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OVERVIEW

Who We Are

Incorporated in 2018, we focus on the development and commercialization of iNO therapy for cardiopulmonary indications. We operate in the gas-based cardiopulmonary device market, with iNOWill as our Core Product centered on therapeutic applications, alongside certain other products relating to diagnostic and therapeutic applications. As of the Latest Practicable Date, we had five approved products (including one Core Product, iNOWill) and five product candidates under development, spanning three major product lines addressing cardiopulmonary care. All our products are independently developed inhouse. Our Core Product, iNOWill, was approved by the NMPA in 2022 and received EU CE certification in 2025. It delivers iNO as a selective pulmonary vasodilator, which is not curative but provides support primarily in acute and critical care settings for patients with severe cardiopulmonary disease such as pulmonary hypertension, requiring ICU and bedside hospital care. While our Core Product currently targets a specific patient subgroup with a relatively limited addressable market, we are pursuing indication expansion for iNOWill to broaden its potential clinical applications and addressable patient population, subject to successful clinical development and regulatory approval.

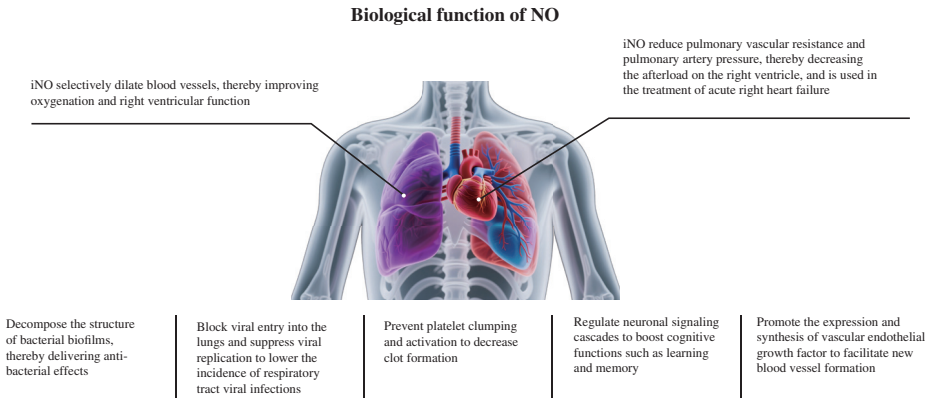
Our product pipeline spans the full cardiopulmonary care continuum, from intensive care and perioperative intervention to inpatient treatment, outpatient monitoring and home-based disease management. Through our three complementary product lines — (i) iNO therapy, (ii) cardiopulmonary circulatory support and (iii) respiratory diagnostics — we aim to address evolving clinical needs across different care settings while progressively building an integrated diagnosis and treatment pathway.

- Within our iNO therapy product line, our Core Product, iNOWill, was approved by the NMPA in 2022 and received EU CE certification in 2025. iNOWill is designed primarily for intensive care settings, where inhaled nitric oxide therapy is used to provide cardiopulmonary support for patients requiring acute respiratory and pulmonary vascular management. Building on our proprietary instant NO generation technology, we are advancing indication expansion from PH to ARDS, COPD and CAP, with the objective of progressively extending iNO therapy beyond its current ICU-focused applications into broader respiratory disease management across the cardiopulmonary care continuum.
- Within our cardiopulmonary circulatory support product line, our Key Product, NovaPulse IABP, was approved by the NMPA in 2025. NovaPulse is designed for mechanical circulatory support in intensive care units, operating rooms and catheterization laboratories, where respiratory and circulatory support are frequently provided in parallel. From a clinical-function perspective, iNO therapy provides pulmonary vascular support by reducing pulmonary vascular resistance and right ventricular afterload, while IABP provides temporary circulatory support principally by reducing left ventricular afterload and augmenting coronary perfusion. Together with iNOWill, NovaPulse enables us to address complementary respiratory and circulatory needs within the same critical care workflow, strengthening our clinical presence in ICU and perioperative care while expanding our cardiopulmonary critical care offering.
- Within our respiratory diagnostics product line, we are developing PELink, our pulmonary function diagnostic platform, to support disease assessment and longitudinal monitoring from hospital settings to outpatient clinics and, ultimately, home-based disease management. Together with VQfit, our portable iNO product candidate intended for outpatient and at-home use, PELink is expected to support home-based diagnosis, treatment and longitudinal monitoring for chronic respiratory diseases.

Clinical Significance of NO and Unmet Needs in Global Cardiopulmonary Care

From fundamental physiology to critical care practice, NO is a clinically important molecule that underpins both normal cardiopulmonary homeostasis and life-support interventions in ICUs. The vasodilatory function of NO was formally recognized by the Nobel Prize in Physiology or Medicine in 1998, establishing the scientific foundation for the development of iNO therapy.

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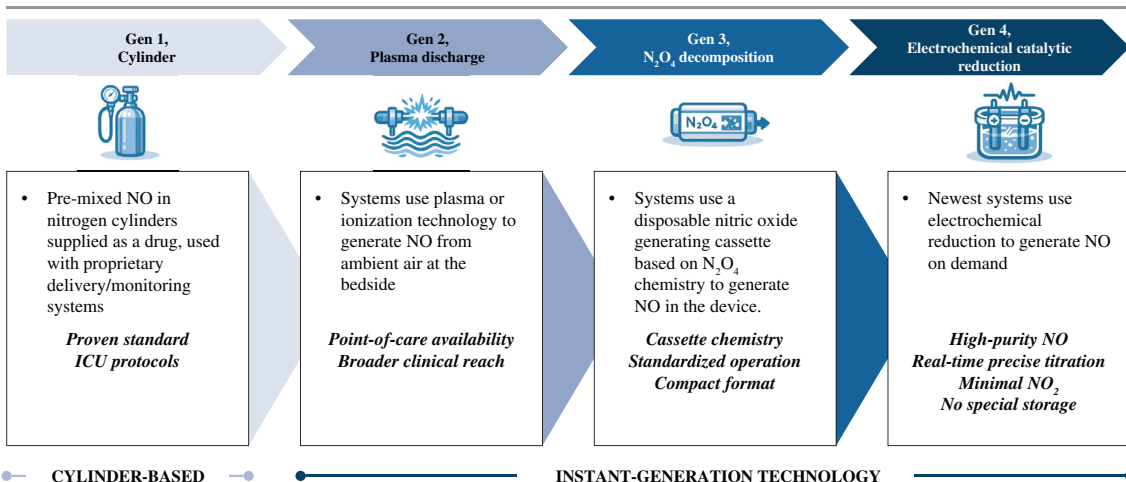
We operate in a underpenetrated and growing global market for NO therapy, driven by the physiological importance of NO and its established clinical utility. Over the past two decades, iNO has become an important therapeutic option across severe cardiopulmonary disease as it can selectively dilate pulmonary vessels and improve oxygenation, enabling lung selective hemodynamic control without compromising systemic blood pressure. A representative example is PPHN. iNO is widely used in NICUs and has been shown to reduce the need for ECMO without increasing mortality or neurodevelopmental impairment. Beyond PPHN, iNO has been increasingly recognized and applied in major indications, including PH, CAP, ARDS and COPD, where rapid, finely titratable and lung selective support is often needed but remains difficult to achieve with existing approaches, severe hypoxemia and respiratory failure, and high burden chronic disease with limited acute rescue and long term management options. According to Frost & Sullivan, in 2025, there were approximately 84.0 million prevalent PH cases and 262.2 million prevalent COPD cases globally, while annual CAP and ARDS cases were approximately 66.6 million and 4.2 million, respectively. These underlying disease populations provide a broad epidemiological base for the clinically relevant high-risk subgroups in which iNO may be used. In parallel, NO is also being explored in broader chronic respiratory conditions such as asthma, which affected approximately 407.0 million people globally in 2025, where exhaled NO may serve as a bio-marker to support diagnosis and longer-term disease management. Beyond these applications, in certain critical-care and perioperative scenarios where patients require both respiratory and circulatory support, iNO therapy may be used together with IABP. The two therapies perform complementary clinical functions: iNO reduces pulmonary vascular resistance and right ventricular afterload, while IABP reduces left ventricular afterload and augments coronary perfusion.

Despite its established clinical value, the widespread adoption of iNO therapy has historically depended on first-generation, cylinder-based delivery systems, which is resource-intensive and structurally cost-heavy, as it typically requires specialized cylinders, trained personnel, reliable supply chain and compliant storage infrastructure. These characteristics have limited the scalability of iNO therapy in emerging markets and in remote or underserved regions of developed countries, and have also constrained the extension of iNO beyond hospital-based care into outpatient pathways, inter-facility transport and home-based settings.

To overcome these structural constraints, the industry has evolved toward instant NO generation technologies, shifting from centralized supply to decentralized, point-of-care production. Second-generation systems, typically based on plasma discharge, are widely used in certain settings to enable bedside NO generation without reliance on cylinder logistics. Third-generation systems further advanced this evolution through N_2O_4 decomposition systems, enabling compact device formats and more standardized consumable-based operation. Fourth-generation electrochemical catalytic reduction generation has emerged to more fully integrate decentralization with clinical-grade control. Our iNOwill system utilizes proprietary fourth-generation technology to generate high-purity NO, combining a cylinder-free form factor with precise dose control and real-time modulation. This approach supports enhanced gas purity and safety assurance while enabling stable, millisecond-level NO delivery and high operational efficiency.

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Evolution of iNO Delivery Generations



Source: Literature Review, Frost & Sullivan Analysis

Our Technology Platform and Product Pipeline

Our gas-liquid precision control technology platform is the cornerstone of our product innovation. It supports end-to-end, closed-loop control of target molecules in both gas and liquid media, spanning generation, real-time sensing and monitoring, and software-enabled regulation. Our platform comprises three integrated technical pillars: (i) NO generation technologies. We have established two NO generation approaches, electrochemical catalytic reduction and plasma discharge, to support different clinical requirements and device configurations; (ii) Gas sensing and molecular monitoring technologies. We have developed complementary sensing capabilities based on electrochemical detection and chemiluminescence to measure NO and other clinically relevant gases and to track respiratory gas composition and dynamics in real time; and (iii) Intelligent flowpath design and control technologies. We have built high-precision, fast-response gas/liquid circuit systems together with proprietary control algorithms to regulate gas release, mixing, flow and timing, supporting breath-synchronized delivery, stable concentration maintenance and safety-oriented fail-safe mechanisms.

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Leveraging our gas-liquid precision control technology platform, we have established a product pipeline as illustrated below:

Segment	Product ⁽¹⁾	Concept/ Application Scenario	Competent Authority/ Registration Classification	Indications	Pre-Clinical	Pipeline Progress Clinical Trials	Registration & Commercialization	Time of Approval	Upcoming Milestone and Timeline
Inhaled NO	★INOwill	iNO (ICU & Inpatient)	NMPA/III ^(a)	PH ⁽¹⁾	China		⁽¹⁾	2022.4	2027Q2 New features upgrade
				COPD	China			-	2027Q2 Registrational trial initiation
				ARDS	China			-	2026Q4 Registrational trial initiation
				CAP	China			-	2029 Registrational trial initiation
	eNOware	iNO (ICU & Inpatient & Transfer)	UDEMI/IIb	PH ⁽¹⁾	China, EU			2025.9	2026Q3 PMCF study initiation
				ARDS	Multi-center (under evaluation)			-	2026Q4 Registrational trial initiation
				PH	the United States			-	2026 Pre-submission review
				ARDS	the United States			-	2028Q1 Registrational trial initiation
	eNOure	iNO (Inpatient & Transfer)	UDEMI/IIb	PH	China		⁽¹⁾	2024.2	Post-approval study
				PH	China	⁽¹⁾		-	2026Q4 Application review
Cardio- pulmonary Circulatory support	VQlit	Portable iNO (Outpatient & At-Home)	NMPA/III	COPD	China	⁽¹⁾		-	2026Q4 Innovative Medical Device Application review
	NovaPulse ▲ IABP	IABP (ICU & Inpatient)	NMPA/III	IABP therapy	China		⁽¹⁾	2025.9	2026Q4 New features upgrade
				Respiratory support+PH				-	2027Q1 Type test
Respiratory Diagnosis	eNOglow	FeNO detection (ICU & Inpatient & Outpatient)	GMPA/II ^(a)	High-precision airway inflammation assessment	China		⁽¹⁾	2024.6	Post-approval study
				Pulmonary function, airway diseases	China	⁽¹⁾		-	2026Q3 Application review
	Pflnak	FeNO detection & Spirometer (Outpatient & At-Home)	GMPA/II ^(a)						
★ Among our product candidates, these class III devices completed the clinical evaluation through comparison of the same variety of medical devices, and the class II devices are exempted from clinical trial requirements									
Core Product	▲ Key Product								

Abbreviations: FeNO=Fractional Exhaled Nitric Oxide. PH=Pulmonary Hypertension. COPD=Chronic Obstructive Pulmonary Disease. ARDS=Acute Respiratory Distress Syndrome. CAP=Community-Acquired Pneumonia.

Notes:

(1) All of our products and product candidates are self-developed.

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- (2) Following our Pre-Submission and subsequent communications with the FDA, the FDA confirmed that iNOWill would be regulated as a Class III device.
- (3) The product has undergone clinical trials that are not required for regulatory registration, in order to generate medical evidence for further product improvement or more effective commercialization.
- (4) Based on our consultations with the relevant Competent Authorities, clinical trials are required for our PRC Indication Expansion and U.S. Registration. On May 28, 2026, we consulted with the Yangtze River Delta Center for Medical Device Evaluation and Inspection of the NMPA (“YDCDEI”) regarding the clinical trial requirements for the proposed expansion of iNOWill into COPD, ARDS and CAP. During the consultation, a Clinical Review Officer of the Review Department advised that registration clinical trials would be required for such indication expansion under the current regulatory framework, primarily because there are no approved equivalent products for these indications. Our PRC legal advisers are of the view that the YDCDEI is the appropriate channel through which we may obtain pre-application communication and guidance from the Center for Medical Device Evaluation of the NMPA (the “CMDE”), and that the review staff member of the clinical group of its Evaluation Department that we consulted with, is competent to address our enquiries in this regard and to provide the relevant confirmation. In late May 2026, we submitted a Pre-Submission to the FDA in relation to our proposed U.S. registration of iNOWill for PH, ARDS and COPD. The FDA provided written feedback in July 2026 and held a formal meeting with us in August 2026. Based on these communications, the FDA indicated that iNOWill would be regulated as a Class III medical device requiring premarket approval (“PMA”) and advised that PH, ARDS and COPD would require new clinical evidence through clinical trials. For the neonatal PPHN indication, the FDA considered it reasonable for a PMA application to rely on comparative evidence consisting of existing published literature, the precedent of the comparable FDA-approved device, non-U.S. real-world evidence, post-market registry data and device nonclinical testing, and based on such feedback we currently expect that a new U.S. clinical trial under an IDE will not be required before submission of a PMA application for that indication. Based on their review of the FDA’s organizational structure and the respective roles of the participating FDA officials, our U.S. legal advisers as to U.S. medical device regulatory matters are of the view that such officials possessed the requisite regulatory authority, technical expertise and institutional competence to provide official guidance regarding the applicable clinical and regulatory requirements for iNOWill.
- (5) iNOWill is registered as a Class III medical device with the NMPA in the PRC and classified as Class IIb in the EU under the EU MDR. At the component level, the NO generation reactor of iNOWill is registered as a Class III medical device with the NMPA and is, in the EU, an accessory to iNOWill N200 classified as Class IIb under the EU MDR, while the tube accessories of iNOWill are applied for registration as a Class II medical device with the Guangxi MPA and are, in the EU, accessories to iNOWill N200 classified as Class IIa under the EU MDR.
- (6) The Class II device is subject to approval and regulatory oversight by the provincial medical products authority, which in this instance is the Guangxi Medical Products Administration.

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Our Commercialization

We possess full-spectrum execution capabilities across the end-to-end product lifecycle — from R&D and clinical development to manufacturing and commercialization — enabling us to implement tailored go-to-market strategies across diverse geographies. In the Chinese mainland, we established ourselves in the iNO therapy market through clinical adoption leadership and a distribution sales model, achieving wide hospital coverage and market leadership. We pursue a two-pronged approach overseas: in emerging markets, we prioritize accessibility and rapid clinical adoption through localized training; in mature markets, such as Europe following our 2025 CE certification, we focus on increasing hospital penetration and engagement to drive the transition from traditional cylinder-based systems to our portable, instant-generation alternatives.

Our Commercialization Strategy of iNOWill

We believe that we can replicate our successful growth trajectory in China to overseas expansion. The sales volume of our Core Product iNOWill grew from 146 units in 2024 to 182 units in 2025. For the six months ended June 30, 2025 and 2026, our sales volume of iNOWill grew from 66 units to 153 units. This sustained growth and market leadership provide strong evidence of our competitiveness and ability to establish market share.

Although the overseas iNO therapy market is currently still dominated by traditional cylinder-based nitric oxide delivery systems, the market is undergoing an underlying transition toward instant-generation technologies. In particular:

- The PRC market demonstrates the commercial viability of instant-generation technologies in a market environment where instant-generation technologies and cylinder-based systems were able to compete simultaneously. As disclosed in the “Industry Overview” section of the Document, when iNO therapy developed in the PRC market, both cylinder-based systems and instant-generation technologies were available in the market. However, conventional cylinder-based iNO therapy had not achieved broad adoption in China given the relatively high cost of imported cylinders, while domestic instant-generation devices gradually established the mainstream delivery model following market entry, supported by guideline endorsement and market education. According to Frost & Sullivan, instant-generation iNO therapy in China grew from RMB16.2 million in 2022 to RMB81.6 million in 2025 and is expected to further increase to RMB2,931.9 million by 2035, representing CAGR of approximately 43.1% from 2025 to 2035. During the same period, the cylinder-based market remained relatively limited in size. Under such competitive market environment, iNOWill achieved the largest market share in the PRC instant-generation nitric oxide delivery market, according to Frost & Sullivan.
- Industry data also supports the increasing global adoption trend of instant-generation technologies. Overseas markets adopted iNO therapy earlier, and traditional cylinder-based systems established the mainstream delivery model before instant-generation technologies became commercially available. As a result, overseas hospitals have historically relied on existing cylinder-based procurement systems, medical gas supply chains and clinical workflows. However, according to Frost & Sullivan, instant-generation technologies are expected to continue gaining share over traditional cylinder-based delivery systems globally. The global instant-generation iNO therapy market is expected to grow from approximately US\$0.11 billion in 2025 to approximately US\$0.49 billion in 2030 and approximately US\$1.40 billion in 2035, representing CAGR of approximately 34.2% from 2025 to 2030 and 23.3% from 2030 to 2035, respectively, significantly exceeding the expected growth rate of traditional cylinder-based systems during the same periods. Such transition is supported by replacement cycles, physician and patient education, market development by industry participants and evolving regulatory and quality requirements in certain markets.

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Second, the transition trend is primarily driven by the product advantages and cost-saving advantages of instant-generation technologies over traditional cylinder-based systems. iNOWill demonstrates operational and product advantages over traditional cylinder-based systems. Unlike cylinder-based systems, iNOWill generates nitric oxide in real time and does not rely on external medical gas factories or cylinder logistics infrastructure. As a result, hospitals are not required to arrange cylinder transportation, storage, replacement or related operational management. In addition, iNOWill features simplified operational procedures, relatively compact equipment size and real-time gas generation capabilities, which improve operational convenience and safety in clinical settings. Such operational advantages may facilitate gradual replacement of traditional cylinder-based systems during hospitals’ equipment upgrade and replacement cycles.

We believe that hospitals have strong incentives in transitioning towards our products. iNOWill offers a clear and compelling cost advantage over traditional cylinder-based nitric oxide delivery systems, which is a key driver for hospital adoption. In addition, iNOWill eliminates the need for cylinder delivery, storage, and handling, thereby removing associated logistics expenses and operational complexity. Importantly, cylinder-based systems also tend to generate avoidable waste. For example, in neonatal emergency settings, a cylinder may only be partially used, with the remaining gas often discarded due to clinical or safety constraints. By contrast, iNOWill produces gas on demand, allowing precise, real-time usage and effectively eliminating such wastage. Taking all these factors into consideration, while conventional cylinders is estimated at approximately \$136,060 per ICU bed annually (US\$57 per treatment hour assuming 2,400 treatment hours per year), according to Frost & Sullivan, iNOWill is estimated to reduce treatment costs to approximately US\$17,500 per ICU bed annually (US\$7 per treatment hour assuming 2,400 treatment hours per year), represents cost savings of approximately 90%. As these figures are estimated based on market research and built on assumptions, it is subject to inherent uncertainties and are subject to change based on various factors. See “Risk Factors — Risks Related to the [REDACTED] — Facts, forecasts and statistics in this document relating to our industry that were obtained from official government publications may not be fully reliable.” In addition, the use of iNOWill can also lead to a relatively short payback period of 6–18 months for hospitals with moderate usage, according to Frost & Sullivan. Given these substantial savings, along with simplified operations and logistics, hospitals have strong economic incentives to transition from traditional cylinder-based systems to iNOWill.

We recorded revenue of RMB45.5 million, RMB63.2 million, RMB22.4 million and RMB58.1 million in 2024, 2025 and the six months ended June 30, 2025 and 2026, respectively. Looking ahead, we are well-positioned to capture significant growth opportunities in the gas-based cardiopulmonary therapeutic and diagnostic device market including the overseas market. Currently, our overseas sales are still at a preliminary stage and we are building our global sales network. For example, iNOWill was certified as a Class IIb medical device for PH under the EU MDR only in September 2025.

Given that the EU CE certification was obtained only on September 30, 2025, iNOWill’s commercialization in the EU contributed only for a limited period in 2025. Against this backdrop, the increase in overseas sales volume from 18 units in 2024 to 40 units in 2025 and the increase in overseas revenue by 106.4% from RMB3.9 million to RMB8.0 million during the same period represent notable commercial progress. Following the EU CE certification of iNOWill in September 2025, we entered into an agreement with a France-based distributor for iNOWill in October 2025, with a contract value of US\$768,000, equivalent of approximately RMB5.3 million. We also recorded shipments to the EU market with an aggregate shipment amount of approximately RMB5.5 million in 2025 and RMB3.8 million for the six months ended June 30, 2026 following the EU CE certification, providing an initial commercial basis for the Company’s expansion into the European market. As of June 30, 2026, our overseas sales volume amounted to 65 units and generated revenue of RMB9.8 million, both of which have already exceeded the record for the entire year of 2025. As we continue to deepen commercialization efforts in the EU, the commercial potential of our overseas business is expected to expand further and the positive commercialization momentum is expected to continue after the Track Record Period.

According to Frost & Sullivan, the global iNO market reached US\$1.05 billion in 2025 and is expected to grow at a CAGR of 8.4% to reach US\$1.58 billion by 2030; the global IABP market reached US\$0.60 billion in 2025 and is expected to grow at a CAGR of 10.1% to reach US\$0.96 billion by 2030; and the global FeNO market reached US\$0.12 billion in 2025 and is expected to grow at a CAGR of 30.4% to reach US\$0.47 billion by 2030. Although our current global market share remains relatively small, this primarily reflects the early stage of our overseas commercialization rather than a lack of market competitiveness. We believe that our differentiated instant iNO generation technology, together with our initiatives in expanding overseas distributor network and marketing activities in Europe, provides a solid foundation for further increasing our market share over time.

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We have been engaging experienced R&D and sales personnel to support our overseas expansions. For example, we cooperate with a CRO to support the PMCF conducted in Europe, which help us carry out clinical studies while efficiently utilizing our in-house medical resources. We also provide product training and technical support to our overseas distributors, who leverage their established local sales channels and customer relationships to conduct customer education, product promotion and after-sales support in their respective markets. The distributorship model allows us to efficiently expand into overseas markets without the need to establish a large local sales force in the initial stage of commercialization. We are actively engaging overseas distributors to help capture overseas market opportunities. As of June 30, 2026, we cooperated with 24 overseas distributors across more than 26 countries and regions. All of our overseas sales were conducted through distributors as of the same date. Engaging distributors is an efficient way to reach wider overseas customers with the distributors’ established sales network in different regions. While the substantial majority of our employees are located in Chinese mainland, we maintain a dedicated team to support our overseas expansion, with 3, 5 and 7 employees as of September 30, 2025, December 31, 2025 and June 30, 2026, respectively. Going forward, we will allocate a portion of our [REDACTED] from the [REDACTED] to support our overseas development. In particular, approximately [REDACTED]%, or HK\$[REDACTED] will be used to grow our overseas business. Specifically, approximately [REDACTED]%, or HK\$[REDACTED], will be used for recruitment of overseas distributors; approximately [REDACTED]%, or HK\$[REDACTED] will be allocated to recruitment of personnel focused on overseas sales and marketing activities, approximately [REDACTED]%, or HK\$[REDACTED] will be used for the participation in high-level overseas academic conferences for iNOWill and approximately [REDACTED]%, or HK\$[REDACTED] will be used for the overseas expert consultancy fees. See “Future Plans and Use of [REDACTED]” for further details.

Our Commercialization Strategy of NovaPulse IABP

We plan to strengthen the synergies between iNOWill and NovaPulse IABP. iNOWill and NovaPulse IABP address different but complementary clinical needs in critical-care and perioperative settings. In clinical scenarios where patients require both respiratory support (offered by iNOWill) and circulatory support (offered by NovaPulse IABP), the two products may be used together as part of the same care pathway. Their complementary functions, overlapping application settings and shared clinical resources enable us to broaden our product offering in ICUs, operating rooms and catheterization laboratories and deepen our engagement with critical-care and cardiovascular departments.

The IABP market in China has historically been supplied predominantly by overseas brands, while the penetration of IABP systems remains limited in a number of hospitals and less-developed regions. We believe that domestically developed IABP systems, supported by local clinical training, maintenance and after-sales services, may facilitate broader access to IABP therapy. We initially plan to focus on cardiology departments, CCUs and catheterization laboratories of leading hospitals and subsequently expand into a wider base of Class III hospitals and selected Class II hospitals.

OUR COMPETITIVE STRENGTHS

Capabilities in Product Development and Market Adoption of Instant-Generation iNO Therapy

We focus on the development and commercialization of iNO therapy for cardiopulmonary indications. We have developed proprietary capabilities across the NO technology chain, spanning NO generation, delivery, monitoring, storage and clinical application. This end-to-end capability enables us to translate NO innovation into products that are safe, portable and adaptable, and to deploy NO-based solutions across multiple cardiopulmonary care settings, including adjacent critical care support and respiratory diagnostics.

We have translated our technological capabilities into a product pipeline. We offer a product portfolio across both therapeutic and diagnostic NO applications, including our Core Product, iNOWill, our Key Product, NovaPulse and the eNOglow analyzer. In addition to achieving regulatory approvals, our products have demonstrated clinical performance and operational advantages, which have supported market adoption. For details of our competitive advantage and product efficiency, see “— OUR PRODUCT PIPELINE — iNOWill — Our Core Product — Competitive Advantages.”

We support the adoption of Instant-Generation iNO Therapy. On the clinical front, we collaborated with leading industry associations to fill application gaps. For example, in 2024, our R&D staff contributed as authors to the Expert Consensus on the Clinical Application of Inhaled Nitric Oxide in Critical and Severe Disease, and our CEO served as a guest expert. We also participated in the revision of the NMPA’s Registration Technical Guidelines for Inhaled Nitric

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Oxide Therapy Devices (《一氧化氮治療儀註冊審查指導原則》). Beyond China, we are supporting the transition from traditional cylinder-based NO systems to portable, instant-generation technologies. According to Frost & Sullivan, we are the first company to obtain EU CE certification for an electrochemical-based NO therapy system. In emerging markets, we have supported clinical adoption by combining product deployment with academic outreach and clinician training. For details of our commercialization activities, see “— OUR COMMERCIALIZATION STRATEGIES” and “— SALES AND MARKETING.”

Proprietary Technology Platform and Differentiated Products

Reliability, Safety and Adaptability Enabled by Our Technology Platform

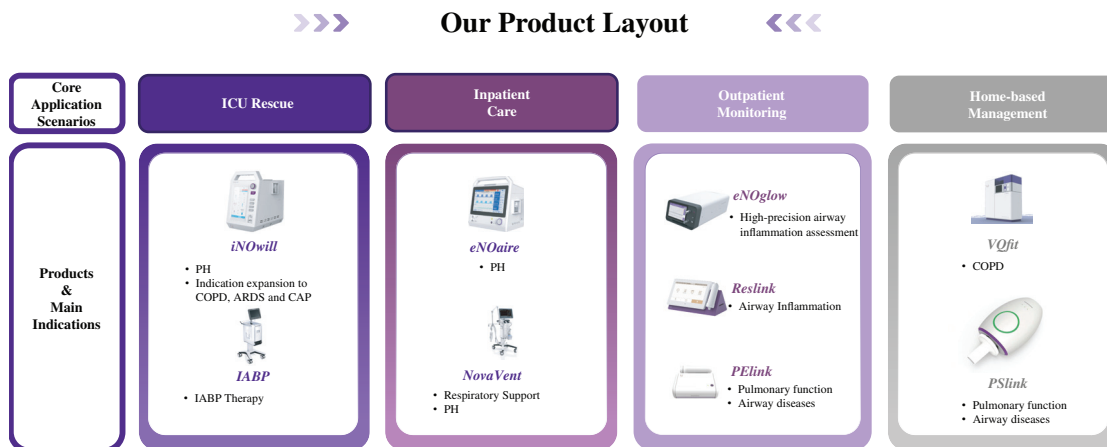
Our gas-liquid precision control technology platform supports deployment across diverse care settings. We generate on-demand NO output across its operating range with electrochemical catalysis, with real-time monitoring of patient-side gas composition and breath-to-breath variability using electrochemical detection and chemiluminescence. Our proprietary control algorithms and high-precision circuit engineering regulate gas release, mixing, flow and timing, supporting breath-synchronized delivery, stable concentration maintenance and safety mechanisms in ICU environments. The algorithms also support real-time dose calculation, automated self-checks, intelligent alarm decisioning and consumable life management. For details, see “— Our Gas-Liquid Precision Control Technology Platform.”

Product Differentiation: iNOWill Setting a New Benchmark

iNOWill is designed to support dosing precision, gas purity and operational safety in clinical deployment. The relevant product specifications include:

(i) *Broad and precisely controllable NO generation range*, (ii) *High output stability and reliable concentration control*, (iii) *Favorable safety profile with rapid therapeutic readiness*, and (iv) *Operational convenience, portability and capacity*. For details of iNOWill’s product specifications, clinical trial results and competitive advantages, see “— OUR PRODUCT PIPELINE — iNOWill — Our Core Product.”

Broad Applications Across the Cardiopulmonary Care Continuum



Across the full continuum of cardiopulmonary care—from ICU rescue, inpatient care to outpatient monitoring and home-based management—we offer a portfolio of gas-based therapeutic and diagnostic devices for use across different care settings. In critical care, iNOWill delivers inhaled NO therapy for neonatal, pediatric and adult ICU patients who require rapid, lung-selective support for severe cardiopulmonary compromise, while NovaPulse IABP provides temporary mechanical circulatory support in ORs, ICUs and cath labs for patients with acute hemodynamic instability where prompt perfusion support is needed; we are also developing NovaVent to integrate mechanical ventilation, iNO delivery and electrical impedance tomography monitoring into an integrated platform for respiratory management. Beyond the ICU, eNOaire extends cylinder-free iNO therapy to general wards and intra-/inter-hospital transport where portability and standardized deployment are critical. In diagnostics, eNOglow enables real-time chemiluminescence-based exhaled NO monitoring through tidal breathing, expanding FeNO use to populations such as neonates, children and ventilated ICU patients, while our Reslink series provides FeNO testing for

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outpatient clinics to support routine airway inflammation assessment and broader access in lower-tier institutions. For home care, VQfit is being developed for chronic respiratory conditions such as COPD, and PELink and PSlink being development to support longitudinal monitoring and remote chronic disease management.

Capabilities Across the Product Lifecycle

We possess capabilities across the full product lifecycle — from research and development, clinical trial and registration, to supply chain management, manufacturing, and commercialization. These capabilities support our product development and commercialization activities.

In-House R&D Capabilities. As of the Latest Practicable Date, we had filed 158 patent applications, among which, 85 patents had been granted, covering key aspects of our technology platform and product portfolio. To date, we have independently or jointly published 18 peer-reviewed scientific articles, including multiple papers in SCI journals with impact factors above 5. For details, see “— RESEARCH AND DEVELOPMENT.”

Clinical Trial and Registration Execution. We maintain a clinical and regulatory team. In China, we have participated in or supported approximately 20 clinical trials, involving more than 50 hospitals. Internationally, we have established research collaborations in Europe and the U.S., with our Core Product iNOwill having received EU CE certification and having completed a Pre-Submission consultation with the FDA in relation to the proposed U.S. registration of iNOwill. We are also actively involved in global multicenter research. For example, we are participating in a Phase III, double-blind, international multicenter randomized study evaluating perioperative iNO in adults undergoing cardiac surgery with cardiopulmonary bypass. For details, see “— OUR PRODUCT PIPELINE — iNOwill — Our Core Product.”

Supply Chain and Manufacturing. We have built a multi-site manufacturing network covering different product categories, supporting production capacity and compliance with applicable quality standards. We have internally developed a wide range of core components to reduce dependency on standardized imported parts and improve performance, stability, and cost control. These include NO-resistant coatings, humidity-controlled sampling tubes and electrochemical NO sensors. These components have been deployed commercially and also sold independently, particularly our ppb-level NO sensors which have provided an alternative to products supplied by multinational suppliers. For details, see “— MANUFACTURING.”

Commercialization Strategy Across Domestic and Overseas Markets. In the Chinese mainland, we commercialize our products. We adopt a hybrid academic promotion and distributor model, covering 31 provinces and almost 700 hospitals as of the Latest Practicable Date. Overseas, we pursue a strategy across emerging and mature markets. As of the Latest Practicable Date, our products had been commercialized in 10 overseas countries and regions, including France and Hungary.

