
2024	National Technology-based SME (Tianjin Tangji) (國家科技型中小企業)	Ministry of Science and Technology

BUSINESS

<u>Year</u>	<u>Award/Recognition</u>	<u>Issuing Authority/Organization</u>
2024	National Patent-Intensive Product — GBS (國家專利密集型產品 — 胃轉流支架系統)	National Intellectual Property Center
2024	Zhejiang Province Golden Seed Plan (Growth Level) (浙江省金種子計劃 (成長級))	Zhejiang Provincial Market Supervision Administration (Intellectual Property Office)