Experienced Global Leadership Team Empowered by Strategic Investors

We are led by an experienced and highly complementary global management team with deep expertise across biomedical research, product innovation, and commercial execution. Dr. Wen Mao, our Chief Executive Officer, has nearly 20 years of experience across academic research and industry commercialization. Mr. Zhang Yuyan, our Chief Technology Officer, has nearly 20 years of experience in high-end medical device R&D and engineering management. Mr. Junlin Ou, our Vice President of Business, has over 20 years of experience across pharmaceuticals, medical devices, diagnostics, and healthcare media. Our management team’s capabilities are further strengthened by the strong support of reputable institutional investors, including Suzhou Lirun and Northern Light Venture Capital. These shareholders provide not only long term capital support, but also strategic resources, industry insights, and access to global networks.

OUR GROWTH STRATEGIES

We believe that our eight years of dedicated and independent exploration and accumulation in the field of iNO treatment, our comprehensive patent portfolio and independent intellectual property rights, and our developed technology platform are designed to help address practical barriers associated with iNO therapy devices. We aim to bring iNO therapy to a wider population and make advanced cardiopulmonary care more convenient, inclusive and widely available. Building on these foundations, we intend to pursue the following strategies to further grow our business.

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Building a Comprehensive iNO-Centric Ecosystem Covering Multiple Indications and Care Scenarios

We are committed to addressing critical clinical needs across cardiopulmonary, respiratory, and anti-infection settings. Central to this commitment is the continued expansion of our iNO therapy pipeline into a broad, multi-indication and multi-scenario clinical ecosystem.

Indication Expansion Across Respiratory Diseases. Leveraging our proprietary instant generation NO technology, we aim to extend the clinical application of iNO therapy from PH to additional high need respiratory conditions such as ARDS, CAP and COPD. We will pursue staged clinical development and regulatory filings for these additional indications, accelerating iNO therapy adoption across the spectrum of respiratory disease. Specifically, approximately [REDACTED]%, or HK\$[REDACTED], of the net [REDACTED] from the [REDACTED] will be used to fund ongoing and planned clinical trials of iNO will for indication-expansion in the PRC, including clinical trials in ARDS, CAP and COPD. See “Future Plans and Use of [REDACTED]” for details.

Multi-Scenario Commercial Penetration. We will prioritize a staged commercialization strategy aligned with indication expansion. Our initial focus will be on establishing clinical benchmarks in ICU and critical care settings, followed by systematic penetration into general hospital wards and outpatient clinics. Ultimately, we intend to support home-based treatment scenarios, adapting product forms and service models to meet the distinct needs of each care environment.

Product Candidate Development. For outpatient and home maintenance therapy, our portable iNO device VQfit will advance clinical research into COPD and other chronic respiratory conditions. These product indication strategies are designed to unlock sustained market uptake and expand the overall addressable patient population. Approximately [REDACTED]%, or HK\$[REDACTED], will be used for the development and registration of our other products and product candidates, such as VQfit, PELink and PSLink, NovaVent and eNOaire in the EU. See “Future Plans and Use of [REDACTED]” for details.

Market Outlook and Synergy. With domestic iNO therapy markets expected to grow rapidly in the coming years, the continued expansion of indications and care scenarios positions us to steadily increase market share and expand our coverage of clinical use cases. Our long term objective is to create a comprehensive iNO enabled clinical ecosystem underpinned by diversified indication and application portfolios, strengthening our leadership position in gas based cardiopulmonary care.

Leveraging Our ICU Presence and Technology Synergies to Broaden the Cardiopulmonary Diagnostic and Therapeutic Pipeline

We will accelerate the development of subsequent product lines to complete a diagnostic to therapy clinical continuum and expand our cardiopulmonary product matrix across care scenarios.

Strengthening Synergies Between iNOwill and Our Cardiopulmonary Circulatory Support Product Line. Building on our medical device R&D and system integration capabilities, we are continuing the commercial development of NovaPulse IABP and its related consumables. iNOwill and NovaPulse IABP address different but complementary clinical needs in critical-care and perioperative settings. iNO therapy reduces pulmonary vascular resistance and right ventricular afterload, while IABP provides temporary circulatory support by reducing left ventricular afterload and augmenting coronary perfusion. In clinical scenarios where patients require both respiratory and circulatory support, the two products may be used together as part of the same care pathway. Their complementary functions, overlapping application settings and shared clinical resources enable us to broaden our product offering in ICUs, operating rooms and catheterization laboratories and deepen our engagement with critical-care and cardiovascular departments.

Completing a Full Cycle Diagnostics and Therapy Loop — NO Breath Testing and Home Diagnostics. We plan to expand our respiratory diagnostics portfolio, including portable FeNO devices. This suite will enable continuous airway inflammation monitoring and directly link diagnostic insights to therapeutic planning, enabling a “detect-treat-follow up” management loop.

Expanding into Home-based Chronic Respiratory Disease Management

We plan to extend our product portfolio from hospital-based acute intervention and clinical diagnostics to the long-term management of chronic respiratory diseases in home settings. We are developing PELink for home-based pulmonary function monitoring and VQfit as a portable therapeutic product for outpatient and at-home use. Together, these products are intended to support an integrated pathway covering home-based diagnosis, treatment and longitudinal monitoring.

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Expanding Our Global Business Footprint Through Targeted Overseas Commercialization

We will continue to strengthen our global presence, leveraging our leadership position in core Asian markets while progressively expanding into major Western markets with differentiated development and commercialization strategies. In North America, we will finalize a clear regulatory and registration roadmap for our iNO therapy to support subsequent FDA filings. Aligned with regulatory availability, we will coordinate regional commercialization efforts through “registration driven sales” strategies. iNO therapy products will be prioritized for market introduction, with diagnostic products trialed in select countries to build early adoption and clinical familiarity. In Asia Market, we have already established commercial presence in emerging markets. These early successes provide important footholds for broader regional expansion. In the EU market, we will initiate post-market clinical trials and multicenter collaborations with local key opinion leaders (KOLs) to develop region specific evidence packages. We plan to use approximately [REDACTED]%, or HK\$[REDACTED] of [REDACTED] from the [REDACTED], for planned PMCF and indication-expansion clinical trials in the European Union. In North American market, we will finalize and implement a clear sales and partnership strategy of iNOwill for the U.S. market, once regulatory clearance is obtained. We plan to use approximately [REDACTED]%, or HK\$[REDACTED] of [REDACTED] from the [REDACTED], for clinical validation and registration of iNOwill for indications including PH and ARDS in the United States. See “Future Plans and Use of [REDACTED]” for details.

Strengthening Commercial Execution to Solidify Regional Leadership

We will continue to deepen our commercialization capabilities and reinforce our positions in existing markets through targeted, data driven execution strategies.

End to End Hospital Coverage. We will extend coverage across hierarchical medical institutions — from tertiary hospitals to community level facilities — matching product specialization with institutional needs. In support of this effort, we will synchronize the rollout of digital chronic disease management tools to complement product use and enhance patient outcomes.

Academic and KOL Driven Market Penetration. Our commercialization strategy is anchored by academic engagement, KOL networks, and strategic hospital penetration. We will continue to establish clinical evidence, cultivate opinion leader support, and drive adoption across all care levels.

Expansion of Commercial Teams. In response to rapid business growth, we will continue to expand our marketing and sales teams, with a focus on refined distributor management, core hospital engagement, and deeper regional operational capacity. Key markets will be prioritized, with tailored local support to accelerate adoption.

Enhancing Our R&D Infrastructure and Manufacturing Capabilities to Support Sustainable Growth

We will invest in infrastructure and talent to support the next phase of technological innovation, capacity expansion, and operational excellence. We plan to upgrade our R&D infrastructure and product line automation to support continuous innovation and enhance our capability to manufacture high-quality products at scale. Approximately [REDACTED]%, or HK\$[REDACTED], will be used for this purpose. See “Future Plans and Use of [REDACTED]” for details.

Frontier Technology Exploration. We will increase R&D investment in advanced technologies by exploring the integration of NO technology with artificial intelligence, patient self-management, and other frontier fields. This will enable the development of smarter, more precise gas-based diagnostic and therapeutic systems and deepen our intellectual property moat.

Production Capacity Optimization. To meet growing market demand, we will optimize production, introducing automated production lines and strengthening production capabilities. Concurrently, we will scale production teams to improve operational efficiency and ensure consistent product quality.

Talent Development and Organizational Capability Building. Leveraging the global vision of our founding team, we will recruit top R&D, manufacturing, and supply chain talent from around the world and build a professional talent pipeline. This approach will provide foundational support for technological upgrades, capacity expansion, and advanced supply chain execution.

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OUR PRODUCT PIPELINE

As of the Latest Practicable Date, we had five approved products and five product candidates under development. Our product pipeline covers critical care, inpatient, outpatient and home-based disease management for cardiopulmonary care, and consists of three major product lines: (i) iNO therapy, (ii) cardiopulmonary circulatory support, and (iii) respiratory diagnostics.

All of our products and product candidates are developed in-house, and we retain global rights to them through active patent registrations and proprietary technical know-how. In particular, we have received regulatory approvals for our products in jurisdictions such as Chinese mainland; EU; Indonesia; Taiwan, China; Malaysia; UK; UAE; Vietnam and Turkey. In the future, we plan to enter into jurisdictions, including the United States, Uzbekistan, Saudi Arabia, Philippines, Israel, Hong Kong, Japan, South Korea, Oman, Mexico, Colombia, Australia, Brazil, Canada and Costa Rica. For details, see “— Overview — Our Technology Platform and Product Pipeline” and “— iNOWill — Our Core Product — Material Communications with Competent Authorities.” Our integrated R&D and manufacturing capabilities enable us to design core components such as electrochemical NO sensors and gasflow sensors and to deploy them across multiple product lines. During the Track Record Period, we primarily generated revenue from the sale of hospital-use therapeutic products through distributors, who then supplied them to medical institutions. In addition, we recorded a small portion of revenue from contract development services where we conduct product development for customers based on our R&D capabilities and maintenance services provided to customers after the sales of products.

iNO THERAPY

As of the Latest Practicable Date, our iNO portfolio comprised two commercial-stage products, iNOWill (our Core Product) and eNOaire, and one product candidate, VQfit. iNOWill is positioned primarily for ICU and hospital bedside use, and has been registered as a Class III medical device in China for PH since 2022 and certified as a Class IIb medical device for PH under the EU MDR since 2025. eNOaire is designed for hospital and transfer scenarios where portability and simplified deployment are particularly relevant, and has been registered as a Class III medical device in China for PH since 2024; we expect to start preparing for CE certificate application in the first quarter of 2026. VQfit is our clinical-stage portable iNO product candidate for outpatient and at-home scenarios to address COPD; we expect to submit innovative medical device application in China in the second quarter of 2026.

Our Core Product forms the foundation of our iNO therapy portfolio. Our other iNO therapy products, including eNOaire and VQfit, were subsequently developed based on this foundation and share certain common technical principles. Our Core Product and our other iNO therapy products differ primarily in their NO generation technologies, intended use scenarios and product design. The principal differences among iNOWill, eNOaire and VQfit in terms of their NO generation technologies, generation and output characteristics, product design and portability, and intended clinical scenarios and care settings are summarized below.

Comparison item	iNOWill (Core Product)	eNOaire	VQfit
<i>NO generation technology</i>	Electrochemical NO generation technology	Plasma discharge technology	Plasma discharge technology
<i>Generation and output characteristics</i>	Supports high-purity NO generation and stable, millisecond-level NO delivery, with a maximum NO concentration of 200 ppm. The higher output supports potential future higher-concentration iNO therapy scenarios, and allows the required therapeutic NO concentration to be delivered with less impact on the overall gas flow through the ventilator circuit.	Maximum NO concentration of 80 ppm; not designed for ICU scenarios requiring high-concentration NO therapy.	Plasma discharge generation designed for its wearable and portable configuration.

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Comparison item	iNOwill (Core Product)	eNOaire	VQfit
<i>Product design and portability</i>	Relatively larger device configuration due to the design requirements of the electrochemical generation technology and reactor system; primarily designed for bedside use rather than patient transfer or home use.	Lighter device design; can operate without connection to an external power supply; and does not require a replaceable NO generation reactor.	Wearable and portable device design.
<i>Intended clinical scenarios and care settings</i>	ICU, NICU and other inpatient settings for critically ill patients requiring precise respiratory support.	Inpatient and patient transfer scenarios where portability and simplified deployment are particularly relevant.	Outpatient and home-based applications, particularly the long-term management of chronic respiratory diseases.

Based on the above, our Directors are of the view that iNOwill, eNOaire and VQfit are complementary products designed for distinct clinical scenarios and care settings, with no material potential for cannibalization among them.

Case Studies for application of our iNO Therapy products

#1 NICU. A newborn with PPHN secondary to meconium aspiration developed severe hypoxemia and required mechanical ventilation. The NICU team initiated iNO therapy using iNOwill for approximately 70 hours, after which the infant was successfully weaned off iNO and ventilatory support as oxygenation improved.

#2 Inter-hospital Transport. A 26-week premature infant with severe BPD and PH required an approximately six-hour transfer from Kunming to Guangdong. The transport team used eNOaire to maintain continuous iNO therapy with ventilatory support during the transfer, enabling continuity of care upon arrival at the receiving NICU.

#3 ICU. An adult patient developed severe respiratory failure with refractory hypoxemia. The ICU team added iNO therapy using iNOwill alongside prone positioning and standard ventilatory measures, with oxygenation improving within 24 hours and subsequent weaning from mechanical ventilation.

iNOwill — Our Core Product

iNOwill, our Core Product, is a portable iNO therapy device that generates medically usable NO on demand at the point of care and integrates NO generation, delivery and real-time monitoring into a single system. iNOwill delivers iNO as a selective pulmonary vasodilator to provide support to patients with severe cardiopulmonary disease in acute and critical care settings. It is primarily positioned for ICU and hospital bedside use, including neonatal, pediatric and adult ICUs, and perioperative cardiac and respiratory care settings for the management of cardiopulmonary disease such as PPHN, PH, ARDS and COPD.

Product Structure

iNOwill comprises the main unit, the NO generation reactor and the tube accessories, as illustrated in the table below. These three components are designed to function together as a single iNO therapy system. In the PRC, iNOwill has been approved by the NMPA as an integrated system for PH and is classified as a Class III medical device. The NO generation reactor is separately registered with the NMPA as a Class III medical device, while we have applied to register the tube accessories with the Guangxi MPA as a Class II medical device. Under the EU MDR, iNOwill and the NO generation reactor are classified as Class IIb, while the tube accessories are classified as Class IIa. Although the NO generation reactor and the tube accessories are classified in their own right as accessories, they are designed for use with iNOwill and are covered by the same EU Declaration of Conformity and EU quality management system certificate. That certificate records no conditions or limitations to its validity.

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Component	Function	Risk Classification /Competent Authorities	Consumables	Lifetime
Main unit	The main unit integrates key functional components, including the nitrogen module to generate nitrogen as the carrier gas, electrochemical NO/NO ₂ /O ₂ sensors to monitor gas concentrations, and control and display components for system operation and parameter adjustment.	No distinct registration approval	N	Seven years
NO generation reactor	A replaceable NO generation reactor that generates nitric oxide for therapeutic use.	PRC (NMPA): III EU (UEM): IIb	Y	120-500 hours
Tube accessories . .	Gas tubing comprising tube accessories intended for use with the system to enable delivery of nitric oxide (NO) gas into the inspiratory limb of the patient’s breathing circuit.	PRC (Guangxi MPA): II EU (UEM): IIa	Y	Single-use tubes or reusable tubes (approximately 60-100 uses)

Based on the NMPA regulatory approval, the main unit, the NO generation reactor and the tube accessories may be manufactured by us or by third-party suppliers that are qualified and compliant with applicable regulatory requirements. As of the Latest Practicable Date, we manufactured the main unit in-house and engaged qualified third-party suppliers to manufacture the NO generation reactor and tube accessories in accordance with our specifications and quality requirements. Upon delivery, we conduct final inspection of these components and complete the final assembly of the integrated iNOWill system. We adopted this arrangement primarily because establishing and maintaining dedicated production lines for the NO generation reactor and tube accessories would require additional capital expenditure and result in higher production costs. The main unit, the NO generation reactor and the tube accessories are designed by us and approved to function together as components of the integrated iNOWill system. Although the NO generation reactor and tube accessories are manufactured by qualified third-party suppliers in accordance with our specifications and quality requirements, they are not interchangeable with corresponding components designed by other manufacturers. iNOWill is compatible with ventilator circuits developed by third-party manufacturers.

Available Models

iNOWill is available in four main unit models (N100, N200, N300 and N350) and four compatible NO generation reactor models (INO-W1, INO-W2, INO-W3 and INO-W4). The main unit models incorporate the same core electrochemical nitric oxide generation technology and intended use, with differences primarily relating to functional configuration and operating specifications. The compatible NO generation reactor models primarily differ in their service life. The principal features of each model are summarized below.

Main unit model	Principal features
N100	Base configuration supporting the core functions of iNOWill, including electrochemical NO generation, continuous NO/NO ₂ /O ₂ monitoring, alarm management, high-frequency oscillatory ventilation (HFOV) compatibility, flow-sensor heating and dynamic current control.
N200	Includes all functions of the N100 model and further incorporates environmental NO monitoring to support environmental gas monitoring during clinical use.
N300	Includes all functions of the N200 model and further incorporates a simplified high-flow nasal cannula (HFNC) mode (without a flow sensor), synchronization-rate display and an expanded standard hardware configuration (including a medical trolley, medical air compressor and uninterrupted power supply (UPS)).

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Main unit model	Principal features
N350	Includes all functions of the N200 model and further supports a broader range of optional hardware configurations and accessories to accommodate different operational requirements.

Reactor model	Service life
INO-W1 . .	Approximately 120 operating hours
INO-W2 . .	Approximately 200 operating hours
INO-W3 . .	Approximately 300 operating hours
INO-W4 . .	Approximately 500 operating hours

The following chart illustrates the display and main unit with NO generation reactor of iNOwill.



Operation Procedure

The following chart illustrates the operation procedure of iNOwill.

- (i)

Install NO generation reactor into its slot and connect iNOwill gas tubing into the ventilator circuit.
- (ii)

Set the target NO concentration and alarm concentration limits for NO, NO₂ and O₂ on the graphical interface. We determine the factory-default alarm concentration limits based on safety considerations and typical clinical use. The default high and low alarm limits for NO are 30 ppm and 0 ppm, respectively, as NO therapy is generally administered at 20 ppm; the default high alarm limit for NO₂ is 3 ppm to limit exposure to this potentially toxic by-product; and the default high and low alarm limits for O₂ are 100% and 18%, respectively, with the 18% threshold providing an early warning against hypoxia relative to the normal atmospheric oxygen concentration of approximately 20.93%. During treatment, physicians may adjust the NO high and low alarm limits within the permitted ranges as illustrated in chart below based on the prescribed NO concentration and the patient’s condition.

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Alarm concentration limits may be preset for NO (5–200 ppm for the high limit and 0–195 ppm for the low limit), NO₂ (1–50 ppm for the high limit) and O₂ (21%–100% for the high limit and 18%–99% for the low limit).

During treatment, iNOWill generates NO in the reactor and injects it into the ventilator circuit in synchrony with the measured ventilator waveform to deliver the prescribed NO concentration. The device continuously monitors NO, NO₂ and O₂ concentrations in the mixed gas and issues an alarm if any monitored concentration exceeds, or where applicable falls below, the preset alarm limit.

Mechanism of Action

iNO acts as a selective pulmonary vasodilator. When delivered via the respiratory circuit, NO reaches ventilated alveoli and diffuses into the pulmonary vasculature, where it activates the guanylate cyclase-cGMP pathway, relaxes pulmonary vascular smooth muscle, reduces pulmonary vascular resistance and lowers pulmonary artery pressure. iNOWill is designed to apply this mechanism in a controlled and verifiable manner at the bedside. The device generates NO on demand via an electrochemical reduction process in the NO generation reactor, introduces the therapeutic gas into the inspiratory limb of the respiratory circuit, mixes it with the ventilator gas stream and deliver to the lung of the patients.

Competitive Advantages

Building on our electrochemical instant-generation NO technologies, the iNOWill series replaces the traditional “gas factory + cylinder logistics” paradigm with a “device + reactant” model and is designed to offer key competitive advantages, including: (i) broad, precisely controllable NO generation using a proprietary electrochemical reactor and integrated nitrogen module that produces approximately 390–3,500 ppm NO on demand, (ii) high output stability and reliable breath-by-breath concentration control through high-frequency flow sensing and embedded algorithms that synchronize NO injection with the inspiratory waveform across different ventilation modes, (iii) a favorable safety profile with rapid therapeutic readiness, reaching target NO levels in about two minutes while maintaining NO₂ typically <1 ppm at the delivery terminus, supported by gas-path purification, continuous NO/NO₂/O₂ monitoring and integrated alarm and purge logic, (iv) operational convenience and bedside portability through a disposable NO generation reactor that avoids cylinder replacement and, according to Frost & Sullivan, provides an approximate one-fifth bedside footprint and about five times the effective bedside gas capacity per replacement compared with traditional cylinder-based systems, and (v) improved logistics, economics and accessibility by reducing reliance on cylinder transport, storage and centralized gas plants and lowering total cost of ownership, thereby supporting wider adoption of iNO therapy in secondary and lower-tier hospitals and in regions with unstable cylinder supply.

Market Opportunity and Competitive Landscape

Globally, instant-generation iNO systems accounted for about US\$0.11 billion in 2025 and are forecast to reach approximately US\$0.49 billion by 2030 at a CAGR of 34.2%, far outpacing the low single-digit growth expected for cylinder-based workflows. In China, the iNO therapy market was approximately US\$12.5 million in 2025 and is projected to grow to about US\$66.9 million by 2030, at a CAGR of 39.6%, with instant-generation platforms already representing around 91% of market value. While the global market remains dominated by established cylinder-based drug-device franchises in the United States and European Union, instant-generation alternatives have gradually gained shares, and iNOWill is one of the instant-generation iNO providers to capture the trend. For details, see “Industry Overview — Global iNO Therapy Market.”

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Development Timeline and Milestones

The table below summarizes the key development milestones of iNOwill.

Year	Key Milestones
2019	Initiated iNOwill R&D and technology validation
2020-2024 .	Filed core patents
2022	Obtained NMPA Class III medical device registration certificate
2022-2023 .	Conducted two clinical trials for postoperative PH in pediatric and adult patient populations that support EU CE certification (collectively, the “ Clinical Trials ”) in collaboration with collaborative hospitals, undertook sponsor equivalent obligations and was treated as the sponsor of the Clinical Trials by the UDEM for the purposes of the CE certification.
2023	Submitted application for CE certification Registered with Indonesian Ministry of Health
2024	Registered with Taiwan TFDA registration; developed and launched Taiwan-specific system variant Achieved cost reduction for the console and reaction module Extended the reaction module service life to 500 operating hours
2025	Obtained CE certification (Class IIb) under EU MDR via UDEM Submitted NMPA registration amendment to enhance oxygen concentration monitoring sensitivity Filed and obtained NMPA Class III medical device registration certificate for NO generation reactor of iNOwill Registered with Turkey Ürün Takip Sistemi
2026	Registered with Medical Device Authority of Malaysia, the United Arab Emirates and the MHRA of the United Kingdom

Following receipt of the NMPA Class III medical device registration certificate in April 2022, we commenced commercialization of iNOwill in the Chinese Mainland by making our first commercial shipment in September 2022. Following receipt of the EU CE certification in September 2025, we made our first commercial shipment of iNOwill to the EU in November 2025. As of the Latest Practicable Date, we had also made commercial shipments of iNOwill to certain other overseas markets, including Indonesia, Taiwan, Vietnam, Türkiye, Malaysia and the United Arab Emirates, with the earliest such shipment made to Indonesia in September 2023.

Material Communications with Competent Authorities

Chinese Mainland — The NMPA and Guangxi Medical Products Administration (the “Guangxi MPA”). In April 2021, we submitted a Class III medical device registration application for iNOwill to the NMPA. In April 2022, we obtained a Class III medical device registration certificate from the NMPA for iNOwill as an integrated system for PH, comprising the main unit, the NO generation reactor and the tube accessories. These components function together, and are regulated, as one integrated iNO therapy system; the subsequent separate registration of certain components did not change the integrated nature of iNOwill. For purposes of such NMPA approval, we conducted the clinical evaluation of iNOwill through comparison with the same variety of medical devices from February 2021 to April 2021, and no registrational clinical trial was required. In May 2025, we submitted a registration amendment application in relation to an upgrade of the oxygen-concentration monitoring sensitivity and related performance specifications of the registered product, and subsequently obtained the Medical Device Change Registration (Filing) Certificate (the “**Change Certificate**”) from the NMPA on March 3, 2026. The registration amendment application is a change to the product technical requirement. Our PRC Legal Advisor confirmed that the Change Certificate does not affect the validity of the original NMPA registration approval for the Core Product and that the Change Certificate is to be used together with it. On December 23, 2025, we obtained a separate Class III medical device registration certificate for the NO generation reactor from the NMPA. In March 2026, we submitted a Class II medical device registration application for the tube accessories to the Guangxi MPA, which had not been approved as of the Latest Practicable Date. Under the applicable PRC medical device regulatory framework, registration units are principally delineated by reference to a product’s technical principles,

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structural composition, performance indicators and scope of application. Accordingly, a component may be registered under a separate registration unit while continuing to form part of, and function only within, an integrated medical device system. The staggered timing reflected our subsequent registration approach for the replaceable consumable components following the original approval of iNOWill as a complete product, rather than the separate development of these components. We pursued separate registration of the NO generation reactor and tube accessories because they have finite service lives, may require replacement during routine clinical use and may be supplied separately for use with iNOWill. On May 28, 2026, we consulted with the Yangtze River Delta Center for Medical Device Evaluation and Inspection of the NMPA (“YDCDEI”) regarding the clinical trial requirements for the proposed expansion of iNOWill into COPD, ARDS and CAP. During the consultation, a Clinical Review Officer of the Review Department advised that registration clinical trials would be required for such indication expansion under the current regulatory framework, primarily because there are no approved equivalent products for these indications. Our PRC legal advisers are of the view that the YDCDEI is the appropriate channel through which we may obtain pre-application communication and guidance from the Center for Medical Device Evaluation of the NMPA (the “CMDE”), and that the review staff member of the clinical group of its Evaluation Department that we consulted with, is competent to address our enquiries in this regard and to provide the relevant confirmation.

European Union — UDEM. We initiated preparation for CE certification of iNOWill in July 2022 and submitted an application to UDEM under the EU MDR in 2023. On September 30, 2025, UDEM issued an EU quality management system certificate under Annex IX, Chapters I and III to the EU MDR covering iNOWill N200 as a complete product, together with the NO generation reactor and the tube accessories as its accessories. Under the EU MDR, iNOWill and the NO generation reactor are classified as Class IIB, while the tube accessories are classified as Class IIA. Although the NO generation reactor and the tube accessories are classified in their own right as accessories, they are designed for use with iNOWill and are covered by the same EU Declaration of Conformity and EU quality management system certificate. The certificate identifies us as the manufacturer.

The table below summarizes the respective regulatory pathways and our corresponding communication responsibilities regarding the Clinical Trials in China and EU.

Jurisdiction/ Regulatory Body	Clinical Trial Requirement	Our Role and Communication Responsibilities
China (NMPA)	Not required for NMPA	The Clinical Trials did not involve communications with the NMPA, as they were not registrational trials required for the NMPA medical device approval. Prior to the commencement of the Clinical Trials, we prepared relevant materials, including research protocol, informed consent forms and the ethical review application, to the hospital ethics committee of the collaborating hospitals.
EU (UDEM)	Required by UDEM in accordance with EU MDR	Pre-trial phase: We engaged in multiple rounds of communication with UDEM regarding the necessity of clinical trials. UDEM concluded that the Equivalence Route was not applicable due to the novel technical features of the device, and that clinical trials would therefore be required to support CE certification. In response, we revised its clinical evaluation strategy to adopt self-generated clinical investigations and submitted a draft clinical investigation plan, covering both the ongoing Pediatric Trial and the proposed Adult Trial, to UDEM. UDEM subsequently reviewed and confirmed the proposed investigation plan. Clinical phase: We led confirmation that the trial design and execution were in accordance with Annex XV of the MDR. Post-trial phase: We prepared the Clinical Evaluation Report (CER), responded to UDEM’s review comments, and finalized the submission. UDEM expressly endorsed the Clinical Trials as “the manufacturer’s own clinical trials,” stating in its Clinical Evaluation Assessment Report that these “directly met the purpose of demonstrating the clinical performance and utility of the device,” and confirming that the results were used to validate iNOWill’s conformity with the applicable safety and performance requirements under the MDR.

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Jurisdiction/ Regulatory Body	Clinical Trial Requirement	Our Role and Communication Responsibilities
		We are preparing to conduct PMCF in Europe, which serves as a part of the ongoing regulatory oversight measures for the UDEM to further validate the safety and performance of certified medical devices in a real-world setting. We will act as the sponsor of trials for PMCF and trials to support application of iNOWill for more indications, and will be responsible for their design, implementation and related regulatory communications.

Note: UDEM, through its Sales Director for China, who acted as its principal contact for the iNOWill’s CE certification, confirmed that clinical trials were required to support CE certification and that we undertook sponsor-equivalent obligations in the Clinical Trials and were treated by UDEM as the sponsor. Our EU legal adviser is of the view that the Sales Director for China, as UDEM’s principal contact for our CE certification process, was competent, in the ordinary course of such person’s responsibilities, to provide UDEM’s confirmation regarding our role as the sponsor for purposes of the CE certification.

United States — The FDA. In late May 2026, we submitted Pre-Submission to the FDA in relation to the proposed U.S. registration of iNOWill. The FDA issued written feedback on July 27, 2026 and held a formal meeting with us on August 4, 2026. Based on these communications, the FDA indicated that iNOWill would be regulated as a Class III medical device requiring premarket approval (“PMA”). The FDA advised that PH, ARDS and COPD would require new clinical evidence through clinical trials. For the neonatal PPHN indication, the FDA considered it reasonable for a PMA application to rely on comparative evidence consisting of existing published literature, the precedent of the comparable FDA-approved device, non-U.S. real-world evidence, post-market registry data and device nonclinical testing, and based on such feedback we currently expect that a new U.S. clinical trial under an IDE will not be required before submission of a PMA application for that indication. Based on their review of the FDA’s organizational structure and the respective roles of the participating FDA officials, our U.S. legal advisers as to U.S. medical device regulatory matters are of the view that such officials possessed the requisite regulatory authority, technical expertise and institutional competence to provide official guidance regarding the applicable clinical and regulatory requirements for iNOWill.

Other Jurisdictions. In Indonesia, iNOWill obtained a medical device approval from the Ministry of Health on May 30, 2023, which classifies iNOWill as a Class C non-radiation electromedical device. The approval was issued to PT Sinovac Biotech Indonesia as the registrant and identifies Novlead as the manufacturer, and is valid until February 2028. In Taiwan, China, iNOWill obtained a Medical Device Registration License from the Taiwan Food and Drug Administration on April 6, 2024, which classifies iNOWill as a Class D device. The license was issued to Xinzhen Instrument Co., Ltd. (信正儀器有限公司) as the local medical device firm and identifies Novlead as the manufacturer, and is valid until April 2029. In Vietnam, iNOWill completed a Class B medical device declaration with the Hanoi Department of Health on September 8, 2025. The declaration was made by CÔNG TY TNHH THIẾT BỊ Y TẾ MINH ANH as the declarant and identifies Novlead as the product owner and manufacturer, and does not have a fixed expiry date. In Turkey, iNOWill registered with Ürün Takip Sistemi on December 29, 2025 as a Class IIb medical device. The certificate was issued to KEYVAC BİYOLOJİK ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ as the authorized representative and identifies Novlead as the manufacturer, and does not have a fixed expiry date. In Malaysia, iNOWill obtained a Medical Device Registration Certificate from the Medical Device Authority of Malaysia on April 15, 2026, which classifies iNOWill as a Class C medical device. The certificate was issued to Medifocus Supplies Sdn. Bhd. as the authorized representative and identifies Novlead as the manufacturer, and is valid until April 14, 2031. In the United Arab Emirates, iNOWill obtained a classification certificate on April 7, 2026. The certificate was issued to VIRTUS MEDICAL EQUIPMENT & SUPPLIES STORE as the local certificate holder and identifies Novlead as the manufacturer. In the United Kingdom, iNOWill was registered with the MHRA on August 5, 2026. The registration was made through Horizon Med Tech Ltd. and identifies Novlead as the manufacturer.

Summary of Clinical Trials

As of the Latest Practicable Date, iNOWill had been or was being evaluated in 14 clinical trials at more than 50 hospitals. These studies cover PH, PPHN, ARDS, COPD, cardiovascular surgery requiring cardiopulmonary bypass, and additional critical-care indications such as high-altitude pulmonary edema, hypoxic respiratory failure in premature infants and lung transplantation.

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Clinical Trials that Support EU CE certification

We conducted the Clinical Trials in collaboration with collaborative hospitals. Although the Clinical Trials were conducted to generate clinical evidence supporting our CE certification application, they were carried out under the public-hospital clinical research funding framework in the PRC. Under this framework, the relevant research funding was awarded to and administered through the collaborative public hospitals. Accordingly, for institutional and administrative purposes, due to the public funding nature of the Clinical Trials, collaborative hospitals were designated as trial sponsors in China. Such designation reflected the applicable institutional arrangement for administering publicly funded clinical research in the PRC and did not affect the allocation of sponsor responsibilities for the Clinical Trials. We, despite not being a named sponsor in China, solely undertook sponsor-equivalent obligations in the Clinical Trials, while the collaborative hospitals primarily performed the institutional and administrative functions associated with the public funding arrangement. UDEM treated us as the sponsor for purposes of the CE certification. For details of work allocation between us and collaborative hospitals, see “— Collaborations Regarding the Clinical Trials for our Core Product iNOWill.” In assessing the Clinical Trials conducted in the PRC supporting EU CE certification, UDEM primarily considered that (i) the EU MDR does not prescribe specific requirements on patient ethnicity or minimum sample size for clinical investigations; (ii) clinical data may be derived from clinical investigations and other clinically relevant experience, including retrospective studies and real-world data; and (iii) the Clinical Trials, together with other supporting clinical evidence, were sufficient to demonstrate the safety and performance of iNOWill for conformity assessment purposes. In particular, at the time of the CE certification, NO therapy products had already been approved and marketed in the EU for the treatment of PH. Accordingly, the Clinical Trials were designed to demonstrate the safety and performance of iNOWill, which adopts electrochemical NO generation technology, rather than to re-establish the clinical efficacy of NO therapy for PH. Against this regulatory and evidentiary background, UDEM accepted the enrolment of 14 adult patients and 18 paediatric patients for the CE conformity assessment. The key milestones of the Clinical Trials are set out in the timeline below.

- July 2022: Initiated preparation for CE certification application, exploring both the Equivalence Route and the Clinical Investigation Route
- October 2022: Commenced patient enrollment for pediatric postoperative PH clinical trial in collaboration with Shanghai Children’s Medical Center (the “**Pediatric Trial**”)
- March 2023 — June 2023: Engaged in multiple rounds of communication with UDEM, during which UDEM concluded that the Equivalence Route was inapplicable and that self-generated clinical investigation data were required for the CE conformity assessment. Accordingly, revised our clinical evaluation strategy and submitted a draft clinical investigation plan to UDEM, covering both the ongoing Pediatric Trial and the proposed adult postoperative PH clinical trial in collaboration with Peking University International Hospital (the “**Adult Trial**”). UDEM subsequently reviewed and confirmed the proposed investigation plan.

As part of its review, UDEM proposed two refinements in June 2023, comprising (i) the inclusion of NO₂ monitoring results as part of the safety and stability assessment evidence and (ii) further enrollment of patients across different age groups to ensure that the overall enrolled patient population appropriately covered the full age range of 0 to 18 years, rather than being concentrated in relatively older or younger age groups. We adjusted the Pediatric Trial enrollment plan in response to UDEM’s feedback and continued enrollment. Patients enrolled prior to the refinements remained part of the Pediatric Trial and formed part of the clinical evidence for the CE conformity assessment. The refinements did not change the treatment, study endpoints or risk profile of the Pediatric Trial. In particular, the age-related refinement resulted in the enrollment of older paediatric patients and did not introduce any additional newborns or infants into the enrolled population. Accordingly, no separate ethics approval from the relevant PRC hospitals was required under applicable PRC requirements. The complete results of the Pediatric Trial were subsequently accepted as part of the clinical evidence supporting the CE certification of iNOWill. Based on the foregoing, our Directors are of the view, and the Sponsor concurs, that commencing the Pediatric Trial before receiving UDEM’s confirmation did not adversely affect the progression of the trial or the CE certification of iNOWill, as UDEM subsequently reviewed and confirmed the clinical investigation plan covering the ongoing Pediatric Trial, proposed the relevant refinements to its enrollment plan and accepted its complete results as part of the clinical evidence supporting the CE certification of iNOWill.

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In assessing the Clinical Trials conducted in the PRC as supporting evidence for the EU CE conformity assessment, UDEM primarily considered that (i) the EU MDR does not prescribe specific requirements on patient ethnicity or minimum sample size for clinical investigations; (ii) clinical data may be derived from clinical investigations and other clinically relevant experience, including retrospective studies and real-world data; and (iii) the Clinical Trials, together with other supporting clinical evidence, were sufficient to demonstrate the safety and performance of iNOWill for conformity assessment purposes. In particular, at the time of the CE certification, NO therapy products had already been approved and marketed in the EU for the treatment of PH. Accordingly, the Clinical Trials were designed to demonstrate the safety and performance of iNOWill, which adopts electrochemical NO generation technology, rather than to re-establish the clinical efficacy of NO therapy for PH. Against this regulatory and evidentiary background, UDEM accepted the enrollment of 14 adult patients and 18 paediatric patients for the CE conformity assessment.

- July 2023: Initiated patient enrollment for Adult Trial in accordance with UDEM-reviewed plan
- September 2023: Completed Pediatric Trial
- November 2023: Completed Adult Trial

The Clinical Trials were conducted in the PRC and were therefore subject to the applicable PRC regulatory requirements governing their conduct. As advised by our PRC Legal Advisor, as the Clinical Trials were not related to the registration of, or the application for registration of any medical device with the NMPA, the GCP requirements applicable to medical device clinical trials for NMPA registration did not apply. As the Clinical Trials were not conducted in the EU, the EU regulatory requirements governing the conduct of clinical investigations in the EU, including the applicable GCP requirements, did not apply to their conduct. Nevertheless, because the clinical data generated from the Clinical Trials were subsequently used to support the CE conformity assessment of iNOWill, the use and assessment of such data were subject to the applicable EU MDR requirements on clinical data and clinical evaluation, including Article 61 and Annex XIV of the EU MDR and other applicable requirements to be confirmed by our EU Legal Advisor. UDEM reviewed the clinical data in accordance with the applicable EU MDR requirements and accepted them as part of the clinical evidence supporting the CE certification of iNOWill.

Peking University International Hospital Trial (The Adult Trial)

Overview

We conducted an adult clinical trial at Peking University International Hospital (Cardiac Surgery Department) between July 2023 and November 2023 to evaluate the safety and effectiveness of iNOWill for postoperative iNO therapy. The study enrolled adult patients with congenital heart disease and pulmonary arterial hypertension who had undergone cardiac surgery. Primary efficacy assessments focused on changes in mean pulmonary artery pressure (mPAP) and oxygenation ($\text{PaO}_2/\text{FiO}_2$) from baseline to post-treatment timepoints, with interim observations during treatment, while safety assessments covered complications and adverse events during therapy and hypoxic rebound during withdrawal of iNO therapy.

Trial design

The Adult Trial was a prospective, open-label, single-arm clinical investigation conducted in adult patients undergoing cardiac surgery for congenital heart disease with pulmonary arterial hypertension. A total of 14 adult patients were planned to be enrolled, and 14 were actually enrolled and included in the analysis. Eligible patients had pulmonary artery pressure greater than 20 mmHg as measured at rest by right-heart catheterization and were assessed as requiring iNO therapy for at least six hours after surgery. Key exclusion criteria included, severe bleeding risk, confirmed methemoglobinemia, anticipated short-term risk of death that would preclude completion of treatment and missing system data preventing analysis.

In accordance with the trial protocol, iNO therapy using iNOWill generally commenced at 20 ppm approximately two hours after surgery, once systemic circulation was considered basically stable, and continued until the end of respiratory support as part of standard postoperative management. The Adult Trial assessed efficacy primarily through changes in mPAP and $\text{PaO}_2/\text{FiO}_2$ from baseline to post-treatment observation timepoints, with interim measurements during treatment. Secondary observations included the time course of hemodynamic and oxygenation changes at approximately two, four and six hours after treatment initiation and the presence or

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absence of hypoxic rebound during withdrawal of iNO. Safety evaluation covered the incidence and severity of adverse events (“AE”), serious adverse events (“SAE”) and treatment-emergent adverse events (“TEAE”), monitoring of NO₂ and methemoglobin as markers of NO-related toxicity and observations of device performance or malfunction.

Trial status

The Adult Trial was conducted and completed within the planned study period from July 2023 to November 2023. All 14 enrolled patients received iNO therapy via iNOWill and completed the planned observation period in accordance with the protocol. The trial proceeded without suspension, early termination or any safety-related protocol amendments requested by regulators or the ethics committee, and all planned efficacy and safety endpoints were evaluated in the full analysis set.

Trial results and key observations

The Adult Trial observed statistically significant improvements in pulmonary hemodynamics and oxygenation following treatment with iNOWill: mPAP decreased from (40.71 ± 11.73) mmHg at baseline to (35.14 ± 12.56) mmHg (p = 0.0012), and PaO₂/FiO₂ increased from (157.6 ± 65.2) mmHg to (221.8 ± 92.3) mmHg (p = 0.0395). Interim assessments at approximately two, four and six hours indicated that these improvements developed during therapy and were sustained, with patients with baseline PaO₂/FiO₂ below 300 mmHg showing statistically significant improvement after six hours that was maintained through withdrawal.

No AE, TEAE or SAE attributable to iNO therapy via iNOWill were reported, and no hypoxic rebound was observed during NO withdrawal. NO₂ and methemoglobin levels remained within protocol-defined safety ranges, with no clinically meaningful NO₂ toxicity, methemoglobinemia, device defects or malfunctions identified. Overall, the investigators concluded that iNOWill demonstrated a favorable safety profile and provided clinically meaningful improvements in pulmonary hemodynamics and oxygenation in this adult postoperative population.

Shanghai Children’s Medical Center Trial (The Pediatric Trial)

Overview

We conducted a pediatric clinical trial at Shanghai Children’s Medical Center between October 2022 and September 2023 to evaluate the safety, delivery stability and clinical performance of iNOWill in pediatric patients after surgery for congenital heart disease. The Pediatric Trial was commenced to support CE certification of iNOWill, based on our preliminary assessment that clinical investigations would likely be required. Our Directors are of the view, and the Sponsor concurs that the earlier commencement of the Pediatric Trial has no implication on the necessity of the Clinical Trials for obtaining CE certification.

Trial design

The Pediatric Trial was a prospective, open-label, single-arm investigation enrolling pediatric patients aged 0 to 18 years with refractory PH following congenital heart disease surgery. A total of 18 patients were planned, and 18 patients were actually enrolled and analyzed. Inclusion criteria focused on patients with persistent elevation of pulmonary artery pressure and inadequate improvement in systemic circulation despite standard pharmacological therapy, consistent with the prevailing pediatric guidelines. Key exclusion criteria included severe left-heart hypoplasia or duct-dependent congenital heart disease, fatal congenital defects with congestive heart failure, congenital methemoglobinemia and severe active bleeding.

In accordance with the trial protocol, NO was delivered by iNOWill, with concentration generally starting at 3 ppm and titrated up to 80 ppm based on clinical need. As part of a structured withdrawal strategy, sildenafil was introduced one to two days prior to planned withdrawal at a dose of 0.3 to 0.5 mg/kg administered once every four to six hours. Primary efficacy assessments compared mPAP and PaO₂/FiO₂ before and after treatment, including evaluation at 24 hours after initiation, with additional indicators such as central venous pressure and NT-proBNP collected to assess postoperative cardiac function. Delivery stability was evaluated by examining NO concentration before and after changes in ventilator parameters, and safety was assessed through regular monitoring of NO₂ and methemoglobin every four hours and systematic recording of all AEs, SAEs and TEAEs, with causality assessment.

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Trial status

The Pediatric Trial completed enrolment and follow-up within the planned study period from October 2022 to September 2023. All 18 enrolled patients received iNOWill therapy via iNOWill and completed the planned observation period in accordance with the protocol. There were no trial suspensions, premature terminations or protocol amendments required by regulators or ethics committees due to safety concerns or other reasons.

Trial results and key observations

The Pediatric Trial showed statistically significant improvements in pulmonary artery pressure and oxygenation following treatment with iNOWill: mPAP decreased from (50.2 ± 20.6) mmHg at baseline to (28.6 ± 10.5) mmHg after treatment ($p = 0.01$), and $\text{PaO}_2/\text{FiO}_2$ increased from $(91.4 \pm 35.9)\%$ to $(103.4 \pm 39.9)\%$ ($p < 0.001$), CVP decreased from (15.3 ± 2.1) mmHg to (13.8 ± 1.3) mmHg ($p < 0.001$), and NT-proBNP decreased from $(10,583.9 \pm 7,938.4)$ pg/ml to $(9,866.0 \pm 7,802.5)$ pg/ml ($p = 0.02$). These results suggest reduced right-ventricular load, improved hemodynamics and better oxygenation in this high-risk postoperative pediatric population.

Monitored NO concentration remained stable before and after changes in ventilator mode and tidal volume. During treatment, mean NO_2 concentration was approximately (0.1 ± 0.02) ppm, and methemoglobin averaged $(0.9 \pm 0.6)\%$ (maximum 2.8%), all within predefined safety ranges. No cases of NO_2 toxicity, clinically significant methemoglobinemia or other treatment-related adverse reactions were observed. Three patients, representing approximately 16.7% of the study population, died during the observation period; investigators attributed these deaths to sepsis, right-heart failure and multiple organ dysfunction syndrome, related to underlying disease and postoperative complications rather than to iNOWill or iNO therapy. No device malfunctions or defects contributing to AEs or SAEs were identified. The investigators concluded that iNO therapy delivered via iNOWill had a favorable benefit-risk profile in this pediatric population.

Collaborations Regarding the Clinical Trials for our Core Product iNOWill

As disclosed above, although the Clinical Trials generated clinical evidence supporting our CE certification application, the relevant research funding was awarded to and administered through the participating public hospitals under the public-hospital clinical research funding framework in the PRC. Accordingly, for institutional and administrative purposes, the collaborative hospitals were designated as the official trial sponsors in China and primarily performed the institutional and administrative functions associated with the public funding arrangement. Such designation did not affect the allocation of sponsor responsibilities for the Clinical Trials. Despite not being named as a trial sponsor in China, we solely undertook all sponsor-equivalent obligations throughout the Clinical Trials and were treated as the sponsor by UDEM for purposes of the CE certification. Our Directors confirm and the Sponsor concurs that we were so treated by UDEM for the purpose of obtaining the CE certification.

An interview was conducted with UDEM’s Sales Director for China in December 2025 (the “**UDEM Interview**”) to confirm the nature of the Clinical Trials and our role therein. Based on the UDEM Interview, UDEM confirmed that:

- The Clinical Trials were treated in the same manner as other UDEM-approved clinical trials, including confirmation of clinical necessity, review of study design for compliance with relevant requirements under the MDR, and assessment of the Clinical Evaluation Report.
- UDEM accepted the Clinical Trials as our own clinical data, treated us as the sponsor for the Clinical Trials, and confirmed that such data formed a key part supporting the CE certification of the iNOWill system.
- We assumed full responsibility for communications with UDEM throughout the CE process, including pre-trial consultation, trial execution and post-trial reporting. UDEM further noted that we are preparing to conduct PMCF in Europe and will act as sponsor for planned PMCF.

To demonstrate our key contributions in the clinical trials for our Core Product iNOWill, a side-by-side comparison of typical sponsor functions as well as our and collaborative hospitals’ responsibilities in the Pediatric and Adult Trials is provided in the following table.

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Clinical Trial Stage	Typical Role in a Registrational Trial	Our Role	Collaborative Hospitals’ Role
1. Product design and development .	Sponsor designs and develops trial device	In both Clinical Trials: <u>We independently designed and developed the iNOwill device and core components including NO generation module and monitoring system.</u>	In both Clinical Trials: N/A
2. Clinical trial design	Co-led by PI and sponsor, including participating hospital reviewing clinical feasibility and ethical compliance, and confirming assessment parameters and outcome	In the Pediatric Trial: We co-led trial design with PI, focusing on device strategy and monitoring protocols. In the Adult Trial: We co-led trial design with PI including endpoints, parameters and monitoring protocols.	In the Pediatric Trial: Collaborative Hospital reviewed grouping logic, feasibility and ethical compliance. In the Adult Trial: Collaborative Hospital confirmed feasibility and ethical compliance.
3. Patient enrollment, including consent collection and CRF completion	Participating hospital obtains informed consent, enrolls patients and completes CRF entries with support from Sponsor	In both Clinical Trials: We monitored inclusion/exclusion criteria, supported patient recruitment, including coordinating across hospital departments to identify eligible patients, specified key CRF data points and supervised CRF completion.	In both Clinical Trials: Collaborative Hospital obtained informed consent, enrolled patients and completed CRF entries.
4. Providing test product, trial site training and device installation .	Sponsor provides devices, installs devices and trains personnel	In both Clinical Trials: We supplied full device systems and consumables; conducted site installation, calibration, and SOP-based training on alarm limits, NO/NO ₂ /O ₂ , settings and purging.	In both Clinical Trials: Collaborative Hospital received training and implemented device operation accordingly in clinical setting.
5. Testing of the device and examination of the patients . . .	Sponsor provides equipment and oversight; participating hospital enrolls and treats patients	In both Clinical Trials: We maintained technical integrity of devices during treatment and provided ongoing technical support and compliance oversight.	In both Clinical Trials: Collaborative Hospital enrolled patients, administered NO therapy using the iNOwill system per training.
6. Safety monitoring and data capture	Organized by the sponsor with participating hospital conducting patient evaluations and safety/efficacy assessments	In both Clinical Trials: We oversaw installation and system monitoring (NO/NO ₂ /O ₂ , concentrations, alarm settings) and ensured product compliance with regulatory and trial protocol.	In both Clinical Trials: Collaborative Hospital conducted patient exams and efficacy/safety evaluation, and logged data in CRFs.
7. Data analysis and report drafting	Participating hospital (to provide anonymized data, execute and prepare the report) and sponsor (to coordinate and assist)	In the Pediatric Trial: We participated in data analysis and conducted final clinical report review. In the Adult Trial: We conducted data analysis and drafted clinical summary report.	In the Pediatric Trial: Collaborative Hospital recorded and anonymized data, and prepared draft report. In the Adult Trial: Collaborative Hospital recorded and anonymized data.

During the clinical phase of both Clinical Trials, we also assumed critical responsibilities in both the development of therapeutic protocol and the operation of therapeutic devices. These responsibilities ensured that physicians and clinical staff administered the therapy consistently, safely and in accordance with trial requirements. The table below summarizes our lead roles across both dimensions:

Component	Our Responsibilities	Collaborative Hospitals’ Responsibilities
Therapeutic Protocol . .	Developed and delivered therapeutic protocol training based on recognized clinical guidelines, including: - Recommended iNO dosing (e.g., 20 ppm for post-cardiac surgery patients) - Clinical indicators for weaning off therapy (e.g., PaO₂/FiO₂ thresholds) - iNO withdrawal procedures to mitigate hypoxic rebound	Assigned designated ICU physicians and respiratory care personnel to receive our training. Performed iNO therapy according to the provided protocol and guidelines.

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Component	Our Responsibilities	Collaborative Hospitals' Responsibilities
Device Operation	Conducted device operation training, including: • System setup: gas source, power supply, circuit connections • Device integration with ventilators, high-flow systems, ECMO and anesthesia machines • Device boot-up and automatic system checks • NO concentration selection and adjustment • Alarm parameter configuration (NO, NO₂, O₂ limits) • Troubleshooting of typical alerts (e.g., source pressure, filter block) • Routine maintenance: component change, cleaning cycles	Assigned designated ICU physicians and respiratory care personnel to receive our training. Operated the iNOWill in accordance with our guidance during training sessions. Performed routine maintenance and logged device usage data for trial records.

Other Trials

We conducted the clinical evaluation of iNOWill for the treatment of PPHN, ARDS and COPD, as set out below. For completed trials, reports show iNOWill therapy all met endpoints of the trials.

Year	Clinical Trials
2022	Acted as sponsor for trial evaluating the effectiveness of iNOWill for patients with PPHN (ongoing)
2023	Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill for patients with PPHN (completed in 2025) Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill for neonatal hypoxic respiratory failure in premature infants (ongoing) Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill in adult patients with ARDS (completed in 2024) Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill following lung transplantation (ongoing) Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill in patients with COPD (ongoing) Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill for high altitude pulmonary edema (completed in 2025)
2024	Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill for adult patients with ARDS (completed in 2025) Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill in patients undergoing surgery for aortic dissection with cardiopulmonary bypass (ongoing) Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill in cardiac surgeries (ongoing)
2025	Acted as sole corporate participant for trial evaluating the effectiveness of iNOWill in adult patients with ARDS (ongoing)

Further Development Plan

Post-Approval Study

Following the grant of CE certification for iNOWill as a Class IIb device under the EU MDR, we plan to sponsor PMCF trials in Europe, as required by UDEM under the MDR. The prospective clinical trial under the PMCF plan is expected to be initiated in the third quarter of 2026 and completed by 2028.

PMCF is a regulatory requirement applicable to all CE certified medical devices under the MDR. Our Directors confirm and the Sponsor concurs that as stated in the EU CE certificate, CE Mark certification obtained by us is not subject to any conditions, restrictions or other contingencies and is not dependent on the PMCF or the PMCF results. The purpose of PMCF is to proactively collect and evaluate clinical data generated from real-world use to (i) confirm the safety and

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performance of the device throughout its expected lifetime, (ii) identify unknown or emerging risks and adverse events, and (iii) ensure the continued acceptability of the benefit-risk profile, among others. PMCF is undertaken by the manufacturer in accordance with a documented PMCF plan, and results are summarized in periodic PMCF reports submitted to the Notified Body. These reports typically include clinical safety and performance metrics, analysis of adverse event rates, and, where applicable, investigation of device-related issues to assess root causes and support ongoing risk-benefit evaluation. PMCF serves as a part of ongoing regulatory oversight measures for the Notified Body over certified medical devices; while the Notified Body may engage with the manufacturer based on PMCF findings, PMCF does not automatically trigger revision or withdrawal of the CE certificate.

We have adopted a comprehensive PMCF plan comprising literature review, user feedback surveys and post-market surveillance, together with clinical trials as part of the overall framework. Such comprehensive approach was determined for the following reasons: (i) the inclusion of prospective clinical trials enables the generation of structured and high-quality clinical data, which enables UDEM to track and assess the device’s safety and effectiveness in real-world clinical use on an ongoing basis, thereby facilitating the acceptance of the PMCF plan; and (ii) the prospective clinical trials would facilitate clinical adoption by hospitals and physicians by providing high-quality clinical evidence to support the use of the device in routine clinical practice. Our PMCF plan has been reviewed and accepted by UDEM as part of the conformity assessment process. On June 16, 2025, UDEM reviewed and approved our clinical evaluation report and confirmed that all corrective actions had been adequately addressed and met the applicable requirements. UDEM, through its Sales Director for China, who acted as its principal contact for the iNowill’s CE certification, further confirmed that the prospective clinical trial forms part of the approved PMCF plan and is required to be conducted under such PMCF plan. Our EU legal adviser further confirmed that the Sales Director for China, as UDEM’s principal contact for the Company’s CE certification process, was an appropriate representative of UDEM to communicate UDEM’s position regarding the approved PMCF plan. Accordingly, we will conduct the prospective clinical trial in accordance with the approved PMCF plan.

As set out in our PMCF plan submitted to UDEM, PMCF implementation for iNowill will comprise a multicenter, prospective, observational PMCF study in European clinical sites, initiated within 12 months after launch in the EU market, with participation from at least three healthcare centers over a three-year period and a planned enrollment of 160 patients, collecting patient demographics, disease and treatment characteristics, NO/NO₂ levels, adverse events and clinical outcomes to further validate electrochemical NO generation, confirm safety and performance under real-world conditions and analyze emerging risks, with interim data summaries planned approximately one and two years after study initiation and final analysis and reporting targeted within three years. As part of our ongoing R&D and clinical development activities relating to the PMCF, we have finalized the draft clinical investigation protocol, identified five clinical centers while evaluating the inclusion of additional centers, and identified the principal investigators. The relevant site agreements and documentation are under review, and we expect to complete site contracting and initiate the PMCF clinical trial in the third quarter of 2026. The trial design of the first-stage prospective clinical trial under the PMCF plan is set out in the table below.

Objective	To evaluate the safety and performance of the iNowill in neonates needing nitric oxide therapy as per standard routine care.
Design	A prospective, multicenter, single arm clinical trial.
Sample Size	A total of 50 participants will be recruited, all receive iNowill treatment.
Number of trial centers . .	Five clinical centers in Europe have been identified, and we are evaluating the inclusion of additional centers.

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Inclusive Criteria	Inclusive criteria: (1) Gestational age $\geq 34^{+0}$ weeks of gestation and postnatal age ≤ 30 days. (2) Echocardiographic diagnosed with pulmonary hypertension. (3) Hypoxemic respiratory failure defined according to specific criteria. (4) The guardian/legal representative has been fully informed of the benefits and risks. Exclusive criteria: (1) Suspected pulmonary hypoplasia. (2) Congenital heart defects (other than a small, hemodynamically insignificant patent ductus arteriosus, or a ventricular septal defect or a patent foramen ovale). (3) Methemoglobinemia (MetHb $>2.5\%$) before the onset of iNO treatment. (4) Need for immediate cardio-pulmonary resuscitation (i.e. terminal conditions). (5) Severely growth-restricted infants (birth weight ≤ 5th percentile or -2 Z-score). (6) Any condition that, in the investigator’s judgment, makes the infant unsuitable for participation in this clinical trial.
Intervention group assignment	Single group: all participants will receive INOwill treatment.
Effective Evaluation	Primary endpoint: Oxygenation metrics (Oxygenation index, Oxygen saturation index, PF ratio, SF ratio) calculated from routinely collected vital parameters (data already available because already registered in clinical care) at the baseline (i.e. before the treatment onset), 60 minutes, 6 hours, 24 hours after the initiation of the treatment and, finally, at the treatment discontinuation. Secondary endpoints: (1) INOwill device set-up time. (2) Technical parameters measured by the INOwill as done by any other common iNO delivery system (i.e. iNO and NO_2 delivered concentrations). (3) Results of a usability assessment survey (dedicated questionnaire).

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- (4) Device-economics estimation analysis (cost/day of treatment).

The PMCF clinical trial does not adopt the same primary and secondary endpoints as the Pediatric Trial and Adult Trial conducted for the CE conformity assessment. Its primary endpoint focuses on oxygenation metrics, while its secondary endpoints primarily assess device performance and use, including device set-up time, delivered NO and NO₂ concentrations, usability and device economics. Accordingly, the PMCF clinical trial is not primarily intended to expand the patient population; its planned enrollment reflects its distinct post-market objective of evaluating device safety and performance during routine clinical use.

- Safety Evaluation (1) Rate of adverse events and serious adverse events.
(2) Rate of device deficiencies.

Compared with pre-market clinical studies conducted for CE conformity assessment, PMCF studies are designed for different regulatory objectives and may therefore involve broader patient populations to generate post-market clinical evidence supporting the continued evaluation of device safety and performance. According to Frost & Sullivan, PMCF studies are commonly designed to evaluate device performance and safety in broader real-world clinical settings and, where justified by the post-market evidentiary objectives, may involve larger sample sizes, longer follow-up periods or more heterogeneous patient populations than pre-market registration studies.

Product Improvement

We plan to continue advancing iNowill through iterative product-generation upgrades, with a focus on improving performance consistency, usability, connectivity and cost efficiency in ICU and perioperative settings.

Indication Expansion

COPD

Therapeutic rationale and potential clinical application

We believe that iNowill may provide clinically meaningful benefits in COPD primarily through improving pulmonary vascular dysfunction and exercise tolerance. COPD patients commonly experience reduced endogenous nitric oxide bioavailability and pulmonary vascular remodeling, which may lead to pulmonary vasoconstriction and pulmonary hypertension. By supplementing nitric oxide directly through inhalation, iNO may reduce PAP and improve pulmonary vascular hemodynamics.

In addition, iNO may improve ventilation/perfusion (“V/Q”) matching and reduce ventilatory demand during exercise, thereby improving exercise capacity and alleviating exertional dyspnea. Published studies have demonstrated improvements in pulmonary hemodynamics and exercise tolerance in COPD patients receiving iNO therapy, including improvements in VO₂peak in certain COPD patient subgroups. iNO may also exhibit anti-inflammatory and anti-infective properties through modulation of macrophage activity and reduction of excessive inflammatory activation.

Based on the above therapeutic mechanisms, iNO therapy may potentially serve as supportive treatment in selected moderate-to-severe COPD patients, particularly those with pulmonary hypertension, impaired pulmonary hemodynamics or exercise-related hypoxemia.

Published clinical evidence

Clinical efficacy

Published clinical evidence further supports the potential clinical applicability of iNO therapy in COPD. Representative studies have demonstrated improvements in pulmonary hemodynamics, ventilation/perfusion matching, oxygenation and exercise tolerance following iNO therapy in

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COPD patients. Roger et al. (1997) reported that inhalation of 40 ppm NO during exercise in COPD patients moderately reduced pulmonary hypertension and prevented the exercise-associated decrease in PaO₂, through redistribution of pulmonary blood flow from low-V/Q units to normal-V/Q units. Vonbank et al. (2003) also demonstrated improvements in pulmonary hemodynamics and exercise capacity in COPD patients receiving iNO therapy. More recently, Collins et al. (2026), a randomized, double-blind, placebo-controlled crossover study, identified a responsive COPD subgroup and demonstrated that patients with a higher pulmonary small-vessel volume fraction (BV5/TVV) experienced significantly greater improvement in peak oxygen uptake (VO_{2peak}) following iNO therapy (interaction $p = 0.02$). The study further reported that, for every 1% increase in BV5/TVV, VO_{2peak} increased by approximately 0.14 mL/kg/min, providing further evidence that iNO therapy may improve exercise tolerance in selected COPD patients with pulmonary vascular abnormalities.

Clinical safety

Published literature also supports the safety profile of iNO therapy when administered under monitored clinical settings. Vonbank et al. (2003) reported that three-month iNO therapy in severe COPD patients was safe, with no increase in toxic reaction products of nitric oxide observed. The relevant expert consensus also recommend routine monitoring of methemoglobin levels and NO₂ concentrations during treatment.

Expert consensus support

The planned indication expansion of iNOwill into COPD is supported by published studies and expert consensus. In particular, the “Chinese Expert Consensus on Clinical Application of Inhaled Nitric Oxide Therapy (2024 Edition)” notes that iNO may be used in chronic pulmonary diseases such as COPD, while generally at concentrations ranging from 20 to 40 ppm. The “Chinese Expert Consensus on Clinical Application of Inhaled Nitric Oxide in Critical and Emergency Care (2024)” further notes that iNO may reduce pulmonary artery pressure, improve pulmonary hemodynamics and ventilation/perfusion matching, and alleviate clinical symptoms in patients with moderate-to-severe COPD.

ARDS

Therapeutic rationale and potential clinical application

We believe that iNOwill may provide clinically meaningful benefits in ARDS primarily through selective pulmonary vasodilation and improvement of V/Q mismatch. ARDS patients commonly experience diffuse alveolar injury, intrapulmonary shunting, pulmonary hypertension and right ventricular dysfunction. iNO selectively dilates pulmonary vessels in well-ventilated alveolar regions, thereby reducing intrapulmonary shunting and improving oxygenation, as reflected by improvements in the PaO₂/FiO₂ ratio. In addition, by reducing PAP and PVR, iNO may improve right ventricular function and reduce right ventricular afterload without materially affecting systemic hemodynamics. iNO may also be used together with prone-position ventilation to further improve oxygenation in patients with refractory hypoxemia.

Based on the above therapeutic mechanisms, iNO therapy may potentially serve as supportive or rescue therapy in selected ARDS patients with refractory hypoxemia, pulmonary hypertension or right ventricular dysfunction, including in combination with prone-position ventilation.

Published clinical evidence

Clinical efficacy

Published clinical evidence further supports the potential clinical applicability of iNO therapy in ARDS. Epidemiological studies have reported that iNO has been used in approximately 24.9% to 65.8% of ARDS patients in the evaluated clinical settings, with its clinical utilization increasing over time. Published studies generally demonstrated that administration of iNO at concentrations commonly ranging from 5 to 20 ppm, with doses up to 40 ppm in certain studies, improved oxygenation in ARDS patients, with treatment durations of up to 30 days. Published evidence further demonstrated that iNO combined with prone-position ventilation resulted in greater improvement in oxygenation than prone-position ventilation alone. In addition, administration of 5 ppm iNO was reported to improve long-term pulmonary function in ARDS survivors, while studies in pediatric ARDS demonstrated that administration of 5–10 ppm iNO shortened the duration of mechanical ventilation and hospitalization, improved ECMO-free survival and enhanced longer-term outcomes. More recent clinical studies further support the potential clinical benefits of iNO.

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therapy in selected ARDS patients. In particular, Di Fenza et al. (2023), a multicenter randomized controlled trial involving 193 patients, reported that administration of 80 ppm iNO for 48 hours resulted in significantly greater improvement in PaO₂/FiO₂ compared with conventional treatment (mean difference 39.1 mmHg; 95% CI 18.1–60.3), corresponding to a 99.5% probability of improving oxygenation. Mekontso Dessap et al. (2023) further reported that, among patients with refractory ARDS meeting ECMO criteria, 51.6% no longer fulfilled the criteria for ECMO following iNO therapy, and this subgroup experienced significantly lower in-hospital mortality (OR = 0.23; 95% CI 0.06–0.89). In addition, Fritzmann et al. (2025) reported that, in severe ARDS patients with right ventricular dysfunction, each additional hour of iNO therapy was associated with a 2.5% relative reduction in the hazard of death (HR = 0.975; 95% CI 0.957–0.993), suggesting that iNO therapy may reduce the excess mortality risk associated with right ventricular dysfunction.

Clinical safety

Published literature also supports the safety profile of iNO therapy when administered under monitored clinical settings.

Di Fenza et al. (2023) reported that high-dose (80 ppm) iNO therapy was well tolerated, with no serious adverse events related to the intervention. Mekontso Dessap et al. (2023) observed no marked increase in methaemoglobin levels above the 5% threshold in the vast majority of treated patients. Fritzmann et al. (2025) further noted that iNO use was not associated with worsening hemodynamics or other safety concerns. The relevant expert consensus also recommend routine monitoring of methemoglobin levels and NO₂ concentrations during treatment.

Expert consensus support

The planned indication expansion of iNO will into ARDS is supported by published clinical evidence and expert consensus. In particular, the “Chinese Expert Consensus on Clinical Application of Inhaled Nitric Oxide in Critical and Emergency Care (2024)” recommends that, for ARDS patients who remain refractory to conventional treatment, iNO may be administered at concentrations generally ranging from 5 to 20 ppm to improve oxygenation, and further notes that iNO may be used in combination with prone-position ventilation to achieve greater improvement in oxygenation. The “Chinese Expert Consensus on Clinical Application of Inhaled Nitric Oxide Therapy (2024 Edition)” further identifies ARDS and acute hypoxemic respiratory failure as important clinical application scenarios for iNO therapy, with an initial recommended dose of 5–20 ppm and doses of up to 80 ppm in selected patients.

CAP

Therapeutic rationale and potential clinical application

We believe that iNO will may provide clinically meaningful benefits in CAP through both respiratory support and direct antimicrobial effects. Similar to ARDS, iNO may improve oxygenation by optimizing V/Q matching, reducing intrapulmonary shunting and rapidly correcting hypoxemia.

In addition, high-concentration iNO has demonstrated direct antiviral and antibacterial activities in published studies. Existing studies suggest that high-concentration iNO may inhibit replication of viruses such as SARS-CoV-2, reduce viral load and exhibit bactericidal effects against multidrug-resistant pathogens, including multidrug-resistant *Pseudomonas aeruginosa* and *Klebsiella pneumoniae*. iNO may also reduce excessive inflammatory responses and mitigate lung injury.

Viral pneumonia, including COVID-19, represents a major subset of community-acquired pneumonia (CAP) and shares key pathophysiological features with other severe pulmonary infections, including hypoxemia, ventilation/perfusion (V/Q) mismatch, and pulmonary inflammation. Therefore, the clinical evidence from published studies on severe viral pneumonias and other pulmonary infections provides relevant scientific support for evaluating iNO therapy in the broader CAP population.

Based on the above therapeutic mechanisms, conventional-concentration iNO therapy may potentially improve oxygenation in selected CAP patients with hypoxemic respiratory failure. In addition, subject to further clinical validation, high-concentration iNO therapy may potentially provide additional antimicrobial benefits through its antiviral and antibacterial effects.

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Published clinical evidence

Clinical efficacy

Published clinical evidence further supports the potential clinical applicability of iNO therapy in CAP and other severe pulmonary infections. Published studies demonstrated that short-term administration of 5 ppm iNO significantly improved intrapulmonary shunting and arterial oxygenation in patients with community-acquired bacterial pneumonia complicated by respiratory failure. During the SARS outbreak, a rescue study involving six patients with severe SARS reported that administration of up to 30 ppm iNO for at least three days significantly improved arterial oxygenation, reduced respiratory support requirements and reduced progression of pulmonary infiltrates. Epidemiological studies conducted during the MERS and H1N1 influenza outbreaks further reported clinical use of iNO to improve oxygenation in approximately 20% and 36% of critically ill patients in the evaluated populations, respectively. In addition, published literature has demonstrated that high-concentration iNO exhibits antiviral activity against SARS-CoV-2 and antibacterial activity against multidrug-resistant pathogens, providing further scientific rationale for evaluating iNO therapy in pulmonary infections. More recent published studies further demonstrated the potential antiviral and antibacterial effects of high-concentration iNO therapy. In particular, Friedrich et al. (2025) reported in a randomized controlled trial that a single six-hour administration of 160 ppm iNO increased oxygen-free days from 8 to 11 days and reduced median hospitalization duration from 7.0 days to 4.5 days in patients with COVID-19. Di Fenza et al. (2023) further reported that administration of 80 ppm iNO accelerated the reduction of SARS-CoV-2 viral load in plasma and sputum compared with conventional treatment. In addition, Yu et al. (2026) demonstrated in a porcine model that administration of 300 ppm iNO reduced multidrug-resistant *Pseudomonas aeruginosa* burden in lung tissue by approximately 2-log, while also improving oxygenation and lung compliance, and reported preliminary clinical feasibility in two ICU patients with multidrug-resistant infections. Kalashnikova et al. (2025) further reported that prophylactic administration of 200 ppm iNO following cardiac surgery reduced the incidence of nosocomial pneumonia from 24.3% to 5.4% (OR = 0.178; 95% CI 0.036–0.89).

Clinical safety

Published literature also supports the safety profile of iNO therapy, including high-concentration regimens, when administered under monitored clinical settings. Friedrich et al. (2025) reported that 160 ppm iNO for six hours was well tolerated with no adverse events. Yu et al. (2026) confirmed the safety of 300 ppm iNO in a phase 1 trial with no adverse events and further reported no iNO-related adverse events in a long-term follow-up of patients exposed to high-dose iNO for more than 6 years. Kalashnikova et al. (2025) also reported that high-dose iNO was safe in the postoperative setting. The relevant expert consensus also recommend appropriate monitoring of methemoglobin levels and NO₂ concentrations during treatment.

Expert consensus support

The planned indication expansion of iNOwill into CAP is supported by published studies and expert consensus. In particular, the “Chinese Expert Consensus on Clinical Application of Inhaled Nitric Oxide in Critical and Emergency Care (2024)” recommends conventional-concentration iNO therapy to improve short-term oxygenation in patients with severe pneumonia-related hypoxemia and further recognizes that high-concentration iNO may reduce pathogen load in pulmonary infections. The “Chinese Expert Consensus on Clinical Application of Inhaled Nitric Oxide Therapy (2024 Edition)” identifies COVID-19-related acute hypoxemic respiratory failure as an important clinical application scenario for iNO therapy. In addition, the Society for Maternal-Fetal Medicine’s Management Considerations for Pregnant Patients with COVID-19 notes that iNO may be considered in pregnant patients with COVID-19 and refractory hypoxemia.

Planned clinical trials for indication expansion

To support our planned indication expansion of iNOwill and our planned U.S. registration, we expect to initiate a series of clinical trials across the PRC, the European Union and the United States for PH, ARDS, COPD and CAP. Unlike our pre-market clinical trials conducted to support the CE conformity assessment of iNOwill, which were designed to demonstrate the safety and performance of our device for delivering NO through a novel electrochemical generation technology, the planned clinical trials are intended to support indication expansion and regulatory approval for indications for which NO therapy has not yet been approved in the relevant jurisdictions. Accordingly, the clinical design and planned enrollment size of each study were determined independently based on its respective regulatory objective, development stage and applicable statistical methodology, rather than by reference to our CE certification studies. The planned enrollment size for each clinical trial was determined based on formal statistical sample size calculations, taking into account the primary

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efficacy endpoint, expected treatment effect, published clinical evidence, anticipated patient dropout rates and operational considerations, including multi-center implementation. The enrollment calculations generally adopted a two-sided significance level of 0.05 and statistical power of 80%.

Specifically, in the PRC, we currently plan to enroll approximately 500 patients for the COPD clinical trial, 350 patients for the ARDS clinical trial and 500 patients for the CAP clinical trial. We currently expect to initiate the ARDS clinical trial in the fourth quarter of 2026, COPD clinical trial in the second quarter of 2027, followed by the CAP clinical trial in 2029. We have adopted a parallel clinical development strategy for the planned PRC indication expansion in COPD, ARDS and CAP because (i) published clinical evidence and scientific rationale support the clinical investigation of iNO therapy across all three indications; (ii) the three indications are primarily managed within respiratory medicine and intensive care departments, enabling efficient utilization of overlapping clinical sites, investigators and patient recruitment resources and (iii) the PRC also provides an efficient and cost-effective clinical development environment, while clinical experience and data generated from the PRC may provide supportive evidence for future regulatory interactions and indication expansion in other jurisdictions, subject to the requirements of the relevant regulatory authorities. For our overseas indication expansion strategy, we currently plan to prioritize ARDS because, compared with COPD, broader published clinical evidence is currently available regarding the application of NO therapy in ARDS, providing a stronger scientific basis for registration clinical development. With respect to CAP, we currently plan to commence clinical development in the PRC only. Compared with ARDS, the currently available published clinical evidence supporting the application of NO therapy in CAP remains relatively limited. Accordingly, we intend to first conduct clinical studies in the PRC to further validate the clinical design, treatment regimen and efficacy endpoints before evaluating potential indication expansion or registration in overseas markets. Accordingly, in the European Union, we currently plan to conduct an international multi-center clinical trial for ARDS with an expected enrollment of approximately [100] patients, which is expected to commence in the fourth quarter of 2026. Subject to the progress of the ARDS program and the clinical evidence generated therefrom, we may subsequently evaluate the clinical development of COPD. In the United States, following our Pre-Submission in late May 2026, the FDA’s written feedback in July 2026 and our formal meeting with the FDA in August 2026, the FDA advised that PH and ARDS would require new clinical evidence through clinical trials. We currently plan to enroll approximately 200 patients for the planned PH clinical trial and approximately 300 patients for the planned ARDS clinical trial, with the ARDS clinical trial currently expected to commence in the first quarter of 2028. Subject to the progress of the ARDS program, we may subsequently evaluate the clinical development of COPD.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET iNO FOR NEW INDICATIONS OR COMMERCIALIZE IN NEW MARKETS SUCCESSFULLY.

eNOaire — Our iNO Therapy Device for Inpatient and Transfer Scenarios

eNOaire is our commercial-stage, cylinder-free iNO therapy device for hospital and patient-transfer scenarios where portability, simplified set-up and cost-efficiency are important. It integrates gas generation, dosing and monitoring in a compact unit with an LCD interface and combined touchscreen/knob/key controls that display ventilator flow waveform, NO delivery flow and real-time NO, NO₂ and O₂ concentrations. Using plasma discharge, eNOaire draws in dry air via an internal pump, generates NO and few NO₂, and then passes the gas stream through NO₂ adsorption media and particulate filters so that NO at the user-set concentration is injected into the ventilator inspiratory limb. A dual-pathway design with separate injection and sampling lines and a dedicated flow-monitoring module allows NO delivery to be synchronized with the inspiratory phase while electrochemical sensors continuously monitor NO, NO₂ and O₂, helping maintain stable and safe iNO concentrations across different ventilation modes and during patient transfers between ICU, operating room and wards. eNOaire has been registered as a Class III medical device with the NMPA for PH since 2024, and we submitted application for CE certification under the EU MDR in April 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP eNOaire FOR NEW INDICATIONS OR COMMERCIALIZE IN NEW MARKETS SUCCESSFULLY.

VQfit — Our iNO Therapy Product Candidate for Outpatient and At-home Use

VQfit is our portable iNO therapy product candidate designed for clinic and at-home scenarios. It is intended to provide supportive iNO therapy for moderate-to-severe patients with conditions such as COPD, interstitial lung disease, right heart failure and pulmonary-disease-and/or hypoxia-induced PH in medical environments such as monitored and general wards, outpatient and respiratory rehabilitation rooms, community rehabilitation facilities, as well as in

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home settings including indoor and outdoor home use and community elderly activity centers. As of the Latest Practicable Date, VQfit had completed key engineering development and pre-clinical testing. In July 2026, we had submitted an innovative medical device application for VQfit to the NMPA.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VQfit SUCCESSFULLY.

CARDIOPULMONARY CIRCULATORY SUPPORT

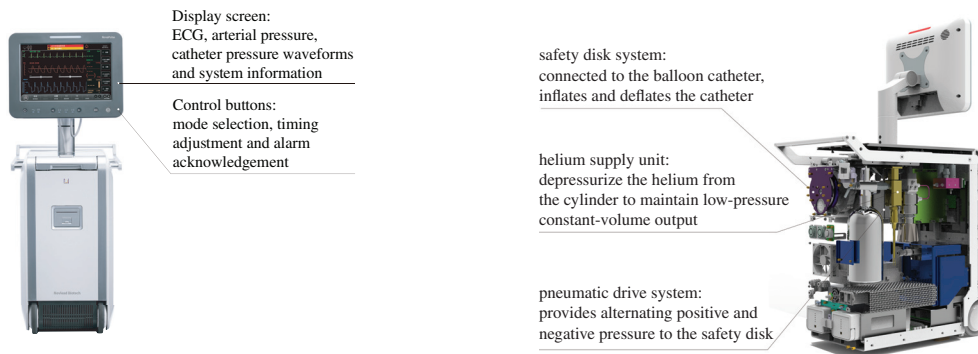
We are extending our product development from iNO therapy into broader cardiopulmonary circulatory support and life-support applications for cardiovascular and perioperative care in operating rooms, catheterization laboratories and intensive-care units. These environments demand stable performance, responsive control and reliable safety management under continuous use. Within this segment, our portfolio comprises NovaPulse, our Key Product and commercial-stage IABP for temporary mechanical circulatory support in these settings, and NovaVent, our ventilator product candidate under development for critical-care respiratory support, designed to integrate mechanical ventilation, iNO therapy and electrical impedance tomography within a synergetic platform.

NovaPulse — Our Key Product

Our Key Product NovaPulse is an in-house developed IABP designed for cardiovascular and perioperative care in operating rooms, ICUs and catheter laboratories where temporary mechanical circulatory support is required. IABP provides temporary circulatory support through counter-pulsation, principally by augmenting coronary perfusion and reducing left ventricular afterload. It is intended to provide circulatory support for indications including heart failure, cardiogenic shock and perioperative support for high-risk interventional and surgical procedures. NovaPulse has been registered as a Class III medical device with the NMPA since September 2025 and has since entered scaled commercial shipment in China, with 48 commercial units shipped by December 31, 2025, including 34 units in December 2025.

Product Structure

The following chart illustrates the product structure of NovaPulse.



Operation Procedure

The following chart illustrates the operation procedure of NovaPulse.

- (i) Insert intra-aortic balloon (IAB) catheter via an appropriate arterial access. Connect IABP console to ECG, invasive arterial pressure lines and the inserted IAB catheter.
- (ii) Select trigger mode and the system will synchronize catheter inflation and deflation with the cardiac cycle at a targeted assist ratio.

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Mechanism of Action

IABP therapy provides temporary support by augmenting coronary perfusion and reducing left ventricular afterload in settings such as acute coronary syndrome, perioperative support in cardiac and non-cardiac surgeries and selected complications of heart failure. It operates via counterpulsation: a balloon catheter positioned in the descending aorta inflates during diastole to increase aortic diastolic pressure and enhance coronary perfusion, and deflates just before systole to reduce aortic end-diastolic pressure and left ventricular afterload, thereby lowering myocardial oxygen demand and improving cardiac output. Through these mechanisms, IABP can support hemodynamic stabilization and organ perfusion in patients with low cardiac output states, cardiogenic shock or perioperative hemodynamic compromise.

NovaPulse delivers IABP therapy by providing controlled pneumatic drive and timing support for balloon inflation and deflation synchronized with the cardiac cycle. The console generates and regulates positive and negative pressure for rapid inflation and deflation and supports assist ratios of 1:1, 1:2 and 1:3 for different levels of support and stepwise weaning. Embedded algorithms analyze ECG and arterial pressure signals to select trigger sources and determine inflation and deflation timing, with options for automatic optimization or user fine-tuning. Safety measures include structural isolation between the pneumatic and catheter systems, dehumidification of the pneumatic pathway and dual-battery-backed operation to support bedside and transport use.

Competitive Advantages

NovaPulse is designed to support efficient and reliable IABP use in clinical settings, with (i) Data management: convenient data entry, precise query and one-click export, enabling seamless traceability of patient history and secure storage; (ii) Dual interaction: an intuitive touchscreen for efficient operation, paired with physical confirmation controls for added safety; (iii) Smart assist adjustment: three assist ratios with intelligent switching to support smooth transitions and match different clinical states; (iv) One-click reporting: rapid export of therapy reports and operating logs to facilitate review and analysis; and (v) Real-time monitoring: continuous checks on sensors, cables and catheter connections with automated alerts to support safe use throughout the procedure.

Market Opportunity and Competitive Landscape

In China, the IABP market is expected to grow from RMB790.1 million in 2025 to RMB1,381.6 million in 2030, representing a CAGR of 11.8%, supported by cath-lab build-out, rising PCI penetration and broader recognition and treatment of severe ischemic events and acute heart failure. The IABP market in China has historically been supplied predominantly by overseas brands, while the penetration of IABP systems remains limited in a number of hospitals and less-developed regions. We believe that domestically developed IABP systems, supported by local clinical training, maintenance and after-sales services, may facilitate broader access to IABP therapy. We initially plan to focus on cardiology departments, CCUs and catheterization laboratories of leading hospitals and subsequently expand into a wider base of Class III hospitals and selected Class II hospitals. For details, see “Industry Overview — China IABP Therapy Market.”

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Development Timeline and Milestones

Year	Milestone
2023	Initiated NovaPulse R&D and technology validation
2024	Submitted application for NMPA Class III medical device registration Completed animal studies
2025	Obtained NMPA Class III medical device registration Commenced commercial shipment Initiated a prospective first-in-man (FIM) clinical trial of NovaPulse (ongoing)

Following receipt of the NMPA Class III medical device registration certificate in September 2025, we commenced commercialization of NovaPulse in the Chinese Mainland by making our first commercial shipment in September 2025. As of the Latest Practicable Date, we had not commenced commercialization of NovaPulse in the EU or any other overseas jurisdiction.

Material Communications with Competent Authorities

We submitted a Class III medical device registration application for NovaPulse to the NMPA in May 2024. After submitting the requested supplemental technical and evaluation materials, including animal-study results, we obtained a Class III medical device registration certificate for NovaPulse in September 2025. For purposes of such NMPA approval, we conducted the clinical evaluation of NovaPulse through comparison with the same variety of medical devices from April 2025 to June 2025, and no registrational clinical trial was required.

Summary of Clinical Trial

In November 2025, we initiated and sponsored a post-approval, single-arm FIM clinical trial of NovaPulse to support marketing and sales efforts. In the trial, NovaPulse was used together with commercially available and investigational balloon catheters, in adult patients with hemodynamically unstable cardiovascular disease requiring IABP support. The study plans to enroll 11 adult patients who require IABP implantation due to hemodynamic instability. As of the Latest Practicable Date, the study was ongoing and six patients were being enrolled; five patients had been enrolled and completed treatment and both had been safely weaned without reported adverse events.

The patient selection criteria is as follows:

Inclusive Criteria	- Critically ill cardiovascular patients with hemodynamic instability assessed by us as requiring IABP implantation, defined as systolic blood pressure < 90 mmHg for more than 30 minutes or requiring catecholamines to maintain systolic blood pressure ≥ 90 mmHg; - Patients with suitable arterial access permitting successful IABP placement; and - Patients who understand the trial purpose, voluntarily consent to participate, sign the informed consent form and agree to undergo relevant examinations and clinical follow-up.
Exclusive Criteria	- Age below 18 or above 90 years; - Pregnant or lactating women;

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- Patients with any IABP contraindication, including: moderate-to-severe aortic regurgitation; ruptured aortic sinus aneurysm; aortic diseases (aortic dissection, aortic aneurysm, aortic trauma, severe aortic atherosclerosis); peripheral vascular disease (e.g., severe iliac artery stenosis or calcification); cardiac arrest or ventricular fibrillation; severe bleeding tendency or hemorrhagic disorders (e.g., active bleeding, severe thrombocytopenia); severe anemia; irreversible brain damage or acute cerebral hemorrhage;
- Patients unable to receive antiplatelet or anticoagulant therapy, or with a history of heparin allergy;
- Patients currently or previously enrolled in other clinical trials that may affect the endpoint events of this study; and
- Patients whom the investigator considers unsuitable for the study due to any underlying medical or psychiatric condition.

The following table sets forth the evaluation criteria and the results of the first five patients who had been enrolled and successfully discharged.

Evaluation criteria	Result for the first five patients enrolled and discharged
Safety: Incidence of adverse events (“AEs”) and serious adverse events (“SAEs”) during the clinical trial period	No CTCAE-defined AE or SAE assessed as related to NovaPulse had been reported.
Clinical operability: the operability of IABP and the flow of the balloon catheter will be assessed by physicians operating the IABP	All ten operability questionnaire items were rated “very satisfied” (score 5) by the treating physicians, indicating favorable clinical operability and reliability of the device.
Efficacy: Counter pulsation pressure, hemodynamic indicators (including cardiac output, cardiac index and mean arterial pressure) and changes in cardiac biomarkers (e.g., NT-proBNP) following IABP implantation	The mean counter pulsation pressure was maintained at 100–110 mmHg during IABP operation. Hemodynamic parameters (cardiac output, cardiac index and mean arterial pressure) showed improvement at 24 hours post-implantation compared with baseline. NT-proBNP decreased at 24 hours post-implantation, although subsequent time-point fluctuations were noted, which may be related to the small sample size, individual variability and the complex conditions of the patients.

Further Development Plan

We plan to focus further development on upgrading NovaPulse with fiber-optic aortic pressure sensing and a compatible fiber-optic balloon catheter, while continuing routine post-market surveillance. The fiber-optic upgrade is intended to improve waveform fidelity and timing accuracy, reduce set-up complexity and susceptibility to artefact compared with conventional fluid-filled pressure lines, and enhance counter-pulsation performance in ICU, perioperative and catheter-lab workflows. Over time, we also expect to support further clinical evaluations of NovaPulse with the fiber-optic configuration to characterize safety, hemodynamic support performance and usability, and to inform subsequent product iterations within the existing intended use.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP NovaPulse FOR NEW INDICATIONS OR COMMERCIALIZE IN NEW MARKETS SUCCESSFULLY.

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NovaVent — Our Product Candidate for General Hospital Respiratory Support

NovaVent is our product candidate being developed as a critical care and inpatient respiratory support system designed to synergistically combine three functions that are conventionally provided by separate devices — mechanical ventilation, iNO therapy and electrical impedance tomography monitoring — into a synergetic platform, with the aim of improving treatment effectiveness while reducing bedside complexity in hospital workflows. We expect to perform type test for NovaVent in the first quarter of 2027.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET NovaVent SUCCESSFULLY.

NovaPath — Our Product Candidate for Cardiopulmonary Bypass and Extracorporeal Life Support

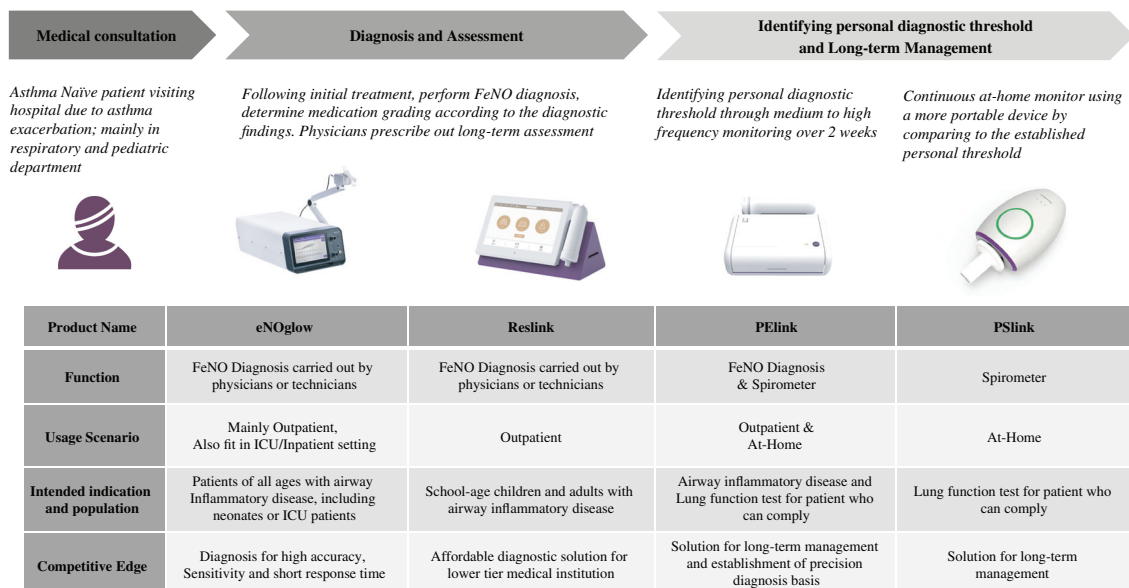
NovaPath is our disposable arteriovenous cannula product candidate being developed to establish high-flow, low-resistance arterial perfusion and venous drainage access for patients requiring cardiopulmonary bypass during cardiac surgery or extracorporeal membrane oxygenation support in critical-care settings. NovaPath adopts biocompatible materials and an optimized wall-thickness design, with the aim of maintaining hemodynamic stability during extracorporeal circulation, reducing the risks of hemolysis and thrombosis, and facilitating cannulation and placement. We expect to submit a Class III medical device registration application for NovaPath to the NMPA in the fourth quarter of 2026.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET NovaPath SUCCESSFULLY.

RESPIRATORY DIAGNOSTICS

We are developing a portfolio of respiratory diagnostic products focused on exhaled nitric oxide (FeNO) and lung-function assessment to enable earlier detection and more refined management of chronic airway diseases across hospital, clinic, primary-care and at-home settings. FeNO is a non-invasive biomarker of airway inflammation used to support the diagnosis and monitoring of asthma, chronic cough, COPD and other airway diseases, while spirometry remains a core tool for assessing airflow limitation and treatment response. Within this segment, we have two major commercial-stage FeNO analyzers — eNOglow, a chemiluminescence-based system designed for high-sensitivity, rapid and multi-mode FeNO measurement for tertiary hospitals, pediatric departments and ICU settings, and Reslink, an analyzer based on our self-developed electrochemical NO sensor targeted at respiratory outpatient clinics and lower-tier hospitals — as well as two portable product candidates: PElink, a outpatient and at-home device combining FeNO and selected lung-function parameters, and PSlink, an at-home spirometry device designed to support high-frequency monitoring of lung function against individualized “personal best” baselines between specialist visits.

The following chart illustrates the portfolio and main application of our major respiratory diagnostic products portfolio.



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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND/OR MARKET OUR RESPIRATORY DIAGNOSTIC PRODUCTS AND PRODUCT CANDIDATES SUCCESSFULLY.

OTHER PRODUCTS AND SERVICES

Our other products and services comprise (i) contract development services where we conduct product development for customers based on our R&D capabilities, (ii) others, primarily including maintenance services provided to customers after the sales of our medical devices. Our maintenance service primarily covers the following with no additional charge: (1) after-sales services, including replacement of defective components, system upgrades, periodic equipment inspections, preventive maintenance and servicing, and (2) post-sales technical training for our distributor engineers. Upon expiration of the warranty period, we may continue to provide maintenance services and components for replacement at RMB150 to RMB41,000 for replacement components, RMB10,000 to RMB120,000 for maintenance services and RMB2,000 to RMB3,000 per distributor engineers trained.

OUR GAS-LIQUID PRECISION CONTROL TECHNOLOGY PLATFORM

Our intelligent gas-liquid precision control technology platform is the cornerstone of our product innovation. It supports end-to-end, closed-loop control of target molecules in both gas and liquid media, spanning generation, real-time sensing and monitoring, and software-enabled regulation. By integrating molecular generation, sensor-based detection, control algorithms and fluidic engineering, we are able to deliver medical gas and fluid solutions with high precision, reliability and scalability across different clinical settings.

Our platform comprises three integrated technical pillars:

NO generation technologies. We have established two NO generation approaches — electrochemical catalytic reduction and plasma discharge — allowing us to adapt NO supply to different clinical requirements and product configurations. Our electrochemical catalytic reduction approach enables NO generation and purification under mild conditions within an integrated process, supporting high-purity, high-concentration therapeutic NO output. Based on bench testing, NO concentration could be generated across a wide range (approximately 390 ppm to 3,500 ppm) under consecutive applied currents (10-90 mA). The electrolytic cell also demonstrated stable NO output at a fixed concentration over five consecutive time periods, supporting reliable dose control. In addition, the system could reach a target therapeutic NO level within approximately two minutes, while maintaining $\text{NO}_2 < 1$ ppm across therapeutic dosing ranges. These capabilities underpin our iNOwill series. Separately, our plasma discharge approach enables a compact generation module and flexible integration with portable or transport-oriented device architectures, supporting products designed for broader in-hospital and mobile use scenarios, including eNOaire, NovaVent and VQfit.

Gas sensing and molecular monitoring technologies. We have developed complementary sensing capabilities based on electrochemical detection and chemiluminescence, enabling measurement of NO and other clinically relevant gas components under different sensitivity and workflow requirements. By combining differentiated sensors, sampling modules and monitoring logic, our systems can track patient-side gas composition and dynamics in real time, including breath-to-breath variability and delivered concentrations of therapeutic NO, key by-products (such as NO_2), oxygen and other parameters, supporting dosing precision and safety management. Our monitoring solutions are embedded across our therapeutic products (including iNOwill and eNOaire) and are also applied in our diagnostic offerings and patient-side respiratory circuits.

Intelligent flowpath design and control technologies. We have built high-precision, fast-response and high-reliability gas/liquid circuit systems, together with proprietary fluid-control algorithms. These capabilities enable controlled gas release, mixing, flow and timing to match clinical therapy and diagnostic requirements, including breath-synchronized delivery, stable concentration maintenance and safety-oriented fail-safe mechanisms. Our control architecture is designed to maintain consistent performance across different care settings and operating conditions and serves as a common technical backbone across all of our core product lines.

Software, algorithms and practical AI-enabled functions are embedded in our technology platform and apply in our product lines to support controllability, verification and usability. In our iNO therapy systems, algorithms adjust NO output in real time based on inspiratory flow to maintain stable patient-side concentration, improve gas utilization and support automated workflow functions such as initiation, weaning and key-component life monitoring. In our IABP system, AI supports more reliable triggering and clinical feedback by enhancing ECG signal recognition in

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noisy ICU environments, analyzing arterial pressure waveforms to provide objective indicators of counterpulsation effectiveness, and enabling predictive maintenance through monitoring of device pressure signatures. In our respiratory diagnostic products, intelligent sampling and signal-processing algorithms help standardize breath collection and improve measurement repeatability, and we are developing data-fusion approaches that link hospital and outpatient or at-home devices by combining parameters such as FeNO, lung function, CO₂ waveforms and symptom/medication logs to support longitudinal monitoring and earlier risk identification.

MAJOR RESEARCH COLLABORATIONS AND LICENSING ARRANGEMENTS

University of Michigan Licensing Arrangement

In March 2020, we entered into a patent license agreement with The Regents of the University of Michigan (“**Michigan**”), which was amended in December 2021 (together, the “**Michigan License Agreement**”). Michigan is the governing body of the University of Michigan, a leading public research university in the United States and an Independent Third Party. Under the Michigan License Agreement, Michigan grants us an exclusive license, with the right to grant sublicenses, in the PRC and Hong Kong over certain Michigan-owned patents and patent applications relating to NO-releasing polymers and gas-delivery devices capable of generating and delivering NO-containing gas streams (the “**Licensed Michigan IP**”). We entered into the Michigan License Agreement at an early stage of our development to support our chosen technical route. As part of our initial technology assessment and patent landscape analysis, we identified that the University of Michigan was among the earliest institutions to publish and establish foundational research in electrochemical nitric oxide generation, with corresponding patent filings across multiple jurisdictions. In connection with our intention to develop and commercialize iNO therapy products based on electrochemical generation technology and to prioritize regulatory registration in China, we obtained the license to address potential patent overlap risks identified at the early stage, support our freedom to operate during product development and registration, and establish an initial patent position in our primary target market. Such exclusive arrangement also limits the ability of other market participants to obtain similar rights within the same jurisdiction, thereby solidifying our positioning in early-stage market development. The Michigan License Agreement also serves as a professional endorsement from a leading academic institution, which enhanced the credibility of our technological approach. This endorsement have also helped us in marketing education and brand communications with hospitals and distributors and supported our product sales. Our Core Product has been independently developed by us and does not rely on, nor is directly based on, the Licensed Michigan IP. Michigan retains customary rights to use the Licensed Michigan IP for academic research, teaching and publication and to license such non-commercial uses to other non-profit organizations. The salient terms of the Michigan License Agreement are set forth below:

- **Payment:** We paid Michigan a one-off, non-refundable license issue fee and agreed to (i) pay an annual license maintenance fee before and after the first commercial sale of any product that utilizes the Licensed Michigan IP (which may be fully or partially creditable against running royalties), (ii) make development and regulatory milestone payments upon the achievement of specified clinical, regulatory and commercial milestones, and (iii) pay running royalties at a single-digit percentage rate on our net sales of products that use the Licensed Michigan IP, subject to customary adjustments and minimum-royalty provisions.
- **Intellectual Property:** Michigan retains ownership of all background intellectual property and patents comprised in the Licensed Michigan IP. We own intellectual property, data and know-how that we independently develop in connection with our products.
- **Termination:** The Michigan License Agreement may be terminated early by mutual agreement, by either party for uncured material breach or insolvency of the other party, or by us at will upon advance written notice.
- **Sublicense:** We are allowed to sublicense the licenses to third parties, provided that we shall notify Michigan in writing of every sublicense agreement and each amendment thereto within thirty days after their execution, and shall require all sublicenses to be consistent with the terms of the Michigan License Agreement. Each sublicense granted by us shall terminate upon the termination of the Michigan License Agreement.
- **Dispute Resolution:** Any dispute under the Michigan License Agreement shall be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Chambers’ Arbitration Institution.

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The patents and their corresponding technologies under the Michigan License Agreement are set forth in the below table. All of the licenses are owned by Michigan and licensed to us.

No.	Patent Summary	Registration No.	Key Technologies Involved
1	A nitric oxide delivery device comprising a shell permeable to nitric oxide	CN104394923B	This patent relates to integrating an electrochemical NO generation device into an implanted catheter for purposes such as anti-infection and anti-thrombosis. The Core Product does not include the following key technical features recited in the claims of this patent: “a shell permeable to nitric oxide” and “a working electrode made of a copper-containing conductive material.” Therefore, the Core Product does not fall within the scope of protection of this patent, and implementation of the Core Product technology does not depend on this patent.
2	A nitric oxide delivery device comprising a shell permeable to nitric oxide	HK40020499B	This patent relates to integrating an NO generation source into an implanted catheter for purposes such as anti-infection and anti-thrombosis. The Core Product does not include a delivery conduit, nor does it include an outlet conduit carrying N ₂ and NO that is configured downstream of the inspiratory gas conduit carrying O ₂ -containing gas, and the N ₂ /NO/O ₂ gas is not mixed within the outlet conduit. Therefore, the Core Product does not fall within the scope of protection of this patent, and implementation of the Core Product technology does not depend on this patent.
3	A gas delivery device comprising a nitric oxide generation system	CN121623046A	This patent relates to an alternative solution for delivering NO-containing gas using an electrochemical NO generation device. The Core Product does not include the following key technical features recited in the claims of this patent: “the delivery catheter is connected to the outlet of an outlet conduit downstream of the inspiratory gas conduit, such that the output gas flow has time to mix within the outlet conduit before being delivered to the destination.” Therefore, the Core Product does not fall within the scope of protection of this patent, and implementation of the Core Product technology does not depend on this patent.

RESEARCH AND DEVELOPMENT

We conduct our product research and development primarily in-house. Our R&D system covers the full product lifecycle from concept formation and feasibility assessment through design and development, pre-clinical testing, clinical evaluation, registration and post-market iteration.

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Our R&D Team. Our R&D team are led by our chief executive officer, Dr. Mao Wen, and our chief technology officer, Mr. Zhang Yuyan. Several senior R&D members have previously participated in the development or industrialization of devices such as ICU ventilators and anesthetic workstations. As of the Latest Practicable Date, our R&D team comprised 47 employees, representing approximately 27.5% of our total headcount, of whom approximately 42.6% held master’s or doctoral degrees. Our R&D personnel cover disciplines including chemistry, pharmacy, material science, mechanic engineering, biomedical engineering and computer science. We have entered into confidentiality and non-compete arrangements with key employees and R&D staff, under which intellectual property conceived and developed during employment belongs to us. As of the Latest Practicable Date, we had not experienced any loss of key R&D personnel (including core R&D members as set forth below in “— Research and Development — Clinical Development.”

Our R&D Costs. We have devoted and expect to continue to devote a significant portion of our resources to R&D as we expand the indications and continue the clinical development of our Core Product, advance other pipeline candidates through clinical trials and conduct additional pre-clinical studies. In 2024, 2025 and the six months ended June 30, 2025 and 2026, our R&D expenses were approximately RMB33.0 million, RMB34.7 million, RMB13.7 million and RMB20.3 million, representing approximately 72.4%, 54.9%, 61.3% and 34.8% of our total revenue, respectively. Of these amounts, RMB12.3 million, RMB14.5 million, RMB5.1 million and RMB8.7 million were attributable to our Core Product, respectively, representing 37.4%, 41.8%, 37.2% and 42.9% of our total research and development costs, and 13.9%, 16.1%, 13.4% and 14.8% of our total operating expenses, in the corresponding years/periods.

Clinical Development. We conduct clinical trials as a core component of our product development, registration and post-market evidence generation strategy. Our clinical affairs function is led by Ms. Zhou Fang, who has approximately 10 years of experience in the medical device and pharmaceutical fields with a focus on device registration, multi-center clinical trials and global regulatory strategy, and is staffed by professionals with medical, pharmacy or biomedical engineering backgrounds. Our clinical team has led the design and execution of registration-enabling and post-market trials for our products.

Our Core R&D Members include the core leadership and other relevant personnel, who collectively possess the qualifications, relevant experience and functional expertise necessary to support the continuous development of our products (including the Core Product). We expect our Core R&D Members to remain with us after the [REDACTED]. The core leadership includes the following Core R&D Members.

Dr. Mao Wen, as chairperson, executive Director and chief executive officer, is responsible for overall leadership and strategic direction of the Core Product, including R&D, registration and commercialization. With over 14 years of experience in biological research and the medical device industry, a doctorate degree in neuroscience, and her prior role as R&D director at Abbott Diabetes Care Inc., Dr. Mao has extensive experience in overseeing complex medical device development programs and managing cross-functional R&D teams. Dr. Mao participated in various research projects including the Nanjing Life and Health Science and Technology Pre-clinical Technology Project (南京市生命健康科技專項臨床前技術項目) in 2022: *Portable Inhaled Nitric Oxide Therapy Device for Neonatal and Adult Pulmonary Hypertension* (《用於新生兒和成人肺動脈高壓治療的便攜式吸入一氧化氮治療儀》); the Nanjing Industrial and Information Technology Development Special Project (南京市工業和信息化發展專項) in 2023: *Breakthrough in Key and Core Technologies for Nitric Oxide (NO) Generation and Sustained-Release in Multi-Scenario Medical Applications* (《多場景醫學應用的一氧化氮(NO)發生、緩釋關鍵核心技術攻關項目》); and the Guangxi Zhuang Autonomous Region Science and Technology Planning Project (廣西壯族自治區科技計劃項目) in 2026: *R&D and Industrialization of Domestically Pioneering Chemiluminescence Nitric Oxide Breath Analyzer* (《國內首創化學發光一氧化氮呼氣分析儀研發及產業化》). Dr. Mao was awarded the Outstanding Youth Award in Pharmaceutical Science and Technology (醫藥科技傑出青年獎) in the 2024 10th Jiangsu Medical Science and Technology Award (2024第十屆江蘇醫藥科技獎) in 2025. She holds 8 patents in relation to NO therapy. Her experience in global product development, registration and commercialization of medical-device products supports the advancement of the Core Product through clinical and regulatory stages.

Mr. Zhang Yuyan, as executive Director and chief technology officer, is responsible for overall technology strategy and product development. He holds a bachelor’s degree in automation and a master’s degree in control theory and control engineering, and has over 17 years of experience in medical-device systems engineering and R&D management, including his prior roles at GE Medical Systems and Suzhou Hengrui Hongyuan Medical Technology Co., Ltd. His experience in systems design, engineering integration and ICU-related device development, including respiratory-support and extracorporeal circulation-related equipment, is highly relevant to the development of electrochemical iNO delivery systems used in critical care settings.

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Ms. Fang Zhou, who joined the Group in May 2022, is the leader of the Company’s clinical affairs function. She holds a master’s degree in traditional Chinese medicine chemistry from China Pharmaceutical University and has clinical research and medical affairs experience at Chia Tai Tianqing Pharmaceutical Group, where she managed clinical research projects and academic promotion for anti-infective product lines. During her tenure at Chia Tai Tianqing, she focused on anti-infective products used in ICU, respiratory, and hematology settings, gaining extensive experience in disease areas closely related to NO therapy, including severe infections and respiratory support. She led multiple clinical trials and real-world studies as project manager and supervised a medical team. Her background in clinical research management, medical academic support and clinical trial execution supports the clinical validation and regulatory advancement of the Core Product. Since joining us, she has built the medical department from scratch, led clinical trials, supported the publication of medical papers and NO-related expert consensuses, and contributed to the registration and launch of products in areas including ICU, cardiology, neonatology and respiratory medicine, which are key therapeutic fields for NO therapy.

In addition to the above, our Core R&D Members comprise personnel with complementary expertise spanning electrochemical NO generation, gas sensing and purification, medical-device systems engineering, hardware and software development, mechanical design and clinical research. Collectively, these members support the in-house development, verification and continued optimization of the Core Product across its principal technical modules, and enable our R&D capabilities in electrochemical catalysis-based iNO technologies to be maintained by a multidisciplinary team rather than being dependent on any single individual.

(i) Electrochemical catalysis, NO generation, sensing and purification

Dr. Mao Yujia joined the Group in November 2021 upon completion of her doctoral studies and is primarily responsible for electrode and electrolytic-cell development. She holds a doctoral degree in chemistry from the University of Houston. Her doctoral research specialized in physical chemistry, particularly the development of super-resolution force spectroscopy and its application to the study of DNA-drug interactions and surface biochemical reactions. During her doctoral studies, she published research papers in journals including *ChemBioChem* and *Nucleic Acids Research* and participated in a U.S. patent application. Dr. Mao’s expertise in surface biochemical reactions, molecular interactions and surface modification directly supports our Core Product’s electrochemical NO generation technology. In particular, she has led the development and formulation optimization of the electrolytic solution used in our Core Product’s electrochemical NO generation system, in which high-valence metal ions are reduced at the cathode to lower-valence states, which in turn reduce nitrite ions in the solution to generate NO. Her research background also supports the investigation and optimization of electrode-surface reactions, electrochemical NO generation mechanisms and surface molecular modification of electrochemical sensors used in our Core Product. The relevant electrolyte formulation has been the subject of a PCT patent application currently pending in the international examination phase.

Mr. Zhao Yangbo joined the Group in July 2020 and is primarily responsible for electrode and electrolytic-cell development. He holds a master’s degree in chemistry from Beijing University of Chemical Technology, where his research specialized in gas sensors. From July 2015 to August 2017, he engaged in purification-material research and development at Zhejiang Taihe Holdings Co., Ltd.. From August 2017 to January 2019, he served as a materials R&D engineer and subsequently an R&D lead at Zhejiang Dun’an Co., Ltd., where he was responsible for catalyst, purification-filter, activated-carbon and ceramic-based material development. From March 2019 to April 2020, he served as an electrochemical engineer at Siwei Ecology Technology Co., Ltd., where he was responsible for electrochemical-device development and related testing. He has over ten years of R&D experience and has participated in two patent applications and one published research paper. During his master’s studies, Mr. Zhao focused on the controllable preparation and performance optimization of metal-oxide-semiconductor-based NO_x-sensitive materials and the mechanisms through which such materials respond to NO and NO₂. He designed multiple metal-oxide gas-sensing material systems based on the adsorption, redox and electrochemical characteristics of NO_x gases, established a standardized gas-sensing test platform and studied NO_x-sensing mechanisms from the perspectives of macroscopic performance, microscopic structure and electronic energy levels. Such experience directly supports our Core Product in several respects, including (i) the design and material selection of its electrochemical NO generation system, (ii) the development and optimization of electrodes and electrolytic cells, (iii) the selection and evaluation of catalyst and NO_x-filtering and purification materials, (iv) the development and iteration of NO, NO₂ and O₂ electrochemical sensors and the gas-monitoring module, and (v) the establishment of testing and performance-evaluation methods for the electrochemical NO generation system.

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Together, Dr. Mao and Mr. Zhao provide complementary capabilities covering the electrochemical reaction mechanism, electrolyte formulation, electrode and electrolytic-cell development, NO_x sensing and gas purification that underpin our Core Product’s electrochemical catalysis-based NO generation technology.

(ii) Medical-device systems engineering, verification and certification

Mr. Kong Xianghai joined the Group in September 2021 and is primarily responsible for whole-system verification of our Core Product. He holds a bachelor’s degree in electric power systems and automation from Xi’an Jiaotong University. From April 2012 to April 2015, he worked at Aikowei Technology Co., Ltd. in product testing. From June 2015 to March 2016, he served as a project manager at Wuxi Chongchi Software Technology Co., Ltd. From May 2016 to May 2018, he served as head of the electrical laboratory at Wuxi Jingwei Metrology Co., Ltd., where he was responsible for metrology-standard establishment and related laboratory management. From June 2018 to April 2019, he worked at Wuxi Haideman Medical Co., Ltd. From April 2019 to August 2021, he worked at GE Healthcare and its service provider, where he was responsible for system testing and TÜV verification testing of medical devices, including CS750 and A180/Proteus anesthesia machines and the R860 ventilator.

Mr. Kong has approximately 14 years of testing experience and is familiar with medical-device testing standards, including YY 0461, ISO 5367, IEC 60601 and GB 9706. His experience directly supports our Core Product’s whole-system verification, including the preparation and execution of test cases for the electrochemical NO generation, gas delivery, gas monitoring and alarm-control functions, verification of system performance under different operating conditions, and testing for compliance with applicable medical-device safety and performance standards and third-party certification requirements.

Mr. Bao Xiaoyi joined the Group in November 2021 and is primarily responsible for whole-system verification of our Core Product. He holds a master’s degree in mechatronic engineering, specializing in electromagnetic compatibility, from Southeast University. From May 2006 to July 2011, he served as a laboratory head at the 14th Research Institute of China Electronics Technology Group Corporation, where he was responsible for hardware and electromagnetic-compatibility testing. From August 2011 to December 2014, he served as a hardware testing manager at Huawei Technologies Co., Ltd. Nanjing Research Institute. During April 2015, he served as a senior testing engineer at Wulian Sensor Co., Ltd. From June 2015 to August 2018, he served as testing manager and project manager at Jusha Display Technology Co., Ltd. From August 2018 to May 2020, he served as testing manager at Shibang Intelligence Technology Co., Ltd. From May 2020 to October 2021, he served as testing lead at Zhongyuan Huiji Biotechnology Co., Ltd. He has over 20 years of experience in hardware and medical-device testing and verification and holds a Project Management Professional qualification.

Mr. Bao’s expertise covers electromagnetic-compatibility design and testing, reliability and mean-time-between-failures testing, CCC, CE and TÜV certification, integrated product development processes and testing-team management. His expertise directly supports the electromagnetic-compatibility design and rectification, reliability assessment, certification testing and quality control of our Core Product, including verification that its electrochemical NO generation, gas-sensing and electronic-control modules operate safely and reliably without unacceptable electromagnetic interference.

Together, Mr. Kong and Mr. Bao provide system-level verification, electromagnetic-compatibility, reliability and regulatory-certification capabilities covering the complete electrochemical NO generation and delivery system of our Core Product.

(iii) Hardware architecture and electronic control

Mr. Geng Xiang joined the Group in March 2020 and currently serves as R&D Manager with primary responsibility for the hardware development and overall R&D management of our Core Product. He holds a bachelor’s degree in microelectronics from Soochow University. From June 2006 to December 2007, he served as an R&D engineer at the 55th Research Institute of China Electronics Technology Group Corporation. From May 2007 to March 2011, he served as an R&D engineer at Inventec Appliances Co., Ltd. From January 2011 to November 2015, he served as a senior engineer at Honeywell S&C. From November 2015 to May 2018, he served as a project manager at A. O. Smith. From June 2018 to September 2020, he served as R&D manager at Jingjie Biotechnology Co., Ltd.

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Mr. Geng has experience in microelectronics, biotechnology-device development, hardware R&D management and coordination of multidisciplinary R&D teams. His experience supports the overall hardware architecture and development management of our Core Product, including coordination of the electronic-control, power-management, gas-sensing and electrochemical NO generation modules and management of their integration into a medical-device system suitable for verification and commercial manufacture.

Mr. Zhang Wangkun joined the Group in March 2021 and is primarily responsible for hardware development of our Core Product. He holds a bachelor's degree in automation from Nanjing Forestry University. From March 2015 to March 2017, he served as an R&D engineer at Jiangsu Huaxi Medical Devices Inc., where he was responsible for the STM32-based hardware and software development of cleaning and disinfection equipment and air-disinfection devices. From March 2017 to February 2021, he served as a hardware engineer at A. O. Smith, where he acted as a principal hardware designer for water-purification products.

Mr. Zhang has over ten years of hardware-development experience and is experienced in schematic and printed-circuit-board design, STM32, DSP and Renesas microcontroller programming, multiple communication protocols, RFID design and electromagnetic-compatibility testing and rectification. His expertise directly supports our Core Product's hardware circuit and electronic-control design, including signal acquisition from NO, NO₂, O₂ and flow sensors, microcontroller-based control of electrochemical NO generation and gas delivery, communication among the generation, monitoring and user-interface modules, electromagnetic-compatibility verification and transfer of the hardware design into commercial production.

Together, Mr. Geng and Mr. Zhang provide the hardware architecture, electronic-control, sensor-interface and production-transfer capabilities required to translate our Core Product's electrochemical NO generation mechanism into a reliable medical-device platform.

(iv) Embedded software, application software and system control

Mr. Zhou Dawei joined the Group in December 2020 and is primarily responsible for software development of our Core Product, including its embedded software, application-layer software and user-interface functions. He holds a master's degree in computer science and technology from Sichuan University, where his research specialized in computer vision and pattern recognition. From July 2012 to September 2014, he served as a software engineer at ZTE Corp., where he was responsible for router quality-of-service software development. From October 2014 to August 2017, he served as a software engineer at Suzhou Huawei Digital Technologies Co., Ltd., where he was responsible for wireless-network software development. From August 2017 to December 2020, he served as a software engineer at GE Healthcare, where he was responsible for upper- and lower-level software development for anesthesia machines.

Mr. Zhou has over ten years of embedded and communications-software experience and is experienced in C programming, Linux-system development, multi-core and multi-threaded processing and medical-device software-development processes. His experience directly supports our Core Product's embedded and application-layer software, including real-time coordination of NO generation and inspiratory-flow-based delivery, acquisition and processing of NO, NO₂, O₂ and flow data, communication among functional modules, user-interface display and interaction, alarm processing and software reliability verification.

Mr. Li Yuan joined the Group in May 2021 and is primarily responsible for embedded software, application-layer software and driver development for our Core Product. He holds a bachelor's degree in automation from Zhongyuan University of Technology. From September 2016 to April 2018, he served as a software engineer at A. O. Smith. From July 2018 to May 2021, he served as a software engineer at Yangzhou Hangsheng Technology Co., Ltd. He has over 10 years of experience in embedded, Linux and Android driver development and is familiar with ARM assembly, Linux-kernel transplantation and customization, U-Boot, FreeRTOS, Android hardware-abstraction layers and communication protocols including SPI, I²C, UART and CAN.

Mr. Li's expertise directly supports our Core Product's underlying software infrastructure, including device-driver development for electrochemical NO generation, gas-sensing and flow-control components, embedded-Linux system transplantation, communication among hardware modules, real-time task scheduling and multi-core and multi-thread performance optimization, thereby supporting the stable and timely control of NO generation, delivery and monitoring.

Together, Mr. Zhou and Mr. Li provide the embedded, driver, application-layer and user-interface capabilities required for real-time control, monitoring and safety management of our Core Product's electrochemical NO generation and delivery functions.

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(v) Mechanical design and core components

Mr. Wu Qing joined the Group in September 2020 and is primarily responsible for mechanical design and core-component design of our Core Product. He holds a bachelor’s degree in materials forming and control engineering, specializing in mold design, from Nanjing Institute of Technology. From December 2006 to September 2009, he served as a mold and structural engineer at Nanjing Aolian Electronics Co., Ltd. From September 2009 to September 2015, he served as a mechanical-structural engineer at Nanjing Bofeng Power Tools Co., Ltd. From October 2015 to August 2020, he served as a senior mechanical engineer at Siemens Numerical Control (Nanjing), where he led the development of the V90PN, S210 and S200 servo drives. One of the relevant designs received a Red Dot Design Award.

Mr. Wu has experience in mechanical-structure and mold design, simulation using NX, Nastran and FloTHERM, product-reliability verification and material selection for plastic components. His expertise directly supports the structural design of our Core Product’s electrochemical NO generation and gas-pathway modules, positioning and protection of electrodes, electrolytic cells, sensors and related components, thermal and airflow simulation, mold development, reliability verification, manufacturability optimization and material selection.

(vi) Clinical research and medical support

Ms. Fang Zhou joined the Group in May 2022 and is primarily responsible for clinical research and medical and academic support for our Core Product. She holds a master’s degree in traditional Chinese medicine chemistry from China Pharmaceutical University, where her research focused on natural-medicinal chemistry and meta-analysis. From July 2016 to April 2022, she served as medical group manager for an anti-infective product line at Chia Tai Tianqing Pharmaceutical Group, where she managed a seven-member team and was responsible for clinical-research projects, medical and academic support and the academic promotion of anti-infective products, including biapenem and tigecycline.

Ms. Fang has experience in clinical-research project management, clinical monitoring, medical writing, meta-analysis and communication with clinical investigators and key opinion leaders in anti-infective and respiratory fields. Her expertise supports our Core Product’s clinical-development activities, including clinical-trial design and implementation, interpretation and communication of clinical evidence relating to iNO therapy, medical support for indication expansion into respiratory and infectious diseases, preparation of scientific publications and engagement with investigators and clinical experts.

We also maintain a separate regulatory affairs team responsible for planning registration pathways and submitting product dossiers to the NMPA and other PRC authorities, as well as to overseas regulators. Our trials are designed to evaluate the safety and clinical performance of our devices under intended use conditions, with endpoints selected based on the clinical role of each device. Certain of our products are exempt from clinical trials in specific jurisdictions based on their classification and applicable laws and regulations; in those cases, we rely on non-clinical performance testing, literature-based evaluation and post-market surveillance to support regulatory submissions and ongoing safety and performance evaluation.

Collaboration with Clinical Trial Institutions. We select leading tertiary hospitals with appropriate expertise, patient resources, technology and equipment as our clinical trial institutions (our “**collaborating hospitals**”). As of the Latest Practicable Date, we had initiated or participated in an aggregate of 20 clinical trials, including 18 in China and two in overseas markets. We typically enter into arrangements with the collaborating hospitals under which we and the investigators prepare a protocol and related documents (including, where applicable, informed consent forms and case report forms) for submission to the ethics committees of the participating institutions. Trials are conducted strictly in accordance with the approved protocol.

Relationship with CROs

We collaborate with contract research organizations (CROs) to support certain of our clinical trials, including the PMCF of iNowill. Our CROs typically provide services including project implementation and management, trial site coordination and subject enrollment. When selecting CROs, we consider their qualifications, track record, the professional experience of their employees and industry reputation. Under these arrangements, we remain responsible for overall trial design and quality management and retain the right to use the clinical data and other deliverables generated from such studies for regulatory submissions and further product development. We monitor our

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CROs through regular communication and review of documentation and deliverables to help ensure that their performance complies with applicable laws, regulations and clinical standards as well as our internal protocols and to safeguard the integrity and reliability of the data arising from our clinical trials.

Below is a summary of the key terms of a typical agreement with our CROs.

Service term	Typically 12 months, with progress tracked against agreed milestones and key timelines.
Scope of services	The CRO typically provides operational support across the principal stages of study execution, including, among others, pre-trial planning and regulatory communications, study start-up and conduct, site monitoring and coordination, data and project management, biostatistics and medical writing. We retain oversight of the CRO’s performance and may require rectification where the CRO fails to comply with the protocol, applicable requirements or agreed standards.
Fee arrangement	Generally fixed service fees, consisted of upfront payments and payments made in stages by reference to agreed milestones such as contract signing, protocol finalization, subject enrollment, site close-out and completion of the clinical trial report.
Legal compliance	The CRO is required to perform the services in accordance with applicable laws, regulations, GCP and relevant industry standards. The CRO is liable for any costs, fines, claims or expenses due to its violations of laws and regulations.
Confidentiality	The CRO is subject to confidentiality and data security obligations, including in relation to personal information and study materials, and is required to return or transfer relevant study documents and data upon completion or termination of the project.
Intellectual property	Clinical data, study documents, deliverables and other project results generated in the course of the services belong to us, subject to each party’s pre-existing intellectual property rights.
Termination	We may terminate the arrangement in specified circumstances, including material breach, persistent delay, failure to meet major milestones, force majeure and other circumstances affecting project performance.

OUR COMMERCIALIZATION STRATEGIES

As of the Latest Practicable Date, our Core Product iNOwill was being developed independently and was not subject to any collaboration or out-licensing arrangements with third parties. We plan to continue developing iNOwill in-house, including product improvement, indication expansion and post-approval studies, and to expand its clinical adoption. As we obtain or pursue regulatory approvals overseas, we intend to introduce iNOwill into selected markets, primarily through registration-driven sales using a combination of our own commercial resources and qualified local distributors, depending on local market conditions.

Being included in the reimbursement list can help deepen the market penetration of our products. As of the date of this Document, our iNOwill, eNOaire, NovaPulse IABP and FeNO were included in the reimbursement list of seven provinces.

Market Strategies for our Core Product

China Market: Solidifying Leadership and Expanding Penetration

In China, our strategy centers on consolidating our position in the underpenetrated iNO market and driving its expansion.

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We reinforce our market leadership through five key pillars:

- **Strategic Partnerships:** Collaborating with top-tier hospitals on clinical trials and national research projects, particularly those renowned for cardiopulmonary disease treatment.
- **Academic Promotion:** Participating in academic and industrial events to engage hospitals and distributors and advance physician education.
- **Specialized Distribution Network:** Partnering with distributors who specialize in ICU, NICU, and Respiratory departments and already represent other Novlead product lines within these segments.
- **Comprehensive Product Portfolio:** Offering a diverse range of models priced between RMB200,000 to RMB800,000, catering to the varying needs of hospitals across different tiers.
- **Experienced Sales Force:** Leveraging a seasoned sales team of more than 30 members with experience in the medical device industry.

We also further expand our market share through the following initiatives:

- Spearheading the development of expert consensus and industry standards.
- Sponsoring health economic studies to demonstrate the value of iNO therapy.
- Continuously expanding our commercial team, encompassing both sales and marketing functions.

European Market: Introducing Disruptive Technology

Having entered the European market in 2025, where traditional gas cylinders have dominated for over a decade, we are adopting a top-down approach to introduce our instant-generation technology. Our strategies include:

- Utilizing Post-Market Clinical Follow-up (PMCF) studies and key academic and industry forums to engage with leading hospitals across Europe.
- Prioritizing the conversion of top-tier institutions from cylinder-based systems to our solution.
- Leveraging our enhanced usability as a key market entry advantage over incumbent cylinder-based systems.

Emerging Markets: Prioritized Expansion

For other emerging markets, we employ a selective entry strategy based on a comprehensive evaluation of factors including GDP, population, regulatory pathways, and market receptivity to iNO therapy. In these prioritized regions, we primarily rely on established local distributors for market penetration.

Global Expert Network & Knowledge Sharing

Internationally, we are cultivating a cross-regional expert network. This includes inviting leading experts from the US and Europe to China to share clinical cases and research findings. Furthermore, we facilitate knowledge exchange between Chinese physicians and their counterparts in emerging markets, where Chinese experts’ extensive practical experience positions them as authoritative pioneers in iNO therapy adoption.

Proven Execution and Impact

We believe our commercial strategy has been successfully executed. We led the drafting of Expert Consensus on the Clinical Application of Inhaled Nitric Oxide in Critical and Severe Disease and Expert Consensus on Clinical Application of Inhaled Nitric Oxide Therapy (2024 Edition). We also participate in the revision of the NMPA’s Registration Technical Guidelines for Inhaled Nitric

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Oxide Therapy Devices and Group Standard for Nitric Oxide Therapy Devices. Our presence in academic and industrial events such as China Medical Equipment Fair, Congress of Chinese Society of Critical Care Medicine has significantly elevated brand visibility.

As a result, we have entered nearly 700 hospitals worldwide and have deployed over 9,000 reactors. Based on our estimates, we have provided treatment to approximately 10,000 patients globally. In Europe, we are contacting several AP-HP (Assistance Publique — Hôpitaux de Paris) hospitals to participate in the PMCF study through CRO.

Market Strategies for our Key Product

As of the Latest Practicable Date, our Key Product NovaPulse IABP was being developed independently and was not subject to any collaboration or out-licensing arrangements with third parties. We intend to further optimize NovaPulse IABP through ongoing engineering refinements and post-marketing clinical evaluation, and to grow its installed base and utilization in cardiovascular centers and catheterization laboratories in the Chinese mainland through tenders, focused sales, marketing, training and service support.

Specifically, in China, we plan to achieve wider market adoption by: (i) leveraging our existing distribution network and cooperate more distributors with experience in cardiology and catheter labs. Our initial focus is on cardiology departments, CCUs, and catheter labs of leading hospitals, especially high-volume cardiac intervention centers that currently use overseas IABP brands. We believe our products are more compelling than overseas brands given their comparable quality and higher affordability. After establishing a presence in leading hospitals, we intend to build on our reputation to expand into a wider base of Class III hospitals and selected Class II hospitals. In addition, as IABP therapy has already been included in certain provincial medical insurance directories, our products are increasingly attractive to hospitals; and (ii) raising product awareness by attending more industry and academic conferences. In the overseas region, we plan to evaluate commercial viability with a priority in the Southeast Asian markets.

Market Strategies for our Other Products

For our other products and product candidates, we plan to advance product development, clinical evaluation and regulatory registration in line with their intended indications and care settings, with the aim of building an integrated “diagnosis — treatment — monitoring” offering from hospital to community and home use.

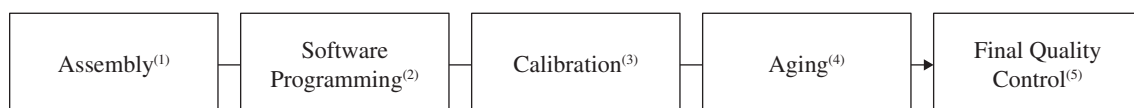
We expect to rely mainly on in-house development, supplemented by project-based collaborations with hospitals for clinical trials, and to adopt a commercial model that combines our own sales and medical teams with distributor networks, with most products marketed primarily through distributors supported by academic promotion, market-access activities and digital tools for physician education and patient follow-up.

MANUFACTURING

As of June 30, 2026, we had two principal manufacturing facilities, which were separately located in Yangzhou, Jiangsu Province and Fangchenggang, Guangxi Zhuang Autonomous Region with aggregate areas of approximately 2,200.0 sq.m. and 1,400.0 sq.m., respectively. Our facility in Yangzhou is primarily used for the manufacture of Class III medical devices, including iNOwill, eNOaire, and NovaPulse IABP. Our facility in Fangchenggang is primarily used for the manufacture of Class II medical devices, including Reslink and eNOglow.

Manufacturing Process

Based on current production planning for our medical devices, the manufacturing cycle from material allocation to finished-goods warehousing typically ranges from six hours to 48 hours. Set forth below is an illustrative flowchart for the manufacturing process of the medical devices.



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Notes:

- (1) Our trained assembly technicians examine the quality of components and integrate mechanical, electrical and sensor modules on dedicated workstations, following our Integrated Product Development framework.
- (2) We flash assembled hardware with the proprietary firmware to ensure traceability of our software releases.
- (3) We verify and adjust our products to ensure their measurements align with our established standards.
- (4) We conduct controlled-environment aging to precipitate products’ early-life failure. It is a burn-in test used to identify and remove products which show signs of product defect. We test each product to improve the reliability, and such tests may take from eight to 72 hours. The tests stimulate real use scenarios and do not introduce extra damage factors. We also monitor the parameters of product performance in real-time during the tests and control the testing duration to make sure the products remain compliant with application quality and performance following such testing.
- (5) We conduct full functional verification, calibration verification and final visual inspection of each unit against design specifications.

On the component level, as of the Latest Practicable Date, we manufactured the main unit in-house and generally outsourced the production of the NO generation reactor and tube accessories to third-party suppliers. On the system level, we assembled all the main unit, NO generation reactor and tube accessories together. We procure components from third-party medical equipment companies. The key components are those have a material impact on the performance of the Core Product. Our procurement of key components amounted to RMB4.3 million, RMB5.2 million, and RMB4.5 million in 2024, 2025 and the six months ended June 30, 2026, respectively. We require the suppliers of key components to sign a quality assurance letter to ensure their products satisfy our standards. If any quality issue is identified, our suppliers agree to repair or replace the relevant products.

We have implemented a set of comprehensive procedures for quality control. We require all our employees and collaborated third parties to strictly follow the operation protocols and implement quality management systems as part of the manufacturing processes, adhering strictly to both domestic and international standards. Our manufacturing facilities comply with the China GMP for Medical Devices (“GMP standards”), ISO 13485: 2016 quality management standards and ISO 14971: 2019 risk management protocols. For details of our compliance with these standards, see “— Quality Control.” For our in-house manufacturing process, we inspect the raw materials procured, implement standards on manufacturing process, validate our manufacturing technique and conduct performance tests of our finished products. For the components we outsource to third parties, we enforce stringent protocols to assure the quality of components we procure, including conducting on-site inspections, monitoring manufacture reports and executing periodic tests. Specifically, before entering into cooperation, we conduct quality and creditability checks on potential suppliers, specify our quality requirement and require suppliers to enter into quality assurance agreements. During the procurement process, we require suppliers to provide reports on manufacturing process and the raw materials they use. Upon delivery, we perform acceptance checks on the finished products. Components that fail to meet our technical specifications are rejected and returned for replacement or refund. Meanwhile, we reserve the right to terminate our collaboration with suppliers who fail to rectify quality defects within a specified timeframe.

We have implemented a comprehensive maintenance system for our machinery. During the Track Record Period, we had not experienced any material or prolonged interruptions of our machinery due to equipment or machinery failure.

Production Capacity, Production Volume and Utilization Rates

As of June 30, 2026, our commercialized products mainly included iNOWill, eNOaire, NovaPulse IABP, Reslink and eNOglow. The following table sets forth their production capacity, actual production volume and utilization rate for the years indicated:

	For the Year Ended December 31,		As of June 30,
	2024	2025	2026
Production capacity (units)⁽¹⁾			
iNO therapy devices (iNOWill/eNOaire)	689	692	514
Cardiopulmonary circulatory support devices (NovaPulse IABP)	N/A	80	153
Respiratory diagnostics devices (Reslink/eNOglow) . . .	225	251	125
Actual production volume (units)			
iNO therapy devices (iNOWill/eNOaire)	465	490	291
Cardiopulmonary circulatory support devices (NovaPulse IABP)	N/A	55	98
Respiratory diagnostics devices (Reslink/eNOglow) ⁽³⁾ . .	218	133	64

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	For the Year Ended December 31,		As of June 30,
	2024	2025	2026
Utilization rate (%)⁽²⁾			
iNO therapy devices (iNOWill/eNOaire)	67.6	69.3	58.6
Cardiopulmonary circulatory support devices (NovaPulse IABP)	N/A	68.9	64.1
Respiratory diagnostics devices (Reslink/eNOglow) . . .	96.9	53.2	51.2

Notes:

- (1) Assuming that the relevant production lines operate 261 days per year and eight hours per day. The effective annual capacity is taking into account adjustment periods and the impact of production line upgrades.
- (2) Utilization rate is calculated based on the actual production volume for the relevant years divided by the production capacity for the relevant year, multiplied by 100.0%.

Our utilization rate for iNO therapy devices increased from 67.6% in 2024 to 69.3% in 2025, which was in line with the increased sales of our products. Our utilization rate for respiratory diagnostics devices decreased from 96.9% in 2024 to 53.2% in 2025, primarily due to our advance production of certain products to ensure stable and timely supply in 2024, in anticipation of planned production line adjustments. We conducted all manufacturing process of our major products in-house, except for the assembly of electrolytic cell modules used in medical devices. For more details, see “— Raw Materials and Suppliers — Raw Materials.”

The production facility in Yangzhou, Jiangsu Province started operation in June 2025, with an overall utilization rate of 78% and the utilization rate of iNOWill of 72%. We generally outsourced the production of the NO generation reactor and tube accessories to third-party suppliers.

SALES AND MARKETING

We collaborate with leading institutions and top-tier hospitals to refine usage protocols, integrate our devices into real-world workflows and monitor usability, safety management and clinical operation. As of June 30, 2026, we had a sales and marketing team of 43 full-time employees. Our sales and marketing team engages physicians through frequent visits, on site product demonstrations and free educational sessions. We also collaborate with KOLs to introduce and recommend our products to physicians and hospitals.

Compliance of the Promotion Efforts

We conduct our marketing and promotion activities in accordance with applicable laws and regulations in the jurisdictions where we operate, as well as our internal compliance and control requirements. We have established internal policies and procedures designed to support compliant promotion practices, including employee codes of conduct and internal controls applicable to marketing and sales activities. We also maintain compliance and internal control functions to support training and oversight, including (i) compliance education and internal training for employees in relevant roles; (ii) internal review and approval practices for promotional materials and external facing communications; and (iii) requirements that distributors and other third-party partners comply with our compliance standards and applicable regulatory requirements. We prohibit improper benefits and other non-compliant practices in connection with marketing and sales activities.

Our Sales and Distribution Arrangement

We sell our products primarily to distributors under a buyer and seller relationship, who then sell the products to hospitals and medical institutions. According to Frost & Sullivan, our sales model is in line with industry practice. Our sales team collaborates with our distributors to identify market opportunities, participate in hospital procurement and tender process and design distribution strategies. We also advise our distributors on order management and aftersales. By working closely with our distributors, we gain valuable insights into the operations of local distributors and the demands of physicians, which help ensure the effectiveness of the marketing activities. During the Track Record Period, we had five direct sales customers, including a hospital to which we sell our products per its request and two medical research institutions to which we sell consumables. In 2024, 2025 and for the six months ended June 30, 2026, our sales to our distributors accounted for 91.7%, 95.0% and 99.5% of our revenue for the respective year/period.

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Sales through Distributors

We generally enter into distribution agreements directly with our tier-one distributors and manage channel coverage on a regional basis. In larger regions, we may appoint multiple regional tier-one distributors, each responsible for designated prefecture-level cities, based on their capability and willingness to undertake coverage and service obligations. Before we deliver products to our distributors, we generally require our distributors in the Chinese mainland to make full prepayment for our products. Our distributors are responsible for collecting payments from hospitals and medical institutions and assume exposure to operational risk that may arise with end-customers.

Two Invoice System

According to the Notice on Opinions on the Implementation of the “Two Invoice System” in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)的通知》) (the “**Notice**”), jointly issued by the Medical Reform Office of the State Council and other seven ministries and commissions on December 26, 2016, the Two Invoice System refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. The Notice requires the gradual implementation of the Two invoice System in drug procurement by public medical institutions, encourages other medical institutions to implement the Two invoice System, and strives to promote the Two invoice System in full swing nationwide by 2018. According to the Notice on Consolidating the Achievements of Canceling Drug Markups and Deepening Comprehensive Reforms in Public Hospitals (《關於鞏固破除以藥補醫成果持續深化公立醫院綜合改革的通知》) promulgated by the former National Health and Family Planning Commission, the Ministry of Finance, the NDRC and other departments on March 5, 2018, high value medical consumables shall be subject to classified and centralized purchase, and the “Two Invoice System” in relation to high-value medical consumables shall be gradually implemented. On July 19, 2019, the General Office of the State Council issued the Notice on Printing and Distributing the Reform Plan for the Management of High-value Medical Consumables (《國務院辦公廳關於印發治理高值醫用耗材改革方案的通知》), which encourages local governments to adopt the Two invoice System on a case-by-case basis in order to reduce the number of intermediaries in the circulation of high-value medical consumables and promote the transparency of purchase and sales. Pursuant to the Reply of the National Healthcare Security Administration (the “**NHSA**”) to Recommendation No. 1209 of the Second Session of the 13th National People’s Congress (《國家醫療保障局對十三屆全國人大二次會議第1209號建議的答覆》) issued by the NHSA on July 23, 2019, Two invoice System for high-value consumables needs to be further discussed given the huge differences between high-value consumables and pharmaceuticals and the complexity of their clinical use and after-sales service. At present, some provinces in China have issued relevant systems for the Two Invoice System for medical consumables. However, there is no specific system and implementation time for the Two Invoice System for medical devices, and the reform is still in progress.

As advised by our PRC legal advisor, as of the Latest Practicable Date, the Two Invoice System in most provinces of the PRC was primarily applicable to pharmaceuticals. The Two Invoice System only applies to medical consumable in a few provinces and it does not specify medical equipment into its coverage. Based on the currently effective policy documents publicly promulgated by the relevant provincial authorities and telephone enquiries with such authorities, our PRC Legal Advisor advised that, among the provinces where our products are sold, only a few provinces (comprise Anhui, Shaanxi, Shanxi, Fujian and Xizang Autonomous Region) explicitly require that the Two Invoice System apply to medical consumables to regulate their distribution. Based on the above and on the confirmations obtained from us and from our medical consumables distributors in these places as of the Latest Practicable Date, and based on the advice of our PRC Legal Adviser, our Directors are of the view, and the Sponsor concurs, that during the Track Record Period and up to the Latest Practicable Date, we and such distributors had complied with the applicable requirements of the Two Invoice System in these places in all material respects. In 2024, 2025 and the six months ended June 30, 2026, our revenue derived from sales into such regions amounted to RMB504.3 thousand, RMB886.5 thousand and RMB248.1 thousand, respectively, accounting for 1.1%, 1.4% and 0.4% of our total revenue, respectively.

With respect to medical devices and other medical consumables, according to Frost & Sullivan, provincial regulatory authorities in China have implemented the Two Invoice System focusing on the procurement of high-value medical consumables by public medical institutions. Our products sold generally do not fall into this category. Furthermore, our Directors have confirmed that during the Track Record Period and up to the Latest Practicable Date: (i) none of our products sold had been included in the relevant reference list under the Administrative Norms on Centralized

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Procurement of High-Value Medical Consumables (for Trial Implementation) (《高值醫用耗材集中採購工作規範(試行)》); and (ii) as of the Latest Practicable Date, we had not received any notice from the competent authorities stating that our products sold should be classified as high-value medical consumables.

With respect to the provinces (such as Shaanxi Province) that have implemented the Two Invoice System for the procurement of all medical consumables, (i) according to Frost & Sullivan, it is an industry norm for public medical institutions in China to verify invoice issuance information, thereby ensuring that the distribution processes for the procured medical consumables comply with the Two Invoice System requirements; and (ii) we are not aware of any resale of our products by any distributor to any sub-distributor located in a province where the Two Invoice System has been applied to our products.

Our Directors are of the view that, during the Track Record Period and up to the Latest Practicable Date, the implementation of the Two-Invoice System has not had any material adverse impact on our operations, based on the following: to the best of their knowledge, during the Track Record Period and up to the Latest Practicable Date, (i) neither we nor any of our distributors had been determined to be in violation of the relevant policies in connection with their engagement of sub-distributors; (ii) we had not been subject to any administrative penalties or investigations by competent authorities in relation to the Two-Invoice System; (iii) we had not been deemed to have violated or circumvented any law, regulations, rules or policies in relation to the Two-Invoice System; (iv) we had not been disqualified from participating in public tendering processes in any province; and (v) we had not received any warning or notice from any competent authorities in relation to the compliance of the Two-Invoice System. Based on the above, the Sponsor concurs that during the Track Record Period and up to the Latest Practicable Date, the implementation of the Two-Invoice System has not had any material adverse impact on our operation.

During the Track Record Period, we were not aware of any instance where our distributors failed to comply with the Two-Invoice System, nor did we terminate our distribution relationship with any distributor due to any breach of distribution agreement or non-compliance event by it.

We have taken measures to ensure strict compliance with the Two-Invoice System and will closely monitor its application, implementation and development to mitigate the risk of any future non-compliance by us. Our distribution agreements do not prohibit distributors from further engaging sub-distributors. Our sales strategy and distribution model are in line with the industry norm, according to Frost & Sullivan. To ensure compliance with the Two-Invoice System, we have implemented the following internal control measures:

- *Pre-contract assessment.* Before approving any distribution agreement, we conduct a pre-contract assessment that covers product category, target province/region, whether the product falls under the Two-Invoice Regime, customer type, supply chain structure, logistics capabilities, and the distributor’s ability to invoice public hospitals directly. If the Two-Invoice System applies, we require that no sub-distributor be involved in the supply chain for those products in that province, and that our distributor sells directly to public hospitals.
- *Contractual compliance obligations.* We require our distributors to comply with applicable laws and regulations when purchasing products from us. All distribution agreements contain a clause requiring distributors to comply with applicable medical devices regulatory laws and regulations, including the Two-Invoice System where applicable. For agreements where the Two-Invoice System applies, the distribution agreement must further explicitly provide that (i) the distributor shall not introduce any sub-distributor and must sell and issue invoices directly to hospitals, (ii) we have the right to unilaterally terminate the distribution agreement and pursue liability and damages in the event of any non-compliance, and (iii) the distributor shall cooperate with our compliance investigations and provide invoice flow data and delivery-related documentation upon request.
- *Ongoing distributor compliance management.* We conduct an annual review of the compliance status of our existing distributors, covering license validity, whether distributors’ sales flows comply with the Two-Invoice requirements, and whether there is any involvement of sub-distributors, and where necessary, we require distributors to provide sample invoices issued to public hospitals for verification. We conduct at least one annual spot-check on distributors’ compliance status, covering no less than 10% of our distributors. In the event of any non-compliance, we will cease product supply and terminate cooperation and have the right to pursue legal remedies.

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- ***Regulatory monitoring.*** We closely monitor announcements from the NMPA and local authorities regarding the expansion of the Two-Invoice System to new regions or product categories of medical devices and medical consumables. We conduct annual training sessions regarding the Two-Invoice System for our employees and provide compliance and training materials to our distributors as needed.

Our Directors believe that the above measures, together with the limited scope of application of the Two-Invoice System to our business, are adequate to ensure our continued compliance.

Our Contracts with Distributors

We entered into distribution agreements with our tier-one distributors, which are essentially sales and purchase agreements. Key terms are summarized below:

Term. The durations of the distribution agreements are typically one year, subject to annual review and renewal.

Designated geographical regions. We designate distribution areas for our distributors and prohibit cross-regional sales unless obtaining prior written consent from us.

Minimum Purchase Requirement. We set annual minimum purchase requirement in respect of distributors’ purchases from us, which can be adjusted through mutual agreement based on market conditions.

Pricing. We determine product prices and may adjust them in response to changes in cost or market environment. We may offer rebates to distributors who meet sales targets specified in the distribution agreements, which can be used to offset their purchases in the following year.

Logistics. We deliver products to distributors’ designated sites. Title and risk transfer to the distributor upon delivery and acknowledgment of receipt.

Exclusivity. We do not allow distributors to sell or promote competing products without our authorization during the agreement term. Within each of the designated distribution scope, we only engage one distributor to conduct sales.

Sub-distribution. Distributors may authorize sub-distributors within their designated areas upon our authorization. See “— Selection and Management of Distributors — Sub-distributors” for more details.

Compliance and confidentiality. Distributors are required to comply with our anti-bribery, fair competition and confidentiality policies, and refrain from disclosing commercial terms or pricing.

Return policy. In line with industry practice, we generally do not accept product returns unless there is a quality issue attributable to us.

After-sales service. For our commercialized products, we typically provide one-year warranty periods for iNOWill products and NovaPulse IABP products, two-year warranty periods for Reslink and eNOglow products and one-year warranty period for eNOaire. We provide warranty to parties that we directly transact with. Therefore, under the distributorship model, we provide warranty to the distributors and under the direct sales model, we provide warranty to the hospitals that we transact with. Pursuant to the warranty terms with distributors and hospitals, during the warranty period, we provide after-sales services with no additional charge, including replacement of defective components, system upgrades, periodic equipment inspections, preventive maintenance and servicing based on the operating condition of the equipment, as well as inspection records and maintenance reports. Upon expiration of the warranty period, we agree to continue to provide maintenance services and components for replacement at discounted fees. Our estimated average warranty cost per unit during the warranty periods is different across products, ranging from RMB1,000 to RMB6,000, depending on the complexity and costs incurred in maintaining different products. For our Core Products, the warranty costs were RMB0.9 million, RMB0.8 million and RMB0.3 million in 2024, 2025 and the six months ended June 30, 2026, respectively. The warranty claims primarily include replacement of components, upgrade of user systems, periodic equipment checking and maintenance for precaution purposes. We received 300, 421 and 182 warranty claims in 2024, 2025 and the six months ended June 30, 2026, respectively.

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Termination. We reserve the right to terminate agreements if distributors violate contract terms, including but not limited to unauthorized cross-regional sales, violation of quality requirements, underperformance or misrepresentation.

For overseas distributors, we entered into similar distribution agreements as distributors in the Chinese mainland, except for the following: (i) the credit terms, we grant them credit terms up to 30 working days; (ii) logistics, we are only responsible for delivering the goods to the domestic ports; and (iii) sub-distribution, we do not require our overseas distributors to get our authorization when engaging with sub-distributors.

We track the inventory levels of our distributors and sub-distributors through a combination of contractual reporting requirements, digitalization initiatives and downstream sales monitoring. First, our distribution agreements require distributors to regularly report their inventory levels and related information to us, enabling us to monitor inventory movements and identify potential inventory build-up in a timely manner. Second, we are developing a CRM system to further digitalize our distributor management and enhance our ability to collect, monitor and analyze inventory information on a more systematic and timely basis. Third, we have adjusted the performance assessment mechanism of our domestic sales team to take into account the hospitals won by our distributors in tenders, rather than focusing solely on sales to distributors. This enables us to monitor downstream sales and hospital adoption and provides an additional reference point for assessing distributors’ inventory levels and sell-through performance. Taking into consideration that (i) the minimum purchase requirements are set at a relatively low threshold based on the distributors’ historical sales performance and are mutually agreed between the parties. Such minimum purchase requirements are therefore intended to reflect reasonably expected demand rather than encourage distributors to make excessive purchases; and (ii) as we do not accept product returns after sales except for returns arising from quality issues, our distributors lack incentive to purchase more than their reasonably expected downstream demand, the Directors are of the view, and the Sponsor concurs, that we are not exposed to material channel stuffing risk.

During the Track Record Period, we were not aware of any material breach of distribution agreements, and we did not have any material disputes with our distributors or sub-distributors. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors or sub-distributors that could adversely affect our reputation, business operations or financial condition. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any customer settled payments with us through accounts belonging to parties other than the contractual counterparties under the corresponding distribution agreements.

Movements of Distributors

The following table sets forth the changes in the number of our tier-one distributors for the years indicated:

	For the Year Ended December 31,		For the Six Months Ended June 30,
	2024	2025	2026
Number of Distributors			
As of the beginning of the year	106	144	192
Additions of new distributors	80	101	67
Terminated*	42	53	47
As of the end of the year	144	192	212

Note:

* Referring to distributors who did not purchase medical devices from us during the specified years.

We annually renew the distribution agreements with selected distributors in accordance with their performances, which primarily leads to the fluctuation in the number of our distributors during the Track Record Period. The number of our tier-one distributors increased from 144 as of December 31, 2024 to 192 as of December 31, 2025 and to 212 as of June 30, 2026, as we expanded sales of our products, particularly NovaPulse IABP and iNOWill. During the Track Record Period, we ceased collaboration with certain tier-one distributors, as we adjusted our distribution development strategy and only continued to collaborate with distributors whose business performances, financial conditions and understandings of our products well align with our needs. During the Track Record Period and up to the Latest Practicable Date, we did not have any material unresolved disputes, disagreement or lawsuits with our distributors, including the departing distributors, as the termination was agreed by both parties.

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Selection and Management of Distributors

We have established a structured distributor management system, focusing on the following key areas:

Strict admission and exit mechanism. We select our distributors based on their qualifications and experience in the medical device industry, particularly their established relationships with hospitals, medical institutions and physicians within their designated regions. Our exit mechanism includes evaluation, communication, project and regional handover and follow-up arrangements with the aim of maintaining market order and ensuring continuity of service for end customers.

Support and supervision. We provide support to capable distributors and aim to cultivate a group of regionally leading distributors with strong execution capability in the iNO therapy, cardiopulmonary circulatory support and respiratory diagnostics. We also require tier-one distributors to deliver consistent training to their sub-distributors.

Ongoing monitoring. We track distributors’ sales performance and may from time to time review compliance with our distribution policies. We regularly collect feedbacks from the physicians and monitor tender status to assess the performance of our distributors. We review the qualifications of our distributors when our agreements with them are due to be renewed.

Regional control. We control our tier-one distributors and sub-distributors by authorizing them to sell designated products to designated hospitals and medical institutions which are specified in their respective authorization letters. We also implement a unified pricing policy, prohibit unauthorized cross-regional sales.

Channel Inventory Control. We manage our network of tier-one distributors by regularly reviewing their sales performances, inventory levels and product delivery status. Our distributors have little incentives to over-purchase from us, for the following reasons: (i) we generally do not accept product returns unless there is a quality issue attributable to us, (ii) we keep ongoing monitoring, including inventory level tracking of both our tier-one distributors and sub-distributors and (iii) while we set minimum purchase requirement for certain distributors, the threshold is low compared to their typical purchase volume, and we do not automatically terminate collaboration with distributors who fail to meet the minimum purchase requirement. During the Track Record Period and up to the Latest Practicable Date, we had not observed any material inventory buildup among our distributors, we believe that we are subject to a low risk of channel stuffing.

Sub-distributors. While we do not enter into distribution agreements with sub-distributors, we exercise indirect management through our distributors. We review sub-distributors’ requisite business licenses and permits before issuing authorization letters to them. We require oversee their sales practices, quality control and compliance performance, and to promptly report any irregularities. We had not identified any cases of unauthorized sales, price manipulation or misuse of our brand by sub-distributors during the Track Record Period.

During the Track Record Period, one of our distributors was our Shareholder (the “**Related Distributor**”). In 2024 and 2025, the revenue contribution from our Related Distributor was immaterial, amounting to RMB60.0 thousands and nil, respectively, which accounted for less than 0.1% and 0% of our total revenue in 2024 and 2025, respectively. We had already ceased business relationship with the Related Distributor. When onboarding distributors who were our connected persons we applied the same selection criteria and procedures as those for the other distributors. The distribution agreement that we entered into with the Related Distributor had the same terms as those in the distribution agreements with the other distributors. Save as disclosed above, during the Track Record Period, to the best of our knowledge, our distributors were Independent Third Parties and they did not have any past or present relationships (business, trust, family, financing or otherwise) with us or our subsidiaries, shareholders, directors or senior management, or any of their respective associates.

Direct Sales

In addition to the sales through our distributors, during the Track Record Period, we recorded five direct sales for the six months ended June 30, 2026. The sales revenue from our direct customers accounted for approximately 0.5% of our sales revenue for the six months ended June 30, 2026. We may, from time to time, have limited direct sales required by specific procurement arrangements or project execution needs while primarily selling our products through distributors.

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Pricing

Our products are generally commercialized under a “device plus consumables” model, where the installed device supports recurring consumable usage during therapy and pricing aligns with utilization patterns in high-acuity settings. For the prices of our products sold to distributors, we determine the pricing of each product taking into account prevailing market conditions, including comparable product pricing, hospital affordability and expected channel margins. The prices of our Core Product sold to hospitals typically range from RMB0.2 million to RMB0.8 million per unit. For the consumables of Core Products, the price of NO generation reactor ranges from RMB3,000 to RMB10,000, and the price of tube accessories is approximately RMB200 per unit. The price of Key Products ranges from RMB60,000 to RMB1.5 million. The prices may differ across various regions, depending on market dynamics, prevailing tender prices, and the competitive landscape, and we may adjust the prices from time to time. In more matured markets where the Core Product is more widely adopted and the demand for its consumables is relatively strong, we may adopt a pricing strategy with a relatively higher margin on consumables and offer the Core Product at a comparatively lower price to facilitate market penetration. In developing markets where adoption of the Core Product remains at an earlier stage and demand for consumables is relatively limited, we may place greater emphasis on generating margin from the Core Product itself. For prices of our products sold to end-customers, distributors are generally expected to price at or above the relevant guidance price (or an agreed minimum price level), subject to limited case-by-case adjustments in certain price-sensitive key hospitals. When a patient receives medical services using our products, the associated costs are typically covered by the medical insurance reimbursement in the patient’s local region. As of the Latest Practicable Date, there was no price guidance set by the PRC government on our commercialized products.

OUR CUSTOMERS

Our customers are primarily distributors in the Chinese mainland and overseas who purchase our products and sell them directly or indirectly to hospitals or medical institutions. In 2024, 2025 and for the six months ended June 30, 2026, the aggregate sales to our five largest customers were RMB11.7 million, RMB18.7 million and RMB22.7 million, representing 25.6%, 29.6% and 39.0% of our revenue, respectively. In each year/period indicated, sales to our largest customer were RMB3.4 million, RMB8.2 million and RMB9.9 million, representing 7.4%, 12.9% and 17.1% of our revenue, respectively. For each year/period during the Track Record Period, all our top five medical devices customers require our distributors to make full prepayment for our products, except for the contract development customer whom we provided services to. We grant credit terms to certain overseas distributors.

The following table sets forth a summary of the sales to our five largest customers for the years/periods indicated.

For the year ended December 31, 2024

No.	Customer	Background	Year of Commencement of Business Relationship	Products/Services Provided	Payment Method	Revenue (RMB in thousands)	Percentage of Revenue (%)
1 . .	Customer A ⁽¹⁾	A medical device seller headquartered in Taiwan, China, with a registered capital of TWD5 million.	2023	iNOwill	Bank transfer	3,388	7.4
2 . .	Customer B ⁽²⁾	A medical device seller headquartered in Shanghai with a registered capital of RMB5 million.	2024	contract development services	Bank transfer	2,830	6.2
3 . .	Customer C ⁽³⁾	A medical device wholesaler headquartered in Shanghai with a registered capital of RMB10 million.	2023	iNOwill and Reslink	Bank transfer	1,836	4.0

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No.	Customer	Background	Year of Commencement of Business Relationship	Products/Services Provided	Payment Method	Revenue (RMB in thousands)	Percentage of Revenue (%)
4 . .	Customer D ⁽⁴⁾	A medical device wholesaler headquartered in Nanning, Guangxi with a registered capital of RMB5 million.	2024	iNOwill and Reslink	Bank transfer	1,825	4.0
5 . .	Customer E ⁽⁵⁾	A medical testing and inspection service provider headquartered in Jinan, Shandong with a registered capital of RMB3 million.	2023	iNOwill and Reslink	Bank transfer	1,825	4.0
Total						11,704	25.6

Notes:

- (1) A medical instrument company specializing in the import and distribution of physiological monitors, medical imaging systems, and respiratory care equipment, headquartered in Taiwan China, incorporated in 1979.
- (2) A medical device company specializing in the agency and sales of second and third-class medical equipment and consumables, headquartered in Shanghai, PRC, incorporated in 2014.
- (3) A medical device company specializing in the import and distribution of advanced international medical systems and clinical solutions, headquartered in Shanghai, PRC, incorporated in 2017.
- (4) A company specializing in the distribution and wholesale of medical instruments and respiratory healthcare products, headquartered in Guangxi, PRC, incorporated in 2021.
- (5) A leading biopharmaceutical company specializing in the R&D and production of gene-engineered drugs and diagnostic solutions, headquartered in Shandong, PRC and incorporated in 2008.

For the year ended December 31, 2025

No.	Customer	Background	Year of Commencement of Business Relationship	Products/Services Provided	Payment Method	Revenue (RMB in thousands)	Percentage of Revenue (%)
1 . .	Customer F ⁽¹⁾	A medical device seller headquartered in Hangzhou, Zhejiang with a registered capital of RMB3 million.	2025	iNOwill, eNoaire, IABP and Reslink	Bank transfer	8,163	12.9
2 . .	Customer G ⁽²⁾	A medical device seller headquartered in Hong Kong with a registered capital of HKD10,000.	2025	iNOwill	Bank transfer	4,088	6.5
3 . .	Customer H ⁽³⁾	A medical device wholesaler headquartered in Shenzhen with a registered capital of RMB10 million.	2023	iNOwill and eNoaire	Bank transfer	2,347	3.7

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No.	Customer	Background	Year of Commencement of Business Relationship	Products/Services Provided	Payment Method	Revenue (RMB in thousands)	Percentage of Revenue (%)
4 . .	Customer I ⁽⁴⁾	A wholly-owned subsidiary of a Antigua and Barbuda-based NASDAQ-listed company which has a market capitalization of more than US\$450 million as of June 30, 2026.	2023	iNOWill	Bank transfer	2,217	3.5
5 . .	Customer B ⁽⁵⁾	A medical device seller headquartered in Shanghai with a registered capital of RMB5 million.	2024	contract development services	Bank transfer	1,887	3.0
Total						18,702	29.6

For the six months ended June 30, 2026

No.	Customer	Year of Commencement of Business Relationship	Products/Service Provided	Payment Method	Revenue (RMB in thousands)	Percentage of Revenue (%)
1 . .	Customer F ⁽¹⁾	2025	iNOWill, eNoaire, IABP and Reslink	Bank transfer	9,917	17.1
2 . .	Customer J ⁽⁶⁾	2026	iNOWill, eNoaire, IABP and eNOglow	Bank transfer	7,687	13.2
3 . .	Customer K ⁽⁷⁾	2025	IABP	Bank transfer	1,952	3.4
4 . .	Customer L ⁽⁸⁾	2026	iNOWill, eNoaire and IABP	Bank transfer	1,642	2.8
5 . .	Customer M ⁽⁹⁾	2026	IABP	Bank transfer	1,501	2.6
Total.					<u>22,699</u>	<u>39.0</u>

Notes:

- (1) A medical device company specializing in the sales of medical equipment and consumables, headquartered in Hangzhou, PRC and incorporated in 2025.
- (2) A trading company specializing in the import and export of medical equipment and consumables.
- (3) A company specializing in domestic trading, including medical devices and other healthcare products, headquartered in Guangdong, PRC and incorporated in 2017.
- (4) A company primarily engaged in the wholesale and retail of pharmaceutical products and medical supplies, headquartered in Singapore and incorporated in 2020.
- (5) A medical device company specializing in the agency and sales of second and third-class medical equipment and consumables, headquartered in Shanghai, PRC, incorporated in 2014.
- (6) A medical device company specializing in the sales of medical equipment and consumables, headquartered in Beijing, PRC and incorporated in 2024.
- (7) A medical device company specializing in the sales of medical equipment and consumables, headquartered in Nanning, PRC and incorporated in 2019.
- (8) A medical device company specializing in science and technology extension services, headquartered in Zhengzhou, PRC and incorporated in 2024.
- (9) A medical device company specializing in engineering and technical research and experimental development, headquartered in Guangzhou, PRC and incorporated in 2013.

In each year/period during the Track Record Period, all of our five largest customers were Independent Third Parties. In each year/period during the Track Record Period, none of our Directors or any Shareholders, who, to the knowledge of our Directors, would own more than 5.0% of our issued share capital immediately following the completion of the [REDACTED], nor any of their respective associates had any interest in any of our five largest customers. There were no five largest customers in each year/period during the Track Record Period who were also our suppliers during the Track Record Period.

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Customer Services

Our customer service team provides training and technical support to distributors and end customers to handle inquiries, technical questions and feedback regarding our products. Once our products are installed onsite and installation reports are returned and recorded, our customer service team coordinates after-sales services to the relevant hospitals and medical institutions. Our customer service team also provides channels for complaints regarding our products, including complaints on the quality of our products and adverse events after relevant procedures are performed on the patients. They investigate the cause of issue raised by our customers and refer the issue to our relevant responsible teams for resolution and correction. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any product complaints, product returns or warranty claims relating to product defects that caused or could cause death, series injuries that were detrimental to life, or series public health safety incidents. During the Track Record Period, we were not aware of any safety incidents caused by using our products.

RAW MATERIALS AND SUPPLIERS

Raw Materials

We procure raw materials to be used in the manufacture of our medical devices. For manufacture of our iNO therapy devices, our raw materials include parker nitrogen membrane, flow sensor, solenoid valve. For manufacture of our cardiopulmonary circulatory support devices, our principal raw materials are vacuum pump, pressure relief valve, combination valve. For manufacture of our respiratory diagnostics devices, our principal raw materials are stepper motor, flow sensor, nafion tube.

During the Track Record Period, our raw materials and equipment primarily include mould, injection mold component, sheet metal machine, printed circuit board assembly (PCBA), sensor pumps and valves. Some raw materials and equipment, such as certain sensors and valves are of overseas origin and are primarily purchased through domestic agents, with a small portion directly imported. We purchased raw materials from these suppliers on a rolling monthly basis, taking into account our production schedule, logistics arrangements and our business strategies. Most of our raw material prices remained relatively stable during the Track Record Period. To manage and mitigate the impact caused by the possible fluctuations of raw material prices, we enter into framework agreements with our suppliers and maintain a list of alternative suppliers available for our key raw materials.

Suppliers

We select our suppliers based on a variety of factors, including their qualification, reputation, pricing, and overall services. We perform thorough due diligence on our suppliers, regularly monitor and review their performance.

In 2024, 2025 and for the six months ended June 30, 2026, the aggregate purchases from our five largest suppliers were RMB8.6 million, RMB14.0 million and RMB8.6 million, representing 30.4%, 40.7% and 36.3% of our total purchases, respectively. Our purchases from our largest supplier in each year indicated were RMB2.6 million, RMB3.4 million and RMB2.5 million, representing 9.2%, 10.0% and 10.4% of our total purchases, respectively. We generally have a credit term up to 30 days for certain suppliers.

The following table sets forth a summary of purchases from our five largest suppliers for the periods indicated.

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For the year ended December 31, 2024

No.	Supplier	Background	Year of Commencement of Business Relationship	Products/Services Purchased or Obtained	Payment Method (RMB in thousands)	Purchase Amount (%)	Percentage of Total Purchases
1 . .	Supplier A ⁽¹⁾	An equipment manufacturer headquartered in Nanjing, Jiangsu, with a registered capital of RMB500 thousand.	2020	equipment	Bank transfer	2,597	9.2
2 . .	Supplier B ⁽²⁾	A mold manufacturer headquartered in Ma'anshan, Anhui, with a registered capital of RMB1 million.	2021	equipment and raw materials	Bank transfer	1,929	6.8
3 . .	Supplier C ⁽³⁾	An electronics manufacturer headquartered in Nanjing, Jiangsu, with a registered capital of RMB10 million.	2021	raw materials	Bank transfer	1,500	5.3
4 . .	Supplier D ⁽⁴⁾	A precision machinery manufacturer and processor headquartered in Wuxi, Jiangsu, with a registered capital of RMB3 million.	2023	equipment and raw materials	Bank transfer	1,432	5.1
5 . .	Supplier E ⁽⁵⁾	A company specialized in injection molding and manufacturing headquartered in Shanghai, with a registered capital of RMB24.8 million.	2023	equipment and raw materials	Bank transfer	1,133	4.0
Total						<u>8,591</u>	<u>30.4</u>

Notes:

- (1) An automation equipment company specializing in automation system design, installation, commissioning, and related technical services, headquartered in Jiangsu, PRC and incorporated in 2004.
- (2) A precision manufacturing and technology company specializing in automotive component manufacturing, IoT equipment R&D, and the production of plastic products and medical equipment, headquartered in Anhui, PRC and incorporated in 2019.
- (3) An electronic engineering company specializing in printed circuit board design, headquartered in Nanjing, PRC, incorporated on October 10, 2009.
- (4) A precision machinery manufacturing company specializing in the production of precision components, processing and sales, and international trade, headquartered in Jiangsu, PRC, incorporated in 2006.
- (5) A high-tech manufacturing and R&D company specializing in injection molding, mold design and manufacturing, polymer material R&D, and electronic assembly, headquartered in Shanghai, PRC and incorporated in September 2001.

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For the year ended December 31, 2025

No.	Supplier	Background	Year of Commencement of Business Relationship	Products/Services Purchased or Obtained	Payment Method	Purchase Amount (RMB in thousands)	Percentage of Total Purchases (%)
1 . .	Supplier E ⁽¹⁾	A company specialized in injection molding and manufacturing headquartered in Shanghai, with a registered capital of RMB24.8 million.	2023	equipment and raw materials	Bank transfer	3,443	10.0
2 . .	Supplier A ⁽²⁾	An equipment manufacturer headquartered in Nanjing, Jiangsu, with a registered capital of RMB500 thousand.	2020	raw materials	Bank transfer	3,205	9.3
3 . .	Supplier B ⁽³⁾	A mold manufacturer headquartered in Ma'an Shan, Anhui, with a registered capital of RMB1 million.	2021	equipment and raw materials	Bank transfer	2,753	8.0
4 . .	Supplier D ⁽⁴⁾	A precision machinery manufacturer and processor headquartered in Wuxi, Jiangsu, with a registered capital of RMB3 million.	2023	equipment and raw materials	Bank transfer	2,478	7.2
5 . .	Supplier F ⁽⁵⁾	A Shenzhen Stock Exchange-listed PCB manufacturer headquartered in Shenzhen, with a registered capital of RMB209.5 million.	2024	raw materials	Bank transfer	2,143	6.2
Total						14,022	40.7

For the six months ended June 30, 2026

No.	Supplier	Year of Commencement of Business Relationship	Products/Service Purchased or Obtained	Payment Method	Purchase Amount	Percentage of Total Purchases
					(RMB in in thousands)	(%)
1 . .	Supplier D ⁽⁴⁾	2023	equipment and raw materials	Bank transfer	2,465	10.4
2 . .	Supplier A ⁽²⁾	2020	raw materials	Bank transfer	2,378	10.0
3 . .	Supplier G ⁽⁶⁾	2023	raw materials	Bank transfer	1,507	6.4
4 . .	Supplier H ⁽⁷⁾	2023	raw materials	Bank transfer	1,155	4.9
5 . .	Supplier I ⁽⁸⁾	2021	raw materials	Bank transfer	1,111	4.7
Total					8,616	36.3

Notes:

- (1) A high-tech manufacturing and R&D company specializing in injection molding, mold design and manufacturing, polymer material R&D, and electronic assembly, headquartered in Shanghai, PRC and incorporated in 2001.
- (2) An automation equipment company specializing in automation system design, installation, commissioning, and related technical services, headquartered in Jiangsu, PRC and incorporated in 2004.

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- (3) A precision manufacturing and technology company specializing in automotive component manufacturing, IoT equipment R&D, and the production of plastic products and medical equipment, headquartered in Anhui, PRC and incorporated in 2019.
- (4) A precision machinery manufacturing company specializing in the production of precision components, processing and sales, and international trade, headquartered in Jiangsu, PRC, incorporated in 2006.
- (5) A technology services company specializing in PCB fabrication and PCBA production, headquartered in Shenzhen, PRC, incorporated on March 2003, and listed on the Shenzhen Stock Exchange.
- (6) An automation device company specializing in technology extension services, headquartered in Wuxi, PRC and incorporated in 2010.
- (7) A mechanical device company specializing in engineering and technical research and experimental development, headquartered in Shanghai, PRC and incorporated in 2007.
- (8) A electronic device company specializing in science and technology extension services, headquartered in Shenzhen, PRC and incorporated in 2007.

Key terms of the supplier agreements we entered into including: (i) quality specifications, where we list quality specifications for the raw materials in each agreement and/or purchase order; (ii) price and pricing policy, where price or pricing policy is specified in each agreement and/or purchase order; (iii) raw materials return/exchange, where we examine raw materials when we receive them and may return any raw materials that do not meet our requirements within specified periods after receipt; (iv) transportation and delivery, where suppliers are responsible for transportation and delivery method is specified in each agreement or purchase order; and (v) confidentiality, where our suppliers shall keep confidential of the information acquired in the performance of the agreement.

In each year during the Track Record Period, all of our five largest suppliers were Independent Third Parties. In each year during the Track Record Period, none of our Directors or any Shareholders, who, to the knowledge of our Directors, would own more than 5.0% of our issued share capital immediately following the completion of the [REDACTED], nor any of their respective associates had any interest in any of our five largest suppliers. In each year during the Track Record Period, none of our five largest suppliers was also our customer.

During the Track Record Period and up to the Latest Practicable Date, we did not have any material disputes with our suppliers or experience any material breach of our supply agreements. We had not experienced any material fluctuations in the pricing of our supplies during the Track Record Period. To the best of our knowledge, as of the Latest Practicable Date, there was no information or arrangement that would lead to termination of our relationships with any of our major suppliers. During the Track Record Period, we did not experience any significant shortages or major quality issues in relation to our key raw materials or components.

INVENTORY

Our inventories consist primarily of raw materials, intermediate goods and finished goods. For raw materials supplied by our suppliers, we generally keep an inventory that would satisfy our production needs, which may vary according to the demand of our customers, sales and production plans. Intermediate goods are products that are used in the production process to make finished goods, which are ultimately sold to end-customers. For details about our inventory control measures policy, see “Financial Information — Discussion of Certain Selected Items from the Consolidated Statements of Financial Position — Assets — Inventories and Contract Costs.”

QUALITY CONTROL

We have a dedicated quality management team, focusing on the establishment, and maintenance of our quality management system. We execute our quality control system in accordance with ISO 13485: 2016 and Chinese GMP for Medical Devices, as well as other applicable GMP standards, including EU MDR, the Australian Therapeutic Goods (Medical Devices) Regulations, the Brazilian RDC ANVISA 665/2022 and the Canadian Medical Devices Regulations (SOR/98-282). We maintain quality documentation and records and implement controls intended to ensure traceability throughout the product lifecycle and timely handling of quality-related events.

The applicability of the standards is set forth below:

- GMP standards is mandatory for medical equipment manufacturers in China and a prerequisite for registration of medical equipment in China. In compliance with GMP, we perform incoming inspections of raw materials, in-process quality inspections at key manufacturing stages and final product inspections before sales to ensure that our products meet the applicable quality specifications.

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- The GB 9706 standards set out the technical requirements for the basic safety and essential performance of medical electrical equipment in China. They are mandatory technical standards applicable to the registration testing of active medical devices in China and govern the electrical safety and performance aspects of product design. Our commercialized products which require electricity, including iNOwill, eNOaire and NovaPulse IABP, are subject to and comply with the GB 9706 standards.
- The ISO 13485: 2016 quality management system establishes standardized procedures covering the entire product lifecycle, including design and development, manufacturing, testing and post-market activities. ISO 13485: 2016 is the recommended standard for many countries and regions in considering approval of medical equipment. We apply ISO 13485: 2016 in the entire process from our product design, manufacture to after-sale services.
- We also apply ISO 14971: 2019 throughout the product lifecycle to identify, evaluate and control product-related risks. ISO 14971: 2019 is a widely-used standard for risk management, assessment and control of product development.
- For products marketed in the EU, we comply with the requirements of the EU Medical Device Regulation (EU) 2017/745 (“EU MDR”). We have established and maintained our quality management system in accordance with the applicable requirements of the EU MDR, which governs, among other things, product conformity assessment, clinical evaluation and post-market surveillance. Our quality management system supports the manufacture and quality control of products intended for the EU market and helps ensure their continued compliance throughout the product lifecycle.

We maintain a comprehensive quality control and management system that is designed to cover key aspects of our product life cycle.

Raw Material Supply. Prior to entering into any formal supply agreement, we perform comprehensive due diligence on potential suppliers, evaluating their operating history, track record, and market reputation. Our quality management team conducts stringent inspections and testing on product samples, complemented by on-site visits to assess production facilities and ensure alignment with our quality requirements.

Manufacture. Design inputs are translated into detailed production specifications, and all manufacturing procedures are documented in controlled work instructions and validated process parameters. Raw-material receipt, storage, and handling are subject to strict verification, including traceability recording, quarantine controls and release testing.

Inventory. Our quality management team is tasked with the inspection, examination, approval of all incoming finished products and the accurate recording of inventory movements. Any deviations identified will be promptly reported to the quality management team for corrective action.

After-sales. Feedback received from our distributors and hospital customers was systematically collected, analyzed, and any quality-related concerns were addressed in accordance with our established procedures.

As of the Latest Practical Date, we had not experienced any significant product quality issues. We have from time to time received customer feedback and complaints primarily relating to usage habits. We have not had any product recalls due to product quality issues, nor have we been subject to any investigations or administrative penalties arising from product quality issues.

Product Liability

Under applicable PRC laws and regulations, a medical institution will be liable for any damage caused to a patient in the course of diagnosis or treatment if the medical institution or any practicing physician is at fault, or if the physician fails to perform diagnosis and treatment obligations in accordance with prevailing medical standards. If any injury to a patient is caused by the defect of a medical device, the patient may claim compensation from the manufacturer or the seller of the medical device.

We would not generally be legally liable for physicians’ misuse of our products unless any injury results from a defect in our products. We have procured product liability insurance and other insurances that we consider appropriate for our operations. During the Track Record Period and as

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of the Latest Practicable Date, we were not involved in any material lawsuits, arbitrations or other legal proceedings relating to product liability, and we had not been subject to any administrative penalties due to quality issues in our products.

PROPERTIES AND FACILITIES

As of the Latest Practicable Date, we had six leased properties in the PRC, with a total aggregate gross floor area of approximately 11,541.45 sq.m.. We are headquartered in Nanjing, Jiangsu Province, with an aggregate leased area of approximately 4,000 sq.m., primarily using for research and development and office use. Our current manufacturing facilities are located in Yangzhou, Jiangsu Province and Fangchenggang, Guangxi Zhuang Autonomous Region. Our Yangzhou manufacturing facility has a leased area of approximately 4,353 sq.m. and our Fangchenggang manufacturing facility has a leased area of approximately 1,400 sq.m..

The relevant lease agreements were valid and legally binding as of the Latest Practicable Date and generally provide a duration of up to ten years. However, as of the Latest Practicable Date, we had not completed the relevant property leasing registrations for four of our leased properties, which are used for our operating center and manufacturing facilities. For details of the non-compliance, see “Business — Legal Proceedings and Compliance — Failure to complete lease registration for five leased properties.”

We did not obtain the relevant construction permit or complete the final acceptance filing for our decoration project at the manufacturing facilities in Yulin, Guangxi Zhuang Autonomous Region (the “**Yulin Project**”) and the decoration project at our Nanjing headquarters (the “**Nanjing Project**”). As advised by our PRC Legal Advisor, based on the applicable legal provisions, the maximum aggregate penalty to which we may be exposed in respect of the Yulin Project and the Nanjing Project is approximately RMB1,011,300. For details of the non-compliance, see “Business — Legal Proceedings and Compliance — Failure to obtain construction permits or complete final acceptance for certain decoration projects.”

As of June 30, 2026, we had no single property with a carrying amount of 15% or more of our total assets, and on this basis, we are not required by Rule 5.01A of the Hong Kong Listing Rules to include in this document any valuation report. Pursuant to section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which requires a valuation report with respect to all of our interests in land or buildings.

COMPETITION

We compete in three segments of the gas-based cardiopulmonary therapeutic and diagnostic device market. In INO therapy, we participate in a global market that was approximately US\$1,054.1 million in 2025 and is expected to reach US\$1,580.4 million by 2030, representing a CAGR of 8.4%, with instant-generation systems driving growth at a CAGR of 34.2%. In China, our cardiopulmonary circulatory support products mainly compete in the IABP market, which is projected to grow from RMB790.1 million in 2025 to RMB1,381.6 million in 2030, representing a CAGR of 11.8%, supported by broader adoption of mechanical circulatory support in cardiac procedures. Our respiratory diagnostics line targets the FeNO diagnostic device market in China, which is expected to expand from RMB226.7 million in 2025 to RMB953.0 million in 2030 at a CAGR of 33.3%, underpinned by increasing recognition of chronic airway inflammatory diseases and growing demand for outpatient and home-based monitoring.

EMPLOYEES

As of the Latest Practicable Date, we had 171 employees in total, which were all located in the Chinese mainland. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Function	Number	% of Total
Research and development	47	27.5
Manufacturing and supply chain	28	16.4
Sales and marketing	44	25.7
Administrative and management	52	30.4
Total	171	100.0

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We generally enter into standard confidentiality and employment agreements with our key management and research staff. We believe that we maintain a good working relationship with our employees. As of the Latest Practical Date, we had not experienced any significant labor disputes or any significant difficulty in recruiting staff for our operations. As of the Latest Practicable Date, we had not established a labor union.

We are committed to attracting, training and retaining talent. We maintain a training system that includes periodic technical training and regular sharing of industry insights. We also conduct compliance training for employees, including training relating to anti-bribery and anti-corruption requirements and other applicable laws and regulations, to mitigate compliance risks in our operations.

In compliance with the relevant PRC labor laws, we are required under PRC law to make contributions to employee benefit plans at a certain percentage of our employees’ salaries, including bonus and allowances, up to a maximum amount specified by the local government. We made full social insurance and housing provident fund contributions for our employees during the Track Record Period, except that we engage third-party human resources agencies to do so for employees whose work locations differed from our main operating entities, which involves potential risks. For details of the non-compliance, see “Business — Legal Proceedings and Compliance — Engagement of third-party human resource agencies to pay social insurance and housing provident fund contributions.”

As of the Latest Practicable Date, we had not received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges with respect to social insurance and housing funds, nor had we received any administrative penalty or labor arbitration application from employees for our agency arrangement with third-party human resources agencies.

We ceased the engagement of third-party human resources agencies for social insurance and housing provident fund contributions with effect from April 1, 2026.

INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we had 85 patents and 196 registered trademarks, as well as 73 patent applications in the Chinese mainland and 13 jurisdictions overseas, such as Canada, United States, Indonesia, Israel, Brazil and South Korea. Our patents, patent applications, registered trademarks and pending trademark applications cover key technology areas including instant NO generation, electrochemical catalytic reduction, plasma discharge, gas sensing and gas and fluid-path control. We believe there is no material legal impediment for us to obtain the approvals for these patent applications and trademarks applications. As of the Latest Practicable Date, all of our 158 patents and patent applications (including those relating to our product candidates including the Core Product and the key components thereof) were developed in-house and owned by us. Among these patents and patent applications, 42 of them (including 16 patents and 26 patent applications) were related to our Core Product, and six of them related to our Key Product. All these patents and patent applications of which were invented and subsequently owned by us. Besides the patents and patent applications we owned, as of the Latest Practicable Date, we also in-licensed a total of six patents and patent applications.

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The table below lists all patents and patent applications directly in relation to our Core Product and the material patents and patent applications directly in relation to our Key Product, as of the Latest Practicable Date:

Number	Related Product	Patent/Application Number	Patent Type	Patent/Patent Application Holder	Inventor	Jurisdiction	Date of Application	Status	Patent Expiration for Granted Patent(s)
1	iNOwill	AU2021401099; JP2023537262; 2021800279304; HK62023070244.6; SG11202304263P; CA3201125; US18/043,900; EP21844628.4; IDP00202305659; IL303679; BR1120230120322; KR1020237024202	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Feng Zhichun (封志純); Dr. Mao; Zhang Yuyan; Geng Xiang (耿 翔); Chen Tao (陳濤); Zhao Yangbo (趙楊波); Wu Qing (吳 清)	Australia; Japan; China; Hong Kong; Singapore; Canada; United States; Europe; Indonesia; Israel; Brazil; South Korea	12/17/2021 12/17/2021 12/17/2021 03/20/2021 12/17/2021 12/17/2021 12/17/2021 12/17/2021 12/17/2021 12/17/2021 12/17/2021	Australia (Granted); Japan (Granted); China (Granted); Hong Kong (Granted); Singapore (Granted); Canada (Allowed); United States (Allowed); Europe (Pending); Indonesia (Pending); Israel (Pending); Brazil (Pending); South Korea (Pending)	12/17/2041 12/17/2041 12/17/2041 12/17/2041 12/17/2041 12/17/2041 12/17/2041 NA NA NA NA NA
2	iNOwill	2020307517458	Design	Nanjing Novlead Biotechnology Co., Ltd.	Wu Qing; Chen Cuihua (陳翠華); Geng Xiang; Cao Guiping	China	12/7/2020	Granted	12/7/2030
3	iNOwill	2020230648669	Utility Model	Nanjing Novlead Biotechnology Co., Ltd.	Wu Qing; Zhao Yangbo; Cao Yu; Geng Xiang; Zheng Panpan (鄭 盼盼)	China	12/18/2020	Granted	12/18/2030
4	iNOwill	2020115028467	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Geng Xiang; Chen Tao; Chen Cuihua; Zheng Panpan; Dr. Mao	China	12/18/2020	Granted	12/18/2040
5	iNOwill	202030751011X	Design	Nanjing Novlead Biotechnology Co., Ltd.	Chen Cuihua; Wu Qing; Geng Xiang; Cao Guiping	China	12/7/2020	Granted	12/7/2030
6	iNOwill	2022221088703	Utility Model	Nanjing Novlead Biotechnology Co., Ltd.	Sun Xin (孫鑫); Zhao Yangbo; Wu Qing	China	8/11/2022	Granted	8/11/2032
7	iNOwill	2022302358204	Design	Nanjing Novlead Biotechnology Co., Ltd.	Wu Qing; Sun Xin; Zhang Yuheng (張宇恒)	China	4/25/2022	Granted	4/25/2037
8	iNOwill	2022218301018	Utility Model	Nanjing Novlead Biotechnology Co., Ltd.	Wu Qing; Hu Jiale (胡佳樂); Sun Xin	China	7/15/2022	Granted	7/15/2032
9	iNOwill	2022218591928	Utility Model	Nanjing Novlead Biotechnology Co., Ltd.	Zhang Yuyan; Wu Qing; Hu Jiale; Sun Xin	China	7/19/2022	Granted	7/19/2032
10	iNOwill	2022108767923	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Wu Qing; Sun Xin; Zhang Yuyan	China	7/25/2022	Granted	7/25/2042

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Number	Related Product	Patent/Application Number	Patent Type	Patent/Patent Application Holder	Inventor	Jurisdiction	Date of Application	Status	Patent Expiration for Granted Patent(s)
11	iNOwill	2022221132566	Utility Model	Nanjing Novlead Biotechnology Co., Ltd.	Wu Qing; Sun Xin; Kong Xianghai; Wang Shengxue (王聖雪)	China	8/11/2022	Granted	8/11/2032
12	iNOwill	2023110310412	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Feng Zhichun; Dr. Mao; Zhang Yuyan; Geng Xiang; Chen Tao; Zhao Yangbo; Wu Qing	China	12/17/2021	Pending	N/A
13	INOwill	2023110325085	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Feng Zhichun; Dr. Mao; Zhang Yuyan; Geng Xiang; Chen Tao; Zhao Yangbo; Wu Qing	China	12/17/2021	Pending	N/A
14	INOwill	2023110330276	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Feng Zhichun; Dr. Mao; Zhang Yuyan; Geng Xiang; Chen Tao; Zhao Yangbo; Wu Qing	China	12/17/2021	Pending	N/A
15	iNOwill	2023800578663; US19/144,448; EP23910732.9; CA3278315; JP2025538636; AU2023416236; HK62025113562.5	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Dr. Mao; Zhang Yuyan; Zhao Yangbo; Mao Yujia; Sun Qiyu (孫啟禹)	China; United States; Europe; Canada; Japan; Australia; Hong Kong	12/27/2023	China; (Pending) United States; (Pending) Europe; (Pending) Canada; (Pending) Japan; (Pending) Australia; (Pending) Hong Kong (Pending)	N/A N/A N/A N/A N/A N/A N/A
16	iNOwill	2025109566268	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Lu Yongqi; Li Yuan (李淵); Bao Xiaoyi (鮑小一)	China	7/11/2025	Pending	N/A
17	INOwill	2023118212028	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Dr. Mao; Zhang Yuyan; Zhao Yangbo; Mao Yujia; Sun Qiyu; Zhao Yangbo; Zhou Dawei (周大威); Chen Tao; Li Yuan; Zheng Panpan; Geng Xiang; Zhang Yuyan	China	12/27/2023	Pending	N/A
18	iNOwill	2022116984503	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Zhao Yangbo; Zhou Dawei; Hu Sizhe (胡思哲); Li Yuan; Geng Xiang; Zhang Yuyan	China	12/28/2022	Pending	N/A
19	iNOwill	202310192266X	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Zhao Yangbo; Zhou Dawei; Chen Tao; Li Yuan; Zheng Panpan; Geng Xiang; Zhang Yuyan	China	3/2/2023	Pending	N/A
20	iNOwill	202310486099X	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Zhao Yangbo; Zhou Dawei; Chen Tao; Li Yuan; Zheng Panpan; Geng Xiang; Zhang Yuyan	China	5/4/2023	Pending	N/A
21	iNOwill	2023101904074	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Zhao Yangbo; Zhou Dawei; Hu Sizhe (胡思哲); Li Yuan; Geng Xiang; Zhang Yuyan	China	3/2/2023	Pending	N/A

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Number	Related Product	Patent/Application Number	Patent Type	Patent/Patent Application Holder	Inventor	Jurisdiction	Date of Application	Status	Patent Expiration for Granted Patent(s)
22	iNOWill	2023115822296	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Zhou Dawei; Li Yuan; Zhang Yuyan	China	11/24/2023	Pending	N/A
23	iNOWill	2025114282069	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Wu Qing; Bao Xiaoyi; Zhao Yangbo; Zhang Xiangqiong; Zhang Yuyan	China	9/30/2025	Pending	N/A
24	iNOWill	202522120300X	Utility Model	Nanjing Novlead Biotechnology Co., Ltd.	Wu Qing	China	9/29/2025	Pending	N/A
25	iNOWill	US19/685,056	Invention	Nanjing Novlead Biotechnology Co., Ltd.	Feng Zhichun; Dr. Mao; Zhang Yuyan; Geng Xiang; Chen Tao; Zhang Yuyan; Wu Qing	United States	6/12/2026	Pending	N/A
26	NovaPulse IABP	2025203225566	Utility Model	Nanjing Novlead Biotechnology Co., Ltd.	Cao Yu; Guan Minghong (關明宏)	China	2/26/2025	Pending	N/A
27	NovaPulse IABP	2025116486802	Invention	Nanjing Novlead Biotechnology Co., Ltd.; Novlead Yangzhou	Zhou Dawei; Hu Yumin (胡毓敏); Zhang Rutao (張如濤); Cao Yu	China	11/12/2025	Granted	11/12/2045

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We also own a number of patents, patent applications, trademarks and trademark applications. For more details, see Appendix VI to this document.

The term of an individual patent may vary based on the countries or regions in which it is granted. We cannot provide any assurance that patents will be issued with respect to any of our owned or licensed patent applications or any such patent applications that may be filed in the future.

We rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our technology and enter into confidentiality arrangements to seek protection for our proprietary technology. We enter into confidentiality and non-competition agreements with our key employees and employees involved in research and development. During the Track Record Period and up to the Latest Practicable Date, none of our employees breached the confidentiality obligations under their employment contracts in a material aspect. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises.

During the Track Record Period and up to the Latest Practicable Date, we were not subject to, nor were we a party to, any third parties’ intellectual property rights infringement claims or litigations and, to the best knowledge of our Directors, they were not aware of any material infringement of our intellectual property rights that had or could have a material adverse effect on our business. We had complied with all applicable intellectual property laws and regulations in all material respects during the Track Record Period and up to the Latest Practicable Date. Based on the freedom-to-operate (“**FTO**”) analysis, as of August 18, 2026, there is no substantial risk of infringement of valid and enforceable issued patents of any third party in the Chinese mainland, Europe and the U.S. that may impact the development and commercialization of our Core Product in the Chinese mainland, Europe and the U.S. and there is no substantial risk of infringement of valid and enforceable issued patents of any third party in the Chinese mainland that may impact the development and commercialization of our Key Product in the Chinese mainland. Our FTO analysis mainly covers Chinese mainland, Europe and the U.S. (“**FTO Regions**”), because (i) the FTO Regions are currently and expected to be our major sources of income. In 2024, 2025 and the six months ended June 30, 2026, revenue from Chinese Mainland accounted for 91.4%, 87.3% and 83.1% of our total revenue in the respective year/period. As we complete UDEM-required PMCF trials in Europe, complete registration in the U.S. and build on our indication expansion in both regions, we expect to continue generating revenue from the U.S. and Europe; (ii) the FTO Regions have well-established patent protection systems, with high patent density and active rights claims. Completing the FTO analysis in the FTO Regions thus help us identify potential infringement risks to the greatest extent and lay a benchmark for subsequent global patent layout; (iii) the FTO Regions are home to our major global competitors, which usually use their domestic patents as a basis to extend patent protection globally through PCT and other means. As such, completing the FTO analysis in the FTO Regions essentially provides a comprehensive identification of patent competition risks for our Core Product from the technology’s origin, and our Directors are of the view that such analysis is sufficient to cover major patent risk exposures globally. For countries like Turkey, which are signatories to the European Patent Convention (EPC), our patent risks in these jurisdictions are effectively identified and covered through the FTO analysis.

LICENSES AND PERMITS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. 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. See “Regulatory Overview” for more information about the material certificates, permits and licenses required for our business operations.

In addition to the registration certificates for our medical devices, the table below sets forth the relevant details of the material licenses required for our operations in the PRC and overseas.

Certificate	Product/Scope	Issue Authority	Certificate Number	Expiration Date
Medical Device Manufacturing License	Class III: 08-03 emergency equipment; 09-08 other physical therapy equipment	Jiangsu MPA	20220174	Until May 2027
Medical Device Operation License	Wholesale of medical devices	Nanjing Municipal Administration for Market Regulation	20220206	Until April 2027

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Certificate	Product/Scope	Issue Authority	Certificate Number	Expiration Date
Certificate for Exportation of Medical Products of the PRC	Nitric Oxide Therapy Device	Jiangsu MPA	20252838	Until April 2027
Medical Device Manufacturing Licence	Class III: 01-10 Other surgical equipment; 08-03 Emergency equipment; 09-08 Other physical therapy equipment	Jiangsu MPA	20250098	Until May 2030

ENVIRONMENTAL, WORKPLACE SAFETY AND SOCIAL RESPONSIBILITY MATTERS

We are committed to complying with ESG reporting requirements following our [REDACTED]. In line with the standards set out in Appendix C2 of the Listing Rules, we have established a three-tiered sustainable development management system with the Board at its core, which serves as the cornerstone for promoting the high-quality development of the enterprise.

As the highest management and decision-making body for corporate governance, the Board has overall responsibility for our sustainable development management. The Board is responsible for assessing and determining our ESG-related risks and opportunities; ensuring that appropriate and effective ESG risk management and internal control systems are in place; formulating our ESG management policies, strategies, priorities and objectives; periodically reviewing our performance against ESG-related targets; and approving the disclosures in our ESG report.

At the management level, we have established a dedicated ESG Working Group that reports to the Board. Its members include senior management and employees with a full understanding of current and emerging ESG issues and our business. The principal functions of the ESG Working Group include implementing the ESG strategies and policies formulated by the Board; conducting internal and external materiality assessments of ESG-related matters; overseeing the preparation of the Group’s ESG reports; monitoring the progress and effectiveness of the Company’s ESG management policies, strategic plans, development targets and corresponding risk response measures and making regular reports to the Board; and promoting the continuous enhancement of the Group’s overall ESG management standards.

At the implementation level of sustainability matters, the relevant departments are responsible for the collection of various sustainability indicators and the implementation of targets, and reporting the completion of their work to the ESG Working Group on a regular basis.

Compliance Management and Anti-Corruption

Bribery and corruption remain strictly prohibited throughout our operations. We require all mid- to senior-level management and employees to strictly adhere to relevant laws, industry norms and standards, professional ethics, and company policies. This fosters a culture of integrity and diligence while preventing actions that could harm the interests of the Company and its shareholders.

We have set up the Compliance and Internal Control Department as a standing body directly under the Board’s Audit Committee to carry out anti-fraud and anti-corruption efforts. We have also established and disclosed reporting channels, allowing all employees and any external parties with direct or indirect economic relationships with the Company to report actual or suspected acts of fraud or corruption via email, including any violations of professional ethics. We continuously conduct training on integrity, compliance management, and anti-corruption to strengthen awareness throughout the Company.

Emissions Targets

We regard environmental protection as a matter of particular importance and have taken measures to ensure full compliance with all applicable regulations. We closely monitor and strictly adhere to national environmental laws and regulations, including the *Environmental Protection Law of the PRC* (《中華人民共和國環境保護法》), the *Water Pollution Prevention and Control Law of the PRC* (《中華人民共和國水污染防治法》), the *Law on the Prevention and Control of Environmental Pollution by Solid Waste of the PRC* (《中華人民共和國固體廢物污染環境防治法》), and the *Energy Conservation Law of the PRC* (《中華人民共和國節約能源法》). To ensure the effective implementation of our environmental protection measures and the proper management

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of emissions and waste, we engage qualified third-party testing agencies annually to inspect and assess wastewater, exhaust emissions, and noise generated by our production facilities. We also commission qualified third-party organizations for the proper disposal of hazardous waste. During the Track Record Period and up to the Latest Practicable Date, we had complied with the relevant environmental, occupational health, and safety laws and regulations in all material respects. We did not record any incidents or complaints during the same period that had a material adverse effect on our business, financial condition, or results of operations.

Metrics and Targets

We have established environmental protection indicators to quantify our conservation efforts and actively monitor our environmental impact. The table below sets out the quantitative data¹ of our environmental performance in 2024, 2025 and the six months ended June 30, 2026.

	Category	Unit	2024	2025	Six Months Ended June 30, 2026
Total Greenhouse Gas (GHG) Emissions and Intensity	Scope 1 – Direct emissions	Tons	0.29	0.41	0.22
	Scope 2 – Energy indirect emissions	Tons	458.04	1,963.18	209.74
	Scope 3 – Other indirect emissions	Tons	171.07	153.14	98.19
	Total emissions ²	Tons	629.41	2,116.73	308.14
	Total emissions intensity	Tons/RMB million revenue	13.82	31.72	5.30
Waste	Hazardous waste	Tons	5.42	3.75	1.29
	Hazardous waste intensity	Tons/RMB million revenue	0.12	0.06	0.02
	Non-hazardous waste	Tons	10.76	8.52	4.54
Energy Consumption	Non-hazardous waste intensity	Tons/RMB million revenue	0.24	0.13	0.08
	Direct energy consumption				
	Gasoline	Litres	110	154	82
	Indirect energy consumption				
	Purchased electricity	'000 kWh	751	3,218	344
Water Consumption	Total energy consumption	'000 kWh	752	3,219	345
	Total energy consumption intensity	'000 kWh/RMB million revenue	16.51	48.24	5.93
	Total water consumption	Tons	5,200	4,202	882
Packaging Materials	Total water consumption intensity	Tons/RMB million revenue	114.17	62.97	15.17
	Total packaging materials used	Tons	1.10	1.34	0.83
	Total packaging material intensity	Tons/RMB million revenue	0.024	0.020	0.014

Notes:

1. The data covers the Group’s major business operations.
2. The Scope 3 emissions include available data arising from Category 6: business travel and Category 7: employee commuting.

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We will monitor GHG emission to assess and manage our environmental impact. As advised by our ESG counsel, our environmental protection performance and emission reduction targets are comparable with international standards and those of our industry peers.

Emissions Targets

GHG Emissions

Metrics and Targets. In 2024, 2025 and for the six months ended June 30, 2026, our Scope 1 GHG emissions were 0.29 tonnes, 0.41 tonnes and 0.22 tonnes, respectively, primarily arising from vehicle exhaust during operations. Scope 2 GHG emissions were 458.04 tonnes, 1,963.18 tonnes and 209.74 tonnes, respectively, mainly derived from electricity consumption required for production. Scope 3 GHG emissions were 171.07 tonnes, 153.14 tonnes and 98.19 tonnes, respectively, primarily arising from paper usage and carbon dioxide emissions generated by business air travel. Based on forecasts for future capacity expansion and production schedules, our target is to maintain the total GHG emission intensity (tCO₂/RMB million revenue) for 2026 at 95% of the level recorded in fiscal year 2025.

Measures to Achieve Targets. We will enhance equipment efficiency through standardized inspections and periodic maintenance to reduce unproductive energy consumption and prevent equipment idling. We encourage low-carbon commuting by promoting public transport and reducing single-occupancy vehicle use. Energy-saving awareness is fostered through policies such as turning off lights when leaving rooms, with daily electricity usage inspections conducted by security personnel. We continue to promote “Green Office” practices by encouraging remote meetings to reduce business travel, implementing paperless workflows through office software and electronic reimbursement systems, and cultivating energy-efficient work and lifestyle habits among employees.

Hazardous Waste

Metrics and Targets. In 2024, 2025 and for the six months ended June 30, 2026, our total hazardous waste emissions were 5.42 tonnes, 3.75 tonnes and 1.29 tonnes, respectively, with hazardous waste intensities of 0.12 tonnes/RMB million revenue, 0.06 tonnes/RMB million revenue and 0.02 tonnes/RMB million revenue, respectively. Our hazardous waste is primarily generated from solid hazardous waste and laboratory waste liquids produced during the production process. Our target is to maintain the hazardous waste emission intensity (tonnes/RMB million revenue) for 2026 at 95% of the level recorded in fiscal year 2025.

Measures to Achieve Targets. We will continue to standardize the management, comprehensive utilization, and harmless disposal of solid waste to ensure clean production and sustainable development while reducing overall waste generation.

Energy Consumption

Metrics and Targets. We consistently advocate for the concept of “energy saving”, encouraging employees to conserve resources, continuously optimizing our resource usage structure, and strengthening management to achieve reduction at the source. Meanwhile, we explore paths for resource circularity and are committed to enhancing energy efficiency. In 2024, 2025 and for the six months ended June 30, 2026, our total energy consumption was 752’000 kWh, 3,219’000 kWh and 345’000 kWh, respectively, with total energy consumption intensities of 16.51’000 kWh/RMB million revenue, 48.24’000 kWh/RMB million revenue and 5.93’000 kWh/RMB million revenue. Within this, direct energy consumption was 1’000 kWh, 1.5’000 kWh and 0.8’000 kWh in 2024, 2025 and for the six months ended June 30, 2026, respectively, primarily comprising gasoline consumed by vehicles; indirect energy consumption was 751’000 kWh, 3,218’000 kWh and 344’000 kWh, respectively, mainly from purchased electricity. Our target is to maintain the electricity consumption intensity (MWh/RMB million revenue) for 2026 at 95% of the level recorded in fiscal year 2025.

Measures to Achieve Targets. We employ standardized inspections and periodic equipment maintenance to enhance operational efficiency, eliminate idle energy waste, and reduce overall consumption.

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Water Consumption

Metrics and Targets. In 2024, 2025 and the six months ended June 30, 2026, our water consumption was 5,200 tonnes, 4,202 tonnes and 882 tonnes, respectively. All of our water is sourced from municipal tap water, and consumption has gradually decreased in recent years. Our target is to maintain the water consumption intensity (tonnes/RMB million revenue) for 2026 at 90% of the level recorded in fiscal year 2025.

Measures to Achieve Targets. We promote water recycling in production processes to reduce net consumption. A “water-saving” culture is fostered through awareness posters in operational areas and real-time monitoring of key water usage points for rapid anomaly response. Process and equipment designs are continuously improved to enhance water efficiency.

Environmental Sustainability and ESG Risks

We regard environmental protection as a matter of particular importance. We closely monitor and strictly adhere to national environmental laws and regulations. To ensure the effective implementation of our environmental protection measures and the proper management of emissions and waste, we engage qualified third-party testing agencies annually to inspect and assess wastewater, exhaust emissions, and noise generated by our production facilities.

Climate-related issues pose a degree of potential risk to our operations. Following the risk management principles of “prevention first, rapid response, and continuous monitoring”, we assess the likelihood and impact of environmental and climate-related threats to our business and take prompt action to mitigate potential losses. The principal climate risks we have identified can be categorized as (i) physical risks, defined as the physical impacts on us resulting from extreme weather events or long-term chronic changes in climate patterns, and (ii) transition risks, defined as risks associated with the transition to a low-carbon economy, which may include policy, legal, technological, market, and reputational risks.

Physical Risk

We believe that climate-related issues may bring an increased risk of severe extreme weather events, such as the effects of more frequent and intense thunderstorms, torrential rain, strong winds, and high temperatures. Extreme weather may disrupt the receipt of raw materials or the delivery of finished products, while climate-related disasters could lead to power outages, or equipment malfunctions, potentially causing production halts or delivery delays. To mitigate such risks, our ESG Working Group is responsible for monitoring weather conditions on a regular basis and developing appropriate contingency plans to minimize operational disruptions. We have implemented backup and redundancy measures for critical facilities to ensure a rapid recovery of operations in the event of disaster. In addition, we maintain a diversified supply chain to reduce dependency on any single supplier.

Transition Risk

With the implementation of the “dual-carbon” strategy, local governments have increasingly focused on controlling fossil-fuel consumption and moving toward a “dual-control” mechanism that regulates both the total volume and intensity of carbon emissions. In this process, power rationing and production restrictions have intensified for high-energy-consuming enterprises, while outdated production capacity is being phased out. These changes could create uncertainty for our supply chain and R&D activities. In addition, medical institutions (particularly Grade A Tertiary hospitals) may, in the future, adopt low-carbon certification as a key procurement criterion, giving preference to environmentally friendly medical devices. In response, we have strengthened ESG training and education to raise awareness company-wide. We will also deepen cooperation with upstream and downstream partners to build a sustainable and competitive ecosystem. Moreover, the tightening of environmental regulations may require us to increase investment in business and operational transformation — for example, by adopting more advanced processes and technologies to reduce production energy consumption.

Identification, Assessment, and Management of Environmental, Social, and Climate-related Risks and Opportunities

We identify material environmental, social, and climate-related issues closely related to our business. Such issues may present certain risks and opportunities to us.

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Identified Risks and Opportunities and Their Impact on Our Business Strategy and Financial Planning

Material Topics	Potential Risks, Opportunities, and Impacts	Measures to Manage and Mitigate ESG-related Risks
Emissions Management . . .	Our emissions primarily consist of wastewater, exhaust gas, and hazardous waste generated during material storage, production, and transportation. Wastewater includes domestic sewage and production wastewater; Exhaust gases mainly include nitric oxide, nitrogen dioxide, methanol, and tetrahydrofuran generated during R&D and production. Hazardous wastes mainly include solid hazardous waste and experimental waste liquids from production and testing.	Our laboratories are equipped with fume hoods and universal extraction hoods, and ventilation facilities such as ducts are installed in reagent cabinets and hazardous waste rooms. Organic waste gases are collected and treated via activated carbon adsorption devices and exhaust gas treatment units to ensure compliant discharge. Production wastewater is treated in sewage treatment rooms, while domestic sewage undergoes pretreatment in septic tanks before being discharged into the municipal sewage network for centralized disposal by local sewage treatment plants. Dedicated hazardous waste warehouses have been established for storage, and we regularly engage licensed third-party service providers to handle disposal.
Extreme Weather Response	Thunderstorms and typhoons can cause power outages, gas shortages, and damage to production and processing facilities, increasing the risk of poor drainage, injuries to onsite personnel, disruption to ground logistics, delays in cargo loading, and postponed project delivery.	We have established the <i>Business Continuity Management Policy</i> , established an Emergency Response Leadership Team, developed contingency plans, and regularly organized employees to conduct drills and training.
Protection of Employment Rights	We respect the lawful employment relationships and rights established with each employee through labor contracts. Although we offer training, promotion opportunities, and comprehensive benefits, we continue to experience natural employee turnover. High turnover increases our human resources costs and results in the loss of valuable experience and knowledge.	We are committed to fostering an inclusive and equitable workplace environment. We have established a performance-based remuneration system, and provided continuous professional skills training and clear career development paths to ensure that all employees enjoy diverse benefits and extensive career development opportunities. Through regular employee communication and feedback mechanisms, we prioritize employee well-being and ensure that the legitimate rights and interests of all employees are fully respected and protected.
Health and Safety	Employees in certain positions may be affected by occupational diseases.	We have implemented occupational disease warning signs, arranged health check-ups, and carried out prevention and control work. Throughout the Track Record Period, we had 0 working day lost by our employees due to work-related injuries.

Social Responsibility

We recognize that corporate development is closely intertwined with social responsibility and believe it is our duty to actively fulfill such responsibilities. We also actively call upon our employees to participate in public welfare and charitable activities beyond their daily work. In 2024, our cumulative donations of medical devices reached a total value of RMB885,000, including Nitric Oxide Therapy Systems and Exhaled Nitric Oxide Detectors. In the first half of 2026, we also donated RMB40,000 to the Nanjing Jiangbei New District Minors’ Protection Center.

Occupational Health and Safety

We are subject to the PRC laws and regulations related to employee health and safety. We have established comprehensive internal policies and measures on environmental and occupational health and safety and provide production staff with adequate protective equipment. Qualified third-party institutions are engaged to conduct occupational hazard assessments of our production environment, identifying potential occupational risks and ensuring they are effectively prevented and controlled.

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This allows us to meet national laws, regulations, standards, and specifications for the prevention and control of occupational diseases. We conduct occupational health examinations for relevant positions at least once a year and arrange regular physical checkups for all employees. In 2022, we passed the Healthy Enterprise assessment in the Nanjing Jiangbei New Area, where it is located.

Employee Management

Adhering to a “people-oriented” management philosophy, we regard our employees as our most valuable resource and asset. We strictly comply with national and regional laws and regulations, including the *Labor Law of the PRC* (《中華人民共和國勞動法》), the *Labor Contract Law of the PRC* (《中華人民共和國勞動合同法》), the *Law of the PRC on the Protection of Minors* (《中華人民共和國未成年人保護法》), the *Provisions on the Prohibition of Using Child Labor* (《禁止使用童工規定》), and the *Special Provisions on Labor Protection for Female Employees* (《女職工勞動保護特別規定》). Internal management procedures have been developed accordingly, standardizing policies on compensation and dismissal, recruitment and promotion, working hours, leave entitlements, equal opportunity, diversity, anti-discrimination and employee benefits and welfare.

We have built an employment management system with unified standards and conduct structured and professional recruitment to provide sustained human resources support for corporate growth. Our HR policies are outlined in various documents, including the Employee Handbook, Human Resources Management Policy, Employee Relations Management Policy and Employee Benefits Management Policy, which define procedures for recruitment, promotion, and daily management. Our human resources management adheres to the principles of equal opportunity, fair competition, comprehensive evaluation and role-fit matching. We have zero tolerance for all forms of discrimination — including gender, sexual orientation, disability, age, race, nationality, family status or other legally protected characteristics — and are committed to fostering diversity. We ensure all employees are treated equally and respectfully in recruitment, training, health and professional and personal development.

Performance Indicators (Social Responsibility)

Adhering to the principles of diversity and inclusion, we are committed to fostering an equal and diverse employment environment while continuously optimizing our workforce structure to maintain our competitiveness both within us and in the broader market.

Social Responsibility		Data as at June 30, 2026
Category	Unit	
Employee Data		
Employees	Total	178
Gender	Male	115
	Female	63
Age group	Below 30	46
	30 to 45	118
	Above 45	14
Average Monthly Employee Turnover Rate		
Average monthly employee turnover	Total	34
Turnover rate		1.84%
By gender (turnover rate)	Male	1.30%
	Female	2.38%
By age group (turnover rate)	Below 30	3.26%
	30 to 45	1.27%
	Above 45	0.00%
Employee Training Data		
Employee training	Number of employees trained	175
	Percentage of employees trained	98.31%

Research and Development (R&D) and Innovation

Innovation and R&D are inexhaustible drivers of our long-term development. We value and encourage technological innovation and provide meaningful rewards and recognition to individuals or teams that successfully apply for new patents. We have established the Design and Development

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Control Procedure, the Design Review Control Procedure, and other documents to standardize our R&D processes, thereby offering clear guidance and necessary support for employees to innovate and enhance their professional skills.

As of the Latest Practicable Date, we held 196 registered trademarks, 85 granted patents (including 26 invention patents, 33 utility model patents and 26 design patents), and 10 copyrights.

We place strong emphasis on the application and protection of intellectual property. In all production and operational activities, we strictly comply with applicable laws and regulations, including the *Trademark Law of the PRC* (《中華人民共和國商標法》), the *Patent Law of the PRC* (《中華人民共和國專利法》), and the *Copyright Law of the PRC* (《中華人民共和國著作權法》). We have issued the Intellectual Property Management Manual, which specifies the responsible departments and their duties in relation to intellectual property, defines the allocation of patent ownership, and sets out the procedures and requirements for patent applications, patent maintenance and abandonment, as well as the mechanisms for intellectual property incentives.

Welfare of Animals and Patient Safety

Throughout the entire product R&D process, we strictly abide by applicable laws and regulations, industry standards and ethical guidelines, ensures the compliance, scientificity, and humanity of all animal trials and human trials, and earnestly fulfills its corporate social responsibility.

As the sponsor of the relevant trials, all of our animal trials are entrusted to qualified third-party Contract Research Organizations (CROs) or professional animal experiment centers. Such entrusted institutions must strictly comply with the relevant national laws and regulations governing animal experiments and the “Replacement, Reduction, Refinement” (3R) principle, and their experimental facilities and operating procedures must comply with relevant ethical standards and industry norms. All animal trial protocols must be submitted to the corresponding Laboratory Animal Ethics Committee for review prior to the commencement of the trial, and the trial may only be conducted after obtaining the written approval of such Committee; during the trial, the entrusted institution shall not arbitrarily deviate from the approved trial protocol; after the completion of the trial, the entrusted institution shall issue a trial summary report, which shall clearly include a detailed account of the implementation of animal welfare. We exercise strict compliance supervision and full-process control over the aforementioned outsourced animal trial activities to ensure that all animal trials are conducted in a legal, humane and scientific manner.

We integrate the safety and rights protection of subjects throughout the entire product R&D process and strictly regulates the management of all human-related research projects (including investigator-initiated clinical trials). All such human research projects must first obtain the written approval of the Ethics Committee of the hosting medical institution and be strictly implemented in accordance with the approved trial protocol. We fully protect the right to know, right to informed consent and right to privacy of subjects, and strictly supervises the process of signing informed consent forms between investigators and subjects within the scope of the relevant requirements of laws and regulations and the Ethics Committee to ensure that the signing process is legally compliant and the expression of intent is genuine. During the trial, a professional medical team is fully responsible for safeguarding the safety and health of subjects and strictly keeps the personal data and relevant information of subjects confidential to prevent information leakage.

Supplier Management

Supply chain management is directly associated with product quality and corporate operations. In view of this, we actively establish stable, long-term partnerships with suppliers from diverse regions to ensure supply chain stability and achieve mutual success. Throughout this process, we have established a series of management systems and procedures, such as the *Supplier Management Control Procedure*, *Contract Manufacturing Control Procedure*, and *Procurement Bidding and Tendering Management Regulations*, to specify management requirements for different categories of suppliers.

We have long conducted objective, rigorous and impartial background checks on potential suppliers and use a standardized process framework to evaluate and manage them, with the aim of building high-quality, long-term and stable partnerships. We have established the Supplier Management Control Procedure, which sets out strict requirements governing the development, selection, management, evaluation and supervision of suppliers. Suppliers are categorized into four

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types (A, B, C, and D) based on material types. Depending on the supplier category, evaluation teams composed of relevant functional departments participate in the supplier onboarding process, primarily reviewing three key modules: corporate capability, corporate qualifications, and quality control management.

When selecting suppliers, we give priority to partners that share our sense of social responsibility and commitment to sustainable development, ensuring that we can source safer, healthier and more environmentally friendly products and services. We take into account suppliers’ position on social responsibility and environmental management by reviewing whether they have obtained relevant system certifications, and their efforts to use environmentally friendly materials where feasible, and we also attach great importance to the environmental and social responsibilities associated with office supplies; for example, in the procurement of consumables, we strive to strike a balance among environmental performance, user-friendliness and cost-effectiveness.

Over the years, we have maintained partnerships with suppliers of varying regional, ethnic, cultural, and professional backgrounds to build a diversified supply chain. At the same time, we emphasize collaboration with local suppliers to promote regional economic development and reduce logistics costs. As of June 2026, we had established cooperative relationships with 404 suppliers across 24 provinces, countries, and regions.

LEGAL PROCEEDINGS AND COMPLIANCE

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any actual or pending legal, arbitration, or administrative proceedings (including any bankruptcy or receivership proceedings) that we believe would have a material adverse effect on our business, results of operations, financial condition, or reputation and compliance.

During the Track Record Period and up to the Latest Practicable Date, our material business operations were conducted in the PRC, with our PRC operating subsidiaries conducting the manufacturing, product registration, sales and clinical trial activities for our products. As confirmed by our PRC Legal Advisor, the business operations we engaged in had been carried out in compliance with applicable PRC laws and regulations in all material respects during the Track Record Period and up to the Latest Practicable Date. We plan to conduct clinical trials in the EU and the U.S. for the further development and registration of our products. As advised by our EU Legal Advisor, our business activities subject to applicable EU laws and regulations had been conducted in compliance with such laws and regulations in all material respects during the Track Record Period and up to the Latest Practicable Date. Based on the due diligence conducted by our U.S. legal advisers as to U.S. medical device regulatory matters within the scope of their engagement, nothing has come to their attention that would cause them to believe that we were in material non-compliance with the applicable U.S. laws and regulations reviewed by them during the Track Record Period and up to the Latest Practicable Date. The details of certain non-material non-compliance incidents are set forth below.

Failure to complete lease registration for five leased properties

As of the Latest Practicable Date, we have not completed the relevant property leasing registrations for five of our leased properties, which are used as our operating center and manufacturing facilities. With respect to such failure of filing lease agreements, our PRC Legal Advisor is of the view that the failure to file lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities can require us to complete filings within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material dispute arising out of our leased properties and were not subject to any penalties imposed by regulatory authorities.

We intend to comply with the lease registration requirements to which we are a party by 2027. We will take steps to facilitate timely completion of lease registrations and take into consideration whether our potential landlord will cooperate with us to complete the registration process in a timely manner when selecting leased properties in the future.

Engagement of third-party human resource agencies to pay social insurance and housing provident fund contributions

During the Track Record Period, we engaged third-party human resources agencies to make social insurance housing provident fund contributions for employees whose work locations differed from our main operating entities, which involves potential risks. On July 31, 2025, the Supreme People’s Court of the PRC issued the Interpretation II by the Supreme People’s Court of the PRC

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on Legal Issues in the Trial of 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)) (the “Interpretation II”), which took effect from September 1, 2025. Pursuant to the Interpretation II, any arrangement not to participate in social insurance, either by unilateral undertaking or mutual agreement between the employees and the employers, is invalid. Further, the Interpretation II specifies that if the employee terminates their labor contract on the grounds that the employer has failed to make social insurance contributions as required by law, and claims economic compensation from the employer, the People’s Court of the PRC shall uphold the claim. As advised by our PRC Legal Advisor, the Interpretation II will not have a material adverse impact on our compliance with social insurance and housing provident fund contribution requirements under the PRC laws considering that (i) with respect to those employees for whom we have engaged third-party human resources agencies to pay social insurance and housing provident funds, neither we nor our subsidiaries in the PRC have made any arrangement (whether by unilateral undertakings or mutual agreements) with such employees to exclude them from participating in statutory social insurance and housing provident fund contribution; (ii) the Interpretation II has neither repealed any existing laws relating to social insurance nor expanded the potential penalty exposure with respect to the payment status of social insurance and housing provident fund. However, there can be no assurance that the relevant PRC authorities do not hold views different from ours. If the relevant PRC authorities determine that we are not in compliance with the Interpretation II, our business, results of operation, financial condition and prospects may be adversely affected.

As advised by our PRC Legal Advisor, there are currently no national laws or regulations that explicitly specify penalties specifically targeting employers that use third-party human resources agencies to make social insurance and housing provident fund contributions for their employees. However, we may be ordered by the local social insurance authorities or the local housing provident fund management centers to rectify such practice, or be subject to penalties for failing to make social insurance and housing provident fund contributions in the employer’s own name. According to relevant regulations, if an employer fails to pay social insurance contributions on time and in full, the competent social insurance and housing provident fund authorities may require the employer to pay or make up the shortfall within a specified period and impose corresponding overdue fines in accordance with the law. Should the employer fail to comply with this requirement by the deadline, the relevant authorities may impose administrative penalties, and the employer will then be obligated to pay such administrative penalties. For details, see “Regulatory Overview — Social Insurance and Housing Provident Fund”. Notwithstanding the foregoing, according to the Circular of the General Office of the State Council on Issuing the Plan for Comprehensively Reducing Social Insurance Contribution Rates (《國務院辦公廳關於印發降低社會保險費率綜合方案的通知》) and the Notice of the State Administration of Taxation on Implementing Measures to Further Support and Serve the Development of the Private Economy (《國家稅務總局關於實施進一步支持和服務民營經濟發展若干措施的通知》), local authorities are prohibited from organizing centralized collections of historical arrears.

We ceased the engagement of third-party human resources agencies for social insurance and housing provident fund contributions with effect from April 1, 2026.

Failure to obtain construction permits or complete final acceptance for certain decoration projects

During the Track Record Period, the relevant construction permit or complete the final acceptance filing for our decoration project at the manufacturing facilities in Yulin, Guangxi Zhuang Autonomous Region (the “**Yulin Project**”), with an aggregate investment amount of approximately RMB565,000. In addition, we did not complete the final acceptance filing for the decoration project at our Nanjing headquarters (the “**Nanjing Project**”). Pursuant to the Notice on the Procedures for Renovation and Decoration Projects of Existing Buildings in Jiangbei New Area (《關於江北新區既有建築裝修改造項目相關手續辦理的通知》), the Nanjing Project falls under a category of works that is exempt from the construction permit requirements.

According to the Measures for Construction Permission Management of Construction Projects (《建築工程施工許可管理辦法》), for any construction project without a construction permit being obtained, the relevant government authority may order to suspend the construction, request for rectification within a specified time limit and impose on the owner of the construction project a fine of 1% to 2% of the contract value of the construction project. According to the Administrative Measures for the Filing of As-built Inspection of Housing, Building and Municipal Infrastructure Projects (《房屋建築和市政基礎設施工程竣工驗收備案管理辦法》), if the construction entity fails to complete the final acceptance filing within 15 days as of the date on which the as-built inspection of the project is passed, the filing authority shall order it to make a rectification within a time limit, and impose a fine of not less than RMB200,000 but not more than RMB500,000.

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As advised by our PRC Legal Advisor, based on the applicable legal provisions, the maximum aggregate penalty to which we may be exposed in respect of the Yulin Project and the Nanjing Project is approximately RMB1,011,300 (being, in respect of the Yulin Project, a maximum fine of 2% of the contract price for failure to obtain a construction permit plus a maximum fine of RMB500,000 for failure to complete the final acceptance filing; and in respect of the Nanjing Project, a maximum fine of RMB500,000 for failure to complete the final acceptance filing). As of the Latest Practicable Date, we have not received any notification, inquiry or administrative fines or penalties in respect of the foregoing matters.

Notwithstanding the foregoing, as advised by our PRC Legal Advisor, the risk that we will be subject to material administrative penalties in connection with the above non-compliances is relatively low, based on the following considerations:

- (i) We confirm that, with respect to the Yulin Project, the relevant construction permit application and final acceptance filing procedures are currently being carried out retroactively;
- (ii) The competent housing and construction authority has issued a written confirmation acknowledging the status of the Yulin Project, confirming that we have not received any penalties in relation to the Yulin Project, and further confirming that, since the date of establishment of Novlead Yulin (the relevant project entity) up to the date of such confirmation, no material violation of the laws and regulations governing construction projects has been found, and no investigation or administrative penalty has been imposed by such authority against Novlead Yulin in respect of any non-compliance with the laws, regulations, rules or normative documents concerning construction planning management;
- (iii) With respect to the Nanjing Project, as confirmed by the competent housing and construction authority through consultation, the decoration project is a small-scale interior decoration work that falls within the supervision scope of such authority but is exempted from the requirement of obtaining a construction permit. As a result, we are permitted to carry out our own as-built inspection for the project and are not required to complete the final acceptance filing; and
- (iv) We further confirm that, as of the Latest Practicable Date, the Yulin Project and the Nanjing Project have not been subject to any investigation or administrative penalty by the competent authorities in connection with the aforementioned non-compliances.

We have enhanced our internal control measures and procedures to manage the associated risks and prevent the recurrence of such incidents. We have formulated and issued the “Decoration Project Compliance Management Policies” (《裝修項目合規管理制度》), which clearly requires obtaining the relevant construction permit prior to construction commencement, completing the final acceptance, and designates personnel in charge of monitoring and ensuring compliance throughout our decoration projects.

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. Our insurance coverage includes (i) social welfare insurance for our employees in accordance with relevant PRC laws and regulations; (ii) workers’ compensation insurance covering work-related death or injury of employees; (iii) medical insurance; (iv) commercial insurance; (v) property insurance and (vi) business disruption insurance, which cover, among other things, public liability and product liability. In connection with our sales through distributors, we do not purchase cargo insurance for goods. As of the Latest Practicable Date, we did not have any outstanding insurance claims. Consistent with industry norm, we do not maintain life insurance for any member of our senior management. In the future, to the extent that any of the foregoing types of insurances becomes mandatory due to changes of law or other reasons, we will acquire such insurance in compliance with law. Our Directors consider that our existing insurance coverage is sufficient for our present operations and in line with the industry practice in the PRC.

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DATA PRIVACY AND PROTECTION

We have instituted a comprehensive data-protection framework that governs the collection, use, storage, transmission and disclosure of information in line with applicable laws, regulations and prevailing industry standards across all jurisdictions of operation. The framework ensures clinical and operational data are handled in accordance with requirements on healthcare-information security, while keeping data subjects fully informed of how their information is managed throughout the process.

During our clinical development and operations, we from time to time collect, store and use certain personal information of our employees, clinical trial participants (subjects and investigators), customers, suppliers as well as business and academic collaboration partners. For example, (i) for clinical research and medical device development purpose, we collect from clinical trial subjects their Subject Identification Codes, demographic data, and health and physiological information related to the clinical trial; and from clinical trial investigators their names and contact telephone numbers; (ii) to facilitate our cooperation with our business partners (including for example, customers, suppliers, as well as business and academic collaboration partners), we typically collect from them their names, titles and telephone numbers of the contact person; and (iii) for general corporate and human resource management purpose, we collect certain personal information of our employees for the performance of their employment duties such as their names, personal ID and contact numbers.

We are involved in cross-border data transfers under the following scenarios: (i) the R&D and registration of medical devices, (ii) manufacturing of medical devices, (iii) sale of medical devices, and (iv) after-sales services for medical devices.

- (i) During the R&D and registration of medical devices, we are engaged in cross-border transfer of data. Our overseas medical device registration involves transmitting data required for registration to overseas regulatory authorities and registration agents (for example, UDEM). Such registration data comprises solely of summary and conclusion data generated from clinical trials conducted in the PRC and abroad and does not contain any identifiable patient personal information or important data.
- (ii) In the manufacturing, sale and after-sales servicing of medical devices, our cross-border data transfer activities include (i) providing to overseas business partners of the personal data of our employees responsible for business liaison, for the purpose of establishing business contacts; (ii) access by employees located overseas to the personal data of contact persons of business partners contained in the sales system deployed domestically by us, for the purpose of facilitating business activities; and (iii) transmitting to overseas customers of the device operation and maintenance data necessary for the troubleshooting and maintenance of medical device malfunctions, for the purpose of performing contractual obligations, provided that such operation and maintenance data does not contain any personal data or important data.

The *Provisions on Facilitating and Regulating Cross-Border Data Flows* set out certain exemptions applicable to cross-border data transfers. Article 3 thereof provides that: “For outbound provision of data that is collected and generated in international trade, cross-border transportation, academic cooperation, transactional manufacturing, marketing, and other activities that do not involve personal information or important data, it is exempted from the requirement to apply for the outbound data transfer security assessment, to conclude a standard contract for personal information transfer abroad, or to undergo personal information protection certification.”

Article 5 thereof provides that: “Under any of the following circumstances, the outbound provision of personal information by data handlers is exempted from the requirement to apply for the outbound data transfer security assessment, to conclude a standard contract for the outbound transfer of personal information, or to obtain the personal information protection certification: (1) it is necessary to transfer personal information abroad for the purpose of concluding and performing a contract to which the individual concerned is a party, such as cross-border shopping, cross-border mailing and delivery, cross-border remittance, cross-border payment, cross-border account opening, flight and hotel reservations, visa processing, and examination services; (2) it is necessary to transfer the personal information of employees abroad for the purpose of cross-border human resources management, to comply with employment policies formulated in accordance with the law, and collective contracts concluded in accordance with the law... (4) Data handlers other than critical information infrastructure operators, who have provided personal information (without any sensitive personal information) abroad accumulatively of less than 100,000 individuals since January 1 of the current year. Reference to outbound provision of personal information as mentioned in the preceding paragraphs does not include important data.”

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In respect of our cross-border data transfer activities, as confirmed by our data compliance legal counsel, we are exempt from applying for the outbound data transfer security assessment, concluding a standard contract for the outbound transfer of personal information or obtaining personal information protection certification, for the reason set out as below.

- (i) When we transfer abroad the personal information of employees responsible for business liaison, such transfer is necessary for conducting cross-border human resources management within the scope of the relevant employees’ duties and in accordance with employment policies formulated in accordance with the law and collective contracts concluded in accordance with the law. Accordingly, pursuant to Article 5(2) of the *Provisions on Facilitating and Regulating Cross-Border Data Flows*, our cross-border data transfers under this scenario are exempt from the aforesaid requirements.
- (ii) When employees located overseas access the personal information of contact persons of business partners contained in the sales system deployed within China by us, such cross-border data transfers only involve the names and telephone numbers of such contact persons and do not involve any sensitive personal information. In addition, we are not a critical information infrastructure operator, and the personal information of fewer than 100,000 individuals is provided abroad under this scenario. Accordingly, pursuant to Article 5(4) of the *Provisions on Facilitating and Regulating Cross-Border Data Flows*, our cross-border data transfers under this scenario are exempt from the aforesaid requirements.
- (iii) The device operation and maintenance data transmitted between us and our overseas customers, which is necessary for the troubleshooting and maintenance of medical device malfunctions, does not contain any personal information or important data. Accordingly, pursuant to Article 3 of the *Provisions on Facilitating and Regulating Cross-Border Data Flows*, our cross-border data transfers under this scenario are exempt from the aforesaid requirements.

Our information systems apply multiple layers of safeguards, including role-based access control, web application firewalls, and intrusion detection and prevention systems. We adopt technical measures such as data encryption, desensitization, verification and regular backup to ensure the confidentiality, integrity and availability of the data we process. In addition, we maintain a tiered internal authentication and authorization system to ensure that confidential and proprietary data can only be accessed by authorized personnel.

The Cybersecurity Review Measures were jointly promulgated by the CAC, the NDRC, the MIIT and ten other Chinese regulatory authorities on December 28, 2021, which became effective on February 15, 2022. Pursuant to the Cybersecurity Review Measures, a cybersecurity review may be triggered under two circumstances: (a) voluntary filing by enterprises, (i) when critical information infrastructure operators procure network products or services that affect or may affect national security; (ii) when network platform operators carry out data processing activities that affect or may affect national security; and (iii) when network platform operators possessing personal information of more than 1,000,000 individuals pursue overseas [REDACTED]; (b) ex officio initiation by regulatory authorities. Where a member entity of the cybersecurity review working mechanism determines that a network product or service, or data processing activity, affects or may affect national security, the Cybersecurity Review Office shall initiate a cybersecurity review upon approval by the Central Cyberspace Affairs Commission in accordance with relevant procedures.

As of the Latest Practicable Date, we had not received any notification from regulatory authorities identifying us as, or determining that we are likely to be, a critical information infrastructure operator. In consideration of Article 10 of the Security Protection Regulations for Critical Information Infrastructure, we do not constitute a Critical Information Infrastructure Operator, and the cybersecurity review filing obligations applicable to critical information infrastructure operators are not applicable to us. In addition, we did not possess the personal information of more than one million individuals. Our [REDACTED] in Hong Kong will not constitute a “[REDACTED] on a foreign stock exchange.” In addition, considering the type, nature, purpose, and scale of our data processing activities, the likelihood of the regulatory authorities initiating a cybersecurity review against us is relatively low. Moreover, we had not received any notice from any member entity of the cybersecurity review working mechanism requiring us to undergo a cybersecurity review or notifying us of the initiation of a cybersecurity review against us. Based on the foregoing, as of the Latest Practicable Date, our Directors and our data compliance legal counsel are of the view that we are not subject to a mandatory cybersecurity review pursuant to the Cybersecurity Review Measures.

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We have formulated and implemented the Data Security Management Policy, Data Storage and Deletion Rules, Personal Information Protection Policy, and Personal Information Protection Impact Assessment Policy to establish a governance framework for personal information protection and data security. The Data Security Management Policy sets out the methods and applicable requirements for assessing the compliance pathways for our outbound data transfers. The Personal Information Protection Policy prescribes the requirements to be observed where, due to business needs, we are required to provide personal information to recipients outside China. The Personal Information Protection Impact Assessment Policy sets out the specific implementation measures for conducting personal information impact protection assessments in respect of the cross-border transfer of personal information. In addition, pursuant to the requirements of Article 55(4) of the Personal Information Protection Law of the People’s Republic of China, we have conducted the statutory personal information protection impact assessments in respect of such scenarios involving the provision of personal information to recipients outside China and have maintained records of the relevant processing activities. We process and store collected personal information of customer contacts, supplier contacts, business and academic collaboration partners, and employees through externally procured third-party ERP systems, OA systems, and CRM systems. We have entered into cooperation agreements (that set forth the parties’ confidentiality obligations regarding data) with systems vendors, which are legally established and operating within the territory of the PRC and have publicly disclosed their data security assurance capabilities through documents such as Privacy Policies available on public channels.

We store data related to medical device clinical trials or research and development exclusively on our employees’ local computers (subject to domain control restrictions), statistical software and physical paper documents. Such data only includes Subject Identification Codes and the subjects’ clinical trial-related data. The mapping table linking the Subject Identification Code to the subject’s true identity is maintained and stored exclusively by the clinical trial institution. Based solely on the Subject Identification Code, we are unable to ascertain the true identity of the subject. Therefore, we do not store personal information that could identify the true identity of subjects. We protect and store existing clinical trial data in accordance with the requirements of relevant laws and regulations, including the Good Clinical Practice for Medical Devices.

In the course of medical device manufacturing, we procure components from overseas suppliers. We collect only the personal information of business contacts of overseas suppliers and provides our employees’ personal information (in their capacity as business contacts) to such overseas suppliers. In this scenario, we rely on the legal basis of “necessity for the conclusion or performance of a contract to which the individual is a party” or “necessity for conducting cross-border human resources management in accordance with legally established labor rules and regulations and collective contracts lawfully concluded,” for the provision of employee personal information overseas. Pursuant to Article 5 of the Provisions on Promoting and Regulating Cross-Border Data Flows, we are exempt from the requirements to apply for a security assessment for data export, enter into standard contractual clauses for the export of personal information, or obtain personal information protection certification.

We engage in overseas medical device sales. When conducting sales activities overseas, our employees access the names and telephone numbers of customer contacts stored in our sales system deployed within the PRC. However, such cross-border data transfers do not involve the transfer of sensitive personal information, and we transfer personal information of fewer than 100,000 individuals overseas in this scenario. Therefore, pursuant to Article 5 of the Provisions on Promoting and Regulating Cross-Border Data Flows, we are exempt from the requirements to apply for a security assessment for data export, enter into standard contractual clauses for the export of personal information, or obtain personal information protection certification.

Our customer service engineers and sales personnel provide after-sales service directly to overseas customers who have purchased medical devices. In this scenario, we only provide overseas customers with data related to device malfunctions (such as device error codes/parameters) that are necessary for the maintenance and operation of the medical device. Such data does not include personal information or important data. Given that this scenario does not involve the provision of personal information or important data, pursuant to the provisions of the Personal Information Protection Law, the Regulation on Network Data Security Management, the Provisions on Promoting and Regulating Cross-Border Data Flows, and other relevant laws, regulations, and normative documents, we are exempt from the requirements to apply for a security assessment for data export, enter into standard contractual clauses for the export of personal information, or obtain personal information protection certification.

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As such, as of the Latest Practicable Date, our cross-border data transfers are in compliance with the requirements of the Personal Information Protection Law, the Regulation on Network Data Security Management, the Provisions on Promoting and Regulating Cross-Border Data Flows, and other relevant laws and regulations.

During the Track Record Period and up to the Latest Practicable Date, as confirmed by our data compliance legal counsel and our EU counsel, we were in compliance with all applicable laws and regulations with respect to data privacy and protection in China and EU during the Track Record Period and up to the Latest Practicable Date, we had not received any claim from any third party against us alleging any violation of such party’s data privacy rights, and we had not experienced any material leakage or loss of patient data or other personal information.

RISK MANAGEMENT AND INTERNAL CONTROL

We have established and maintain comprehensive risk management and internal control systems, consisting of policies and procedures that we consider appropriate for our business operations. These systems are designed to ensure that major risks arising from our operations are properly identified, evaluated and mitigated in a timely manner.

Our Board and its committees serve as the decision-making and supervisory bodies responsible for overseeing the effective operation of the risk management and internal control systems. The Board regularly reviews reports from management and the internal audit department on our operational performance and internal control evaluation results. The management team is responsible for implementing the risk management and internal control policies in daily operations and is subject to periodic evaluation and supervision by our Compliance and Internal Control Department.

Risk Management

The Audit Committee of our Board studies macroeconomic, industry, technological and market trends that may affect our medium- to long-term growth, and advises the Board on strategic planning and major industrial opportunities. Our management is responsible for formulating and executing our strategic plans, conducting annual reviews of progress, and organizing quarterly business management meetings to monitor execution.

At the operational level, under the guidance of our management team, each functional department performs its respective duties while coordinating with others to supervise overall operations.

Internal Control

We have established an internal control framework in accordance with our corporate governance and internal control policy, and continuously refine our business processes covering, among others, corporate social responsibility, human resources, treasury, investment, procurement, asset management, sales, R&D, project management, related party transactions, financial reporting, information disclosure, budgeting and IT system management. Our Board holds ultimate responsibility for the establishment and effective implementation of our internal control system.

Anti-Bribery, Anti-Corruption and Compliance Controls

We strictly comply with all applicable anti-bribery, anti-corruption, anti-monopoly and fair competition laws and standards in the jurisdictions where we operate.

The Compliance and Internal Control Department serves as the permanent body for our anti-corruption/anti-fraud efforts, responsible for organizing and executing company-wide anti-corruption/anti-fraud initiatives. We have set up a dedicated whistleblowing email address, which is managed by the Compliance and Internal Control Department.

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AWARDS AND RECOGNITION

The table below sets forth a summary of the major awards and recognition that our Company had received as of the Latest Practicable Date:

Year	Awards	Awarding Organization/Authority
2025	Jiangsu Province Potential Unicorn Enterprise (江蘇省潛在獨角獸企業)	Jiangsu Provincial Productivity Center (江蘇省生產力促進中心)
2024	Jiangsu Province Innovative Product (江蘇省創新產品)	Department of Industry and Information Technology of Jiangsu Province (江蘇省工信廳)
2023	National High-tech Enterprise (國家高新技術企業)	Torch High Technology Industry Development Center, Ministry of Science and Technology (科學技術部火炬高技術產業開發中心